Frequently Asked Questions

on

Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

April 2014
Foreword

The purpose of this Frequently Asked Questions (FAQ) document is to clarify certain aspects of Directive 2012/19/EU (hereafter referred to as the “Directive”), which entered into force on 13 August 2012 and which Member States were required to transpose into national law by 14 February 2014. At that time, Directive 2002/96/EC (the “old WEEE Directive”) was repealed.

The document is principally intended to help competent public authorities and economic operators interpret the provisions of the Directive in order to ensure compliance with the Directive’s requirements. However, the Directive being addressed only to the Member States, the rights and obligations for private parties exclusively flow from the measures enacted by the authorities of the Member States to implement it.

When formulating the answers to the questions raised in this FAQ document the two following criteria have been applied:

- they should not deviate from the answers given in the FAQ document of August 2006 on the old WEEE Directive, unless the underlying legal text has changed, answers can now be given in a more precise manner, or, in a few cases, a different interpretation has proved necessary;

- they should not deviate from the answers to identical ‘frequently asked questions’ contained in the RoHS 2 FAQ document, unless differences in the objectives and nature of the two Directives require a different answer;

This FAQ document is considered to be a ‘living document’ and the Commission may update it as necessary in light of the experience with the implementation of the new Directive and any future requirements. This document supersedes the FAQ document on the old WEEE Directive and the latter document has been repealed.

Finally, as is customary, this FAQ document reflects the views of DG Environment and as such is not legally binding. The definitive interpretation of Union law is the sole prerogative of the Court of Justice of the European Union.

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PART 1: Decision tree - How can I find out if the Directive applies to my product?

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1. General questions on the implementation of the Directive

1.1. When does the Directive start to apply?

The new WEEE Directive 2012/19/EU (hereafter mentioned as “the Directive”) entered into force on 13 August 2012 and had to be transposed into national law by 14 February 2014. At that time, the old WEEE Directive (Directive 2002/96/EC) is repealed.

The period between 13 August 2012 and 14 August 2018 is a transitional period. During this period the scope of the Directive is identical to the scope of the old Directive (10 categories of electrical and electronic equipment (EEE)) with the exception of photovoltaic panels (PV panels), that have been added to the scope of the Directive with immediate effect.

From 15 August 2018 onwards the scope of the Directive is widened to include all EEE. All EEE shall then be classified within 6 categories instead of the existing 10 categories.

1.2. Where can information on the provisions of the Directive be obtained?

The legislation applicable to individuals and undertakings is primarily the national legislation of EU Member States transposing the Directive. Questions of individual stakeholders are therefore best addressed to the national authorities responsible for the transposition and implementation of the Directive, a list of which can be found here: http://ec.europa.eu/environment/waste/weee/contacts_en.htm.

Questions on practical issues concerning the registration of producers can be addressed to national registers, a list of which is included in the list of national contact points mentioned above. Information on registration can also be obtained from the ‘European WEEE Registers Network’ (EWRN), a network representing many national registers of Member States. EWRN can provide information concerning the registration practices in these Member States. The network can be contacted via https://www.ewrn.org/contact-us.

Questions to the European Commission can be sent to DG Environment. For a list of useful links see the Commission’s web-page: http://ec.europa.eu/environment/waste/weee/links_en.htm

![Diagram showing the timeline of the Directive's implementation](image)
2. SUBJECT MATTER & PURPOSE OF THE DIRECTIVE- Article 1

2.1. What is the overall aim of the Directive?

The Directive aims to prevent or reduce the negative environmental effects resulting from the generation and management of WEEE and from resource use.

As reflected in the Directive’s recital 6, its key purpose is to contribute to sustainable production and consumption by, as a first priority, the prevention of WEEE and, in addition, by the re-use, recycling and other forms of recovery of such wastes. The Directive thus incorporates the waste hierarchy as established in Article 4 of Directive 2008/98/EC on waste.¹

3. SCOPE- Article 2

3.1. What are the criteria for determining whether a product falls within the scope of the Directive?

To answer this question two key aspects have to be considered:

1. Does the equipment meet the definition of EEE?
   and

2. Does the equipment fall under any of the exclusions?

Article 2 of the Directive defines the scope of the Directive and lists the equipment excluded from the scope.

Part 1 of the Appendix to this FAQ document contains a “decision tree” to be used for determining whether specific equipment meets the definition of EEE and as such falls within the scope of the Directive.

Part 2 of the Appendix gives a description of the criteria determining whether a product falls within the scope of the Directive as well as a description and a number of examples concerning the scope exclusions.

3.2. What is the scope of the Directive from 15.8.2018 onwards?

Starting from 15 August 2018, the Directive will have an ‘open scope’ and all EEE must then be placed in one of the six new categories set out in its Annex III. Under the open scope, any equipment that falls under the definition of EEE as set out in Article 3(1)(a) is in scope.

From the open-scope period onwards, EEE is only out of scope if it falls under one of the exclusions explicitly mentioned in Article 2, paragraphs (3) and (4).

3.3. Do Member States have to change/redesign the categories in Annex I of the Directive during the transitional period?

No. Until the end of the transitional period (14 August 2018), the same 10 categories of EEE as in Directive 2002/96/EC remain in force as regards targets and reporting obligations. However, in the new Directive there is an addition in category 4 in Annex I: during the transitional period, category 4 not only includes consumer equipment but photovoltaic panels as well. It is only from 15 August 2018 onwards that all EEE shall be classified under the 6 categories set out in Annex III of the Directive as regards targets and reporting.

Member States and other relevant actors are free to design and use additional (sub-) categories, as long as reporting to the Commission is in line with the requirements of the Directive.

3.4. Does the Directive apply to EEE for professional use?

Yes. Preambular paragraph 9 makes it clear that the Directive covers all EEE used by consumers and EEE intended for professional use. All types of electrical and electronic equipment that meet the definition of EEE as set out in Article 3(1)(a) fall within the scope of the Directive unless they benefit from an exclusion on the basis of Article 2. It should be noted however that:

1. According to Article 7(1), until 2015 the collection target (4kg/inhabitant/year) only relates to WEEE from private households; from 2016 onwards the collection target will cover both types of WEEE (see also question 7.8).

2. For WEEE from private households financing provisions are set out in Article 12 while for WEEE from users other than private households these provisions are set out in Article 13.

3.5. Does the Directive apply to batteries?

A producer of electrical and electronic equipment containing a battery is also regarded as a battery producer under the Batteries Directive. This is to ensure that there will be a responsible producer for all batteries placed on the EU market regardless of whether the batteries are put on the market themselves or incorporated in EEE. Member States should avoid any double charging of producers in case batteries are collected with the appliance on the basis of the WEEE Directive.

Batteries incorporated in WEEE will be collected on the basis of the WEEE Directive. However, as required in Annex VII of the Directive, after collection, they will be removed (manual, mechanical, chemical or metallurgic handling) from the WEEE and they will count for the collection targets of the Batteries Directive. They are also subject to the recycling requirements of the Batteries Directive.

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3.6. Do components fall within the scope of the Directive?

Components cover the range of items that, when assembled, enable an EEE to work properly. Components placed on the market separately in order to be used to manufacture and/or repair an EEE fall outside the scope of the Directive unless they have an independent function themselves.

However, a self-assembly kit that consists of components that form an EEE when assembled is an EEE at the stage when it is sold as an assembly kit (Example: remote controlled electric helicopter delivered as an assembly kit).

3.7. Do Radio Frequency Identification (RFID) tags fall within the scope of the Directive?

Yes. RFID tags (active and passive) meet the definition of EEE as set out in Article 3(1)(a) and thus fall within the scope of the Directive, unless they benefit from an exclusion on the basis of Article 2.

3.8. Do antennas and cables fall within the scope of the Directive?

Antennas and cables used for the transfer of electrical currents and electromagnetic fields meet the definition of EEE as set out in Article 3(1)(a) and thus fall within the scope of the Directive.

However, cables that are components of another EEE (either internal – permanently attached – or externally connected and removable, but sold together or marketed/shipped for use with the EEE) do not fall within the scope of the Directive. Cables placed on the market individually that are not part of another EEE are considered as EEE themselves.

3.9. Do printer cartridges fall within the scope of the Directive?

This depends on the type of the printer cartridge.

A printer cartridge falls within the scope of the Directive if it meets the definition of EEE given in Article 3(1)(a) and does not fall under the exclusions of Article 2 of the Directive. The decisive criterion is the fulfilment of the definition of EEE. Thus, printer cartridges which contain electrical parts and are dependent on electric currents or electromagnetic fields in order to function properly fall within the scope of the Directive.

Printer cartridges which merely consist of ink and a container, without electrical parts, do not fall within the scope of the Directive.

3.10. Do inverters fall within the scope of the Directive?

An inverter (i.e. an electrical device that changes direct current (DC) to alternating current (AC), commonly used to supply AC power from DC sources such as solar panels or batteries) falls under
the definition of EEE given in Article 3(1)(a) and thus falls within the scope of the Directive. An example of an inverter that falls within the scope of the Directive is one used in a photovoltaic installation.

However, an inverter does not fall within the scope of the Directive in the following cases:

- when it is designed and placed on the market as a component to be integrated into another EEE,
- when it benefits from an exclusion on the basis of Article 2: e.g. it is specifically designed and installed as part of another type of equipment that is excluded from or does not fall within the scope of the Directive, and the inverter can fulfil its function only if it is part of that equipment.

3.11. Is any equipment that contains photovoltaic cells, modules or panels a photovoltaic panel under category 4 of Annex I of the Directive?

No. This depends on the precise nature of the equipment. A photovoltaic (PV) panel is a piece of electrical equipment which has been designed with the sole purpose to generate electricity from solar light for public, commercial, industrial, rural and residential applications. This definition does not include equipment with integrated PV cells whose function is to generate the electricity needed to make that equipment work. The following non-exhaustive list illustrates equipment containing a solar cell which are not to be considered as photovoltaic panels, but falling into other categories of equipment covered by the Directive: solar air conditioning, solar backpack, solar cell phone charger, solar fan, solar keyboard, solar lamp, solar notebook, solar powered calculator, solar powered fountain, solar powered radio, solar powered refrigerator, solar powered watch, solar road stud and solar garden light.

This kind of equipment should not be reported as a PV panel under category 4 of Annex I but should be reported under the respective category (e.g. a pocket calculator with a small PV panel should be reported under category 3 of Annex I, a luminaire with a small PV panel should be reported under category 5 of Annex I).

3.12. Can any equipment featuring screens larger than 100cm² be considered as falling under category 2 of Annex III?

No. EEE containing screens greater than 100cm², but whose main focus is different from displaying images or animated or un-animated information on a screen, shall not be considered as belonging to category 2 of Annex III as this would distort the information content of reports. Products like washing machines, refrigerators and printers (which happen to have a screen larger than 100cm² and whose main function is different from that of a monitor), should be reported under their specific category and not under category 2 of Annex III.

3.13. Does all lighting equipment fall within the scope of the Directive?

Yes, for both the transitional and the open scope period all the different kinds of lamps and luminaries fall within the scope of the Directive unless they benefit from an exclusion on the basis of Article 2. From the open scope period the exception of ‘luminaries in households’ (see category 5 in
Annex II of the Directive) is no longer applicable, while filament bulbs (filament lamps) continue to be excluded from the scope of the Directive.

Whatever source of light meets the definition of EEE as contained in Article 3(1)(a) is a lamp falling within the scope of the Directive. This includes light sources using LED or OLED technology and LED retrofit lamps placed on the market as individual products. However, light sources such as LED chips or integral modules placed on the market in order to be integrated or built-in in LED lamps or luminaires do not fall within the scope of the Directive because they are components of an EEE.

As regards the categorisation of lighting equipment into EEE categories:

- During the transitional period, all the different kinds of lighting equipment (both lamps and luminaires) fall under category 5 ‘lighting equipment’ of Annex I;
- During the open scope period, lighting equipment can be classified in three different categories of Annex II, according to the type and the size of the equipment i.e.
  - All the different types of light sources fall under category 3 (‘Lamps’) and
  - Luminaries fall either under category 4 (‘large equipment’) or under category 5 (small equipment), depending on their size.

3.14. What type of equipment falls under the exclusion in Article 2(3)(b) as ‘specifically designed and installed as part of another equipment...’?

If equipment is specifically produced in order to be installed as part of another type of equipment that is excluded from or does not fall within the scope of the Directive and can fulfil its function only if it is part of that equipment, such equipment is ‘specifically designed’ and falls out of the scope of the Directive (Article 2(3)(b)). In these cases “specifically designed” equipment means that it is tailor made since it is designed to meet the needs of a specific application in the equipment that it is part of.

Examples of specifically designed equipment to be installed as part of another type of equipment that is excluded from the scope of the Directive include:

- equipment specifically designed, dimensioned and customized to be used as part of a specific large-scale fixed installation (‘LSFI’) (e.g. sensor equipment with a size, electrical interface and mounting features designed to fit inside drill heads).
- equipment designed specifically to be installed as part of a large-scale stationary industrial tool ‘LSSIT’ (e.g. pumps designed for transport of cooling lubricants for LSSIT).

Examples of specifically designed equipment to be installed as part of another type of equipment that does not fall within the scope of the Directive include navigation devices designed for specific models of cars and incorporated into the car and galley equipment designed for an individual aircraft or range of aircraft. Conversely, equipment intended to be fitted, for example, to any automobile such as hands-free phone systems and retrofit satellite navigation devices is not ‘specifically designed’ and does not benefit from this exclusion.
3.15. Is R&D equipment excluded from the scope of the Directive?

As per Article 2(4)(f) of the Directive, equipment specifically designed solely for the purposes of research and development (R&D) that is only made available on a business-to-business basis is excluded from the scope of the Directive to help reduce unnecessary burdens on research, scientific advancement, development and innovation in the EU.

Standard equipment, such as monitoring devices or instruments for chemical analysis and other laboratory equipment, that can be used both for R&D applications and in commercial or other applications, does not benefit from this exclusion. Neither does the exclusion apply to equipment designed and placed on the market to test, validate or monitor R&D equipment and/or prototypes.

Examples of EEE that may benefit from this R&D exclusion include:

• non-finished products such as prototype or sample/test EEE (these products are still part of the development and pre-production process and not marketed).
• In-house custom built ‘development vehicles’ used solely for the development, testing, validation and evaluation of such non-finished products, including the evaluation of regulatory compliance, product performance and determination of customer acceptability.

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

3.16. Is all medical equipment excluded from the scope of the Directive?

No. As per Article 2(4)(g) the exclusion from the scope of the Directive only applies to medical equipment (medical devices and in vitro diagnostic medical devices) that is expected to be infective prior to end of life. Furthermore, active implantable medical devices are excluded to avoid an obligation to remove electrical equipment from deceased persons for reasons.

Examples of exclusions as medical equipment expected to be infective prior to end of life include:

• Single use medical equipment (e.g. electrodes used to attach to a baby’s head in order to monitor the health condition of the baby during birth; the electrodes are disposed of as infective hospital waste; the monitor itself, which has no contact with the patient, is not excluded).
• Medical equipment that due to national regulation shall be collected and treated via an infectious health hazard regime (clinical waste).
3.17. Is equipment such as IT and telecommunication equipment used within a large-scale fixed installation or a large-scale stationary industrial tool excluded from the scope?

This depends. Equipment which is not specifically designed and installed as part of an excluded installation or tool is not excluded from the scope. Smoke detectors, computers and cables are examples of equipment that is in scope. Only if for example a computer is specifically designed for a large-scale installation or tool, (e.g., an industrial PC to be integrated in and attached with the large-scale fixed installation), and if that computer can only function and be used within the large-scale fixed installation (because of its special hardware and/or construction), it is excluded as part of a large-scale fixed installation. If not placed within the large-scale fixed installation, such a computer has no possible functionality or use of its own.

3.18. Is lighting equipment covered by the exclusion of large scale fixed installations?

No. Article 2(4)(b) states that any equipment that is not specifically designed and installed as part of a large-scale fixed installation does not benefit from this exclusion. Lighting equipment is normally not specifically designed to be part of a specific installation, and is therefore in scope of the Directive.

4. DEFINITIONS- Article 3

4.1. What does ‘dependent on electric currents or electromagnetic fields in order to work properly’ mean?

‘Dependent on electric currents or electromagnetic fields in order to work properly’ means that the equipment needs electric currents or electromagnetic fields (e.g. not petrol or gas) to fulfil its basic function (i.e., when the electric current is off, the equipment cannot fulfil its basic function). If electrical energy is used only for support or control functions, this type of equipment is not covered by the Directive. Examples of equipment that does not need electricity to fulfil its basic function, (but only requires, for example, a spark to start), include petrol lawn mowers and gas stoves with electronic ignition only (see also Appendix, Part 2).

Some types of equipment that now fall within the scope of the new RoHS Directive (Directive 2011/65/EU)³ as a result of its more specific definition of ‘dependent’ (on electricity) given in article 3(2), may still be outside the scope of the new WEEE Directive, as the Directive does not contain this more specific definition according to which ‘dependent’ means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function.

4.2. What are large-scale fixed installations (LSFI) and large-scale stationary industrial tools (LSSIT)?

Two of the WEEE scope exclusions listed in Article 2(4) refer to combinations of EEE in a professional context, i.e. "large-scale stationary industrial tools" (Article 2(4)(b)) and "large-scale fixed installations" (Article 2(4)(c)).

Both "large-scale stationary industrial tools" and "large-scale fixed installations" are defined in Article 3(1) (b) and (c) respectively. More information on the meaning of "large-scale" is provided in the RoHS 2 FAQ document (Q 3.1.).

4.3. Is a company manufacturing EEE in a Member State but exporting 100% of its production considered to be a producer in that Member State?

No. According to Article 3(1)(f)(i), a company that is established in a Member State and manufactures EEE under its own name or trademark is considered to be a producer only if it also markets EEE under its name or trademark within the territory of that Member State.

4.4. Can a manufacturer or seller not established in any Member State be considered as a producer of EEE?

Yes. According to Article 3(1)(f)(iv), in cases where the manufacturer or seller established in a non-EU country sells EEE directly to an end-user located in a Member State by means of distance communication, this manufacturer or seller is considered to be the producer of that EEE and must comply with the requirements of the Directive (i.e. he has to be registered in the national registry of each Member State where he sells, to fulfil take-back obligations, to report on the quantities placed on the market of each Member State).

However, if a manufacturer or seller established in a non-EU country sells EEE to a professional seller in a Member State then the latter meets the definition of producer under Article 3(1)(f)(iii) and he/she is the one to comply with the requirements of the Directive.

4.5. Does any natural or legal person who places on the market of a Member State, on a professional basis, EEE from a third country or from another Member State need to have the equipment branded under his/her own name in order to be considered as a producer?

No. Any natural or legal person placing on the market of a Member State on a professional basis EEE from a third country or from another Member State meets the definition of producer under Article 3(1)(f)(iii) irrespective of whether the EEE is branded under his own name or not.

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4.6. **What is 'EEE likely to be used by both private households and users other than private households' (the waste of which 'shall in any event be considered WEEE from private households')?**

This term, which in the Directive has been added to the definition of 'WEEE from private households' given in Article 3(1)(h), refers to electrical and electronic equipment which due to its nature can be assumed to be used by both private households and users other than private households (professional users). Such equipment should be registered and reported as household equipment and its waste should be considered WEEE from private households.

Examples of such equipment include:
- personal computers and telephones which are used both by private households and in a commercial/industrial context;
- standard photovoltaic panels operating at a voltage or having a power consumption or generating electricity inside the range available in private households.

Examples of electrical and electronic equipment which due to its nature should not be assumed to be used by private households include:
- medical devices used only in hospitals and medical centres (e.g. medical X-ray equipment);
- EEE operating at a voltage or having a power consumption or generating electricity outside the range available in private households (e.g. large scale photovoltaic systems designed for professional use) and EEE requiring professional licenses or entry-intro-service authorisations to operate (e.g. base stations requiring the license of the telecommunication regulator).

4.7. **Does the placing on the market on a professional basis of EEE already used in one Member State within the territory of another Member State meet the definition of 'placing on the market'?**

Yes. The Directive is applied at Member State level; only equipment moved within a Member State remains in the same market in which it was originally placed.

If EEE is placed on the market of a Member State from another Member State on a professional basis, is considered a new 'placing on the market', in line with Article 3(1)(k). This interpretation applies to any second hand, reused or remanufactured EEE that is sold on a professional basis. It does not apply to the resale of used EEE by the end user.

5. **SEPARATE COLLECTION- Article 5**

5.1. **What are the responsibilities of distributors for separate WEEE collection?**

Article 5(2)(b) of the Directive obliges distributors to accept a discarded item when a new equivalent item is purchased. If Member States want to derogate from this provision, they have to ensure that
returning the WEEE is not thereby made more difficult for the final holder and that it remains free of charge for the final holder.

Article 5(2)(c) requires distributors, at retail shops with sales areas relating to EEE of at least 400m², to accept very small WEEE (no external dimension more than 25cm) when returned to them, with no further obligation to the end-user to buy EEE of an equivalent type. If Member States want to deviate from this requirement by applying alternative existing collection schemes, such schemes must be shown to be at least as effective, and the assessment must be made available to the public.

5.2. **How to measure external dimensions of ‘very small’ EEE?**

In line with Article 5(2)(c) ‘very small’ EEE is EEE that has no external dimension more than 25cm. To measure the external dimensions of:

a) **‘very small’ equipment with curved surfaces:**
Simply draw a box around the equipment and measure its dimensions.

b) **‘very small’ equipment with accessories:**
Measure the dimensions by drawing a box around the equipment without any accessories that can be removed from it and measure the dimensions of the accessories separately. For example if a cell phone is discarded with its charger, these are two products. In this case, the dimensions of the cell phone and the charger should be measured separately by drawing a box around each one of them.

c) **cables:**
Measure the dimensions by drawing a box around the best compact form to pack the cables.

6. **RE-USE CENTERS — Article 6**

6.1. **Can re-use centres have access to collection points?**

Yes. Article 6(2) requires Member States to promote that collection schemes or facilities provide, where appropriate, for the separation at collection points of WEEE to be prepared for re-use and to grant personnel from re-use centres access to that WEEE, provided that the re-use centres are accredited, in line with Annex IV (point 16) of the EU Waste Framework Directive 2008/98/EC.

Regarding access of re-use centres to collection points, a number of different practices existing in Member States can be applied. For example, if producer responsibility systems establish collection points, they can also control access to all collection points and cooperate with accredited re-use centres. The access could also be granted on the basis of individual contracts between the respective operators and re-use centre(s); examples of ‘operators’ include municipalities or associations of municipalities (operating municipal collection centres), private waste companies (operating compliance scheme’s regional collection centres) or social enterprises (operating collection centres as contractors for municipalities and/or compliance schemes).
7. COLLECTION RATE- Article 7

7.1. Who is responsible for achieving the collection rates?

In line with Article 7(1) Member States shall ensure that the collection rates referred to in paragraph 7(1) are achieved.

For the achievement of the collection rate, Member States shall ensure that collective and/or individual systems are set up, adequate and accessible collection points are established and action to increase collection is taken and promoted (e.g. nationwide awareness campaigns).

National authorities have to ensure that collection rates are achieved taking into account all the channels, as specified in Article 16(4). Member States should put in place measures to gather information on all WEEE that has been separately collected. It is critical for Member States to ensure that anyone who handles WEEE (e.g. recyclers, waste collectors, local authorities, traders), properly reports it, including the type and the quantity of WEEE they handle.

7.2. Can Member States set more ambitious collection rates?

Yes. According to the last paragraph of Article 7(1), Member States may set more ambitious rates for separate collection of WEEE and shall in such a case report this to the Commission.

7.3. Do Member States need to choose between a “collection rate based on 65% of EEE placed on the market in the three preceding years” and a “collection rate based on 85% of WEEE generated on their territory”?

No. Article 7(1) does not require Member States to choose. From 2019 onwards (seven years after entry into force), Article 7(1) merely requires Member States to demonstrate achievement of either one of the collection rates. This means that Member States are permitted to demonstrate annual compliance with either the former or the latter collection rate, and that they do not need to choose in advance on which basis the collection rate will be reported.

7.4. How shall Member States calculate the collection rate based on 65% of EEE placed on the market in the three preceding years or the collection rate based on 85% of WEEE generated on their territory?

From 2019 onwards, the minimum collection rate to be achieved annually shall be 65% of the average weight of EEE placed on the market in the three preceding years in the Member State concerned, or alternatively 85% of WEEE generated on the territory of that Member State as foreseen in Article 7(1).

Member States that prefer to demonstrate compliance with the former collection rate for a reference year (x), should calculate the average weight of EEE placed on the market in the three preceding years, meaning years (x-1), (x-2) and (x-3). So, for the first year that this target applies,
2019, the collection rate should be calculated as a percentage of the weight of EEE placed on the market in years 2018, 2017 and 2016.

Member States that prefer to demonstrate compliance with the latter collection rate for a reference year (x) should calculate the weight of the WEEE generated that year (x). So, for the first year that this target applies, 2019, the collection rate should be calculated as a percentage of the weight of WEEE generated on the territory of the Member State the same year 2019.

To calculate the weight of EEE placed on the national market and the weight of WEEE generated in their territory Member States shall apply the methodologies to be established by the Commission according to Article 7(5).

7.5. Can Member States require that information on all WEEE collected separately through all routes is reported to them free of charge?

Yes. Article 7(2) requires that Member States gather information on all separately collected WEEE. Member States collect that information from collection and treatment facilities, distributors and producers or third parties acting on their behalf. The information should be transmitted to Member States free of charge. However, significant room for national implementing rules is left to Member States as regards national systems for data collection.

7.6. Are Member States required to collect information on WEEE collected through all routes?

Yes. According to Article 16(4), Member States are required to collect information on WEEE collected through all routes. This means that Member States should adopt measures to involve all actors in WEEE collection and to receive information on the quantities and categories of WEEE collected through all routes.

There are significant flows of WEEE outside producer responsibility schemes set up and operated by producers and it is important that all WEEE separately collected by different routes counts towards the collection rate. These so called ‘complimentary WEEE flows’ are collected by an array of actors, ranging from small-scale door-to-door collectors to large-scale scrap dealers and recyclers. The challenge for Member States is to ensure that these ‘complimentary WEEE flows’ are properly measured and that all separately collected WEEE undergoes proper treatment.

Given the complexity of WEEE flows, and on the basis of Article 16(4), Member States may opt to use substantiated estimates of WEEE collected through all routes to demonstrate or to help them demonstrate the achievement of the collection targets laid down in Article 7(1). Substantiated estimates have to be supported by independent scientific methodologies and be based as far as possible on real market data.
7.7. **Should the collection rate be applied to specific product categories?**

No. The collection rate referred to in Article 7(1) does not set individual collection rates for specific product categories. It refers to the national target to be achieved for WEEE in general and not to each one of the different WEEE categories.

Article 7(6) states that the Commission shall examine setting possible individual collection rates for one or more categories set out in Annex III, particularly for temperature exchange equipment, photovoltaic panels, small equipment, small IT and telecommunication equipment and lamps containing mercury. By 14 August 2015 the Commission shall present a report on this matter, if appropriate, accompanied by a legislative proposal.

7.8. **How does the collection rate set out in Article 7(1) relate to WEEE from users other than private households?**

Until 31 December 2015 a collection target of at least 4 kilograms on average per inhabitant per year of WEEE from private households or the same amount of weight of WEEE as was collected in that Member State on average in the three preceding years, whichever is greater, shall apply.

However, from 2016 onwards the minimum collection rate shall be 45 %, calculated on the basis of the total weight of WEEE collected in a given year in the Member State concerned and expressed as a percentage of the average weight of EEE placed on the market in the three preceding years (2013-2014-2015) in that Member State. This means that from 2016 onwards a single minimum collection rate applies to the total amount of WEEE, both from private households and from users other than private households.

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8. **INFORMATION FOR USERS & INFORMATION FOR TREATMENT FACILITIES - Articles 14 & 15**

8.1. **When EEE is marked when it is placed on the market of a Member State, does this EEE has to be re-marked when it is traded between Member States?**

No. If the manufacturer of the EEE (or anyone cooperating in the supply chain) marked the EEE when it was placed on the market of a Member State and the EEE is traded to another Member State, the party responsible for marking the EEE (e.g. producer) in that other Member State shall not be obliged to re-mark the EEE, since the information requested under Articles 14(4) and 15(2) already exists on the EEE.

If the manufacturer of the EEE (or anyone cooperating in the supply chain) did not mark the EEE when it was placed on the market of a Member State and the EEE is traded to another Member State, the party responsible for marking the EEE in that other Member State shall mark the EEE.
9. AUTHORISED REPRESENTATIVE- Article 17

9.1. Do producers have the right to appoint an authorised representative, instead of being established in a Member State?

Yes. According to Article 17(1), Member States shall ensure that a producer as defined in article 3(1)(f)(i) to (iii) established in another Member State is allowed, by way of exception to Article 3(1)(f)(i) to (iii), to appoint a legal or natural person established on its territory as the authorised representative that is responsible for fulfilling the relevant obligations of that producer in its territory.

To illustrate this, consider the case of a company A established in a Member State (MS1) which sells EEE to one or more companies (e.g. companies X, Y) in another Member State (MS2). According to article 17(1), MS2 shall allow company A to appoint an authorised representative responsible for fulfilling the obligations of company A in MS2. This means that for the quantities that company A places on the market of MS2, the authorised representative is responsible for fulfilling the relevant obligations (e.g. registration, reporting to schemes, etc). It also means that the companies X, Y should not declare these quantities and they do not have any producer obligation concerning these quantities. If company A does not appoint an authorised representative in MS2, the companies X, Y (as producers in MS2 according to Article 3(1)(f)(iii)) are the responsible producers in that Member State.

With regard to producers as defined in Article 3(1)(f)(iv), article 17(2) of the Directive states that the Member State in which they are established shall ensure that these producers appoint an authorised representative in the Member State(s) to which they sell EEE by means of distance communication while not being established in that Member State(s), in order to have somebody ensuring compliance with their obligations as producers.

Distance sellers in the sense of Article 3(1)(f)(iv) that are established in a third country have to be registered in the Member State to which they sell EEE. Where such producers are not registered directly in the Member State that they sell to, they have to be registered through an authorised representative.

10. INSPECTION AND MONITORING- Article 23

10.1. Does Article 23(2) mean that Member States must impose the criteria in Annex VI for all shipments of used EEE?

No. On the basis of Article 23(2) Member States are required to apply the requirements of Annex VI only in cases where there is suspicion that a shipment of used EEE is a shipment of WEEE. The minimum requirements for shipments should not hinder the legal trade of used equipment. Where
there is a suspicion that a shipment is de facto an illegal shipment of waste, Annex VI gives Member States the legal instrument to clarify the situation\(^5\).

For example, suspicion can be raised because of improper packaging of used EEE. Insufficient packaging for protecting items from damage during transportation, loading and unloading operations is an indication that an item may be waste. Used EEE that is properly packaged is therefore unlikely to be suspected to be WEEE.

10.2. Does Article 23(2) also apply to shipments of used EEE between Member States?

Yes. Article 23(2) applies both to shipments of used EEE from and to the EU as well as to shipments of used EEE between Member States.

10.3. Can the producer/person responsible for the shipment be charged with the storage cost even if the used EEE suspected to be WEEE is proven not to be WEEE?

Yes. Article 23(3) of the Directive allows Member States to charge the costs of appropriate analyses and inspections and storage to the producer or third parties acting on his behalf or to other persons arranging the shipment regardless of whether or not the suspected used EEE was proven to be WEEE.

11. MINIMUM REQUIREMENTS FOR SHIPMENTS — Annex VI

11.1. Is the ‘holder’ of used EEE always the legal owner of this EEE?

No. Annex VI point (1) refers to the ‘holder of the object’ who intends to ship or is shipping used EEE; Points (1)(c) and (5) of Annex VI refer to the ‘holder who arranges the transport’. The ‘holder of the object’ is the natural or legal person who is (directly or indirectly) in possession of the used EEE, but who is not necessarily the legal owner of the used EEE.

11.2. Does the appropriate protection against damage during transportation, loading and unloading require both sufficient packaging and appropriate stacking of the load?

Yes. When used EEE is shipped with the intention of re-use it is expected that it is properly protected through both sufficient packaging and appropriate stacking (similar protection as for transport of new products).

11.3. What is the meaning of a ‘warranty’ in the context of Annex VI point 2(a)?

In the context of Annex VI (point 2(a)), a ‘warranty’ can be considered to be either an obligation under national legislation of producers towards consumers for the lack of conformity of equipment on the sale of consumer goods, or any written agreement by a seller or producer to repair or replace equipment if it does not meet the specifications set out in the guarantee statement or in the relevant advertising.

Warranties include, for instance, the legal and consumer guarantees under Directive 1999/44/EC as well as warranties provided by manufacturers and sellers in relation to business to business transactions involving EEE. The term also covers additional contractual undertakings, e.g. extended warranties, or obligations undertaken in the context of sales, service, maintenance and repair agreements.

11.4. Does the derogation from the requirements referred to in point 2 of Annex VI apply when used EEE to be shipped is under a leasing contract?

According to the definition of WEEE in Article 3(1)(e), EEE becomes WEEE when its holder discards or intends or is required to discard the EEE. Used EEE under a valid leasing contract and which is shipped by a person engaged, on a professional basis, in a leasing business, is not WEEE as long as there is no intention from the holder to discard it. Therefore such EEE is not ‘suspected to be WEEE’, unless there is another reason to believe that the used EEE is not destined for further use (e.g. insufficient packaging and unappropriated stacking of the load).

11.5. In which cases does the derogation in Annex VI point 2(b) apply?

Point 2(b) of Annex VI applies to used EEE for professional use sent for refurbishment or repair under a valid contract with the intention of re-use, sent to
- the producer; or
- a third party acting on behalf of the producer; or
- a third-party facility in countries to which Decision C(2001)107/Final of the OECD Council concerning the revision of Decision C(92)39/Final on control of transboundary movements of wastes destined for recovery operations applies.

11.6. What is the purpose of the ‘declaration by the liable person on its responsibility’? What form shall this declaration take?

The purpose of the ‘declaration by the liable person on its responsibility’ referred to in point 4(b) on Annex VI is to identify the natural or legal person taking responsibility for the shipment with regard to the Annex VI requirements. The liable person is the one who has arranged the shipment. The declaration could be made, for instance, by adding an appropriate text to the declaration required under Annex VI point 1(c).
11.7. Is it necessary to carry all information mentioned in point 5 of Annex VI in order to prove that an object is used EEE?

No. Shipments of used EEE which are covered by one of the derogations of point 2 do not need to be accompanied by documentation of point 1(a), 1(b) and point 3. The wording of point 5 of Annex VI could be misunderstood as additionally calling for documentation that is not required when a shipment of used EEE is taking place according to one of the derogations of Annex VI point 2.

11.8. Does EEE that is excluded from the scope of the Directive have to meet the Annex VI requirements when shipped?

No. EEE that is excluded from the scope of the Directive (e.g. defective large-scale stationary industrial tools and large-scale fixed installations) is not subject to the minimum requirements for shipments of Annex VI.
Appendix

The aim of this appendix is to help illustrate the scope of the Directive.

The Appendix is divided into two parts:

**Part 1:** Presents a decision tree which can be used by producers to find out if the Directive applies to their products as well as by national authorities to decide on whether specific equipment is in scope of the Directive or not.

**Part 2:** Presents a description of the criteria determining whether or not specific equipment is in scope of the Directive and provides specific examples.
PART 1: Decision tree - How can I find out if the Directive applies to my product?

To find out if the requirements of the Directive apply to your product follow the decision tree below. Go through each box. If you can answer **YES** to criterion 1 and to one of the criteria 2-5 in the first box the equipment is considered to be an EEE and is, as a point of departure, **IN** scope of the Directive. If you can answer **NO** to all of the criteria in the first box, your equipment is not regulated by the Directive.

If you can answer **YES** to one of the criteria A-J in the second box, your equipment is likely to be excluded from the scope of the Directive. The first three criteria (A, B, C) apply already during the transitional period while the rest apply from 15 August 2018 onwards. In case of doubt, contact the national authority in the Member State concerned. If no exclusion criteria apply for your equipment it is **IN** scope of the Directive.

**Decision Tree**
PART 2: Description of the criteria determining whether or not specific equipment is in scope of the Directive- examples

This section of the appendix presents the 15 criteria defining what is in and what is out of scope of the new WEEE Directive. A purpose of each criterion is given and — where appropriate — examples of misinterpretation of the criteria are presented. This is done in order to clarify the possible grey areas of each criterion.

In the first column, the numbers used in this appendix are shown: Inclusion criteria 1-5 and exclusion criteria A-J. The second column, gives the criterion text from the Directive and the third column, states the purpose of the criteria (why was it introduced) and examples of misinterpretation. The reason for introducing the purpose is that while discussing whether EEE is in or out of scope, words are often interpreted/ understood/ translated differently so that the initial meaning can be lost.

Example: Under the old WEEE Directive 2002/96/EU it became a common ‘rumour’ that professional equipment within category 6 that is fixed to the wall is considered out of scope. This is however far from the wording of the Directive, which does not mention ‘fixed’ as an independent criterion to exclude equipment from scope in general.

Criteria determining EEE falling within the scope of the Directive

<table>
<thead>
<tr>
<th>No</th>
<th>Criterion</th>
<th>Explanation</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Equipment designed for use with a voltage rating not exceeding 1000 Volt for alternating current and 1500 Volt for direct current,</td>
<td><strong>Purpose:</strong> To exclude equipment where the voltage of the electrical input or output exceeds the specified and common limits.</td>
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<td></td>
<td></td>
<td><strong>Example of misinterpretation:</strong> The exclusion of tools/machinery/equipment where the voltage that appears inside the equipment exceeds the limits. For example, the electric flyswatter that short-circuits when a fly hits the wires and briefly releases a high voltage, despite being powered by two AA batteries.</td>
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<tr>
<td>2</td>
<td>Equipment dependent on electric currents or electromagnetic fields in order to work properly,</td>
<td><strong>Purpose:</strong> To ensure that equipment that does not need electricity to fulfil its basic function, (but only requires, for example, a spark to start), is excluded from the scope of the Directive. Examples are petrol lawn mowers, lighters, gas stoves with electronic ignition only.</td>
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<td></td>
<td></td>
<td><strong>Example of misinterpretation:</strong> The exclusion of equipment that is differentiated through an electric function (e.g., an electrical toothbrush falls clearly within the scope of the Directive since it depends on electric currents or electromagnetic fields in order to work properly and should not be excluded because it can still be used as a simple toothbrush if electric current or electromagnetic field is off.</td>
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</table>

6 In any case equipment meeting the definition of EEE falls within the scope of the Directive unless it benefits from an exclusion on the basis of Article 2 of the Directive
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<tbody>
<tr>
<td>3</td>
<td><strong>Equipment for the generation of electric currents or electromagnetic fields,</strong></td>
<td><strong>Purpose:</strong> To ensure that all generators of electricity, designed for use with a voltage rating not exceeding 1 000 Volt for alternating current and 1 500 Volt for direct current, are included in the scope of the Directive, including power generators working by combustion, wind, water, solar or other means of power. The purpose is not to include an entire power plant, but merely the equipment for the generation of electric currents or electromagnetic fields. <strong>Example of misinterpretation:</strong> The inclusion into the scope of an entire power plant or the inclusion of a generator that is covered by any of the exclusions from the scope (e.g. generator specifically designed and installed as part of another type of equipment that is excluded or does not fall within the scope of the Directive).</td>
</tr>
<tr>
<td>4</td>
<td><strong>Equipment for the transfer of electric currents or electromagnetic fields,</strong></td>
<td><strong>Purpose:</strong> To ensure that all media for the transfer of electric currents or electromagnetic fields, including wires, cables, transformers and antennas, are included into the scope as EEE unless they are covered by any of the exclusions from scope. <strong>Example of misinterpretation:</strong> The exclusion of cables and antennas with the argument that they have no independent function. Their core function is transferring electric currents or electromagnetic fields.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Equipment for the measurement of electric currents or electromagnetic fields,</strong></td>
<td><strong>Purpose:</strong> To ensure inclusion into the scope of equipment for the measurement of electric currents or electromagnetic fields even if it is not in itself power consuming, for example a voltmeter. <strong>Example of misinterpretation:</strong> Not identified.</td>
</tr>
</tbody>
</table>
## Exclusions from the scope of the Directive

<table>
<thead>
<tr>
<th>A</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>To ensure that equipment which is necessary for the protection of the essential interests of the security of Member States (e.g., military intelligence equipment) and war material for specifically military purposes can be constructed with otherwise banned constituents and disposed of without bringing their construction to the knowledge of the public. Thus, it is essential that the equipment is not commercially available for other users than national security and military forces and will not follow ordinary waste streams.</td>
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<tr>
<td><strong>Example of misinterpretation:</strong></td>
<td>The exclusion of equipment which is publicly available with the argument that it is either part of or monitors for example a military weapons stock. An army green torch and military material where the secrecy of the equipment is not significant for national security do fall into the scope of the Directive.</td>
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<thead>
<tr>
<th>B</th>
<th>Equipment which is specifically designed and installed as part of another type of equipment that is excluded from or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>To ensure that equipment designed to be installed as part of another type of equipment that is either excluded from the scope or does not fall within the scope of this Directive and does not have an independent functionality of its own is not covered by the new WEEE Directive.</td>
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</tbody>
</table>
| **Examples:** | - Equipment designed to be installed as part of a ship or a car which can fulfil its function only if it is part of a ship or a car and is disposed according to the legislation for end-of-life vehicles and ships is covered by this exclusion. Such an example is an integrated radio or a equipment for navigation. 
- Equipment designed to be installed as part of a LSFI. |
| **Example of misinterpretation:** | To consider that this exclusion also covers equipment with an independent function on the ground that it may happen to be part of another installation. For example, it is a mistake to exclude from the scope of the Directive an integrated refrigerator because it could be considered part of a kitchen cupboard which is excluded from the scope of the Directive or respectively to exclude from the scope a normal TV panel that is permanently mounted on a wall because it could be considered part of the wall. |

<table>
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<tr>
<th>C</th>
<th>Filament bulbs</th>
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<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>To exclude equipment which is already being phased out of the European market.</td>
</tr>
<tr>
<td><strong>Example of misinterpretation:</strong></td>
<td>The exclusion of lamps which are explicitly mentioned in Annex IV of the new WEEE Directive as in scope.</td>
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</table>
| **D** | **Equipment designed to be sent into space.** | **Purpose:**
|   | To exclude equipment that is not designed to get back to earth. | **Example of misinterpretation:**
|   | The exclusion of equipment used for the process to control satellites etc., but never leaves the ground. | The exclusion of equipment originally designed to be sent into space, which has subsequently found applications on ground. |
| **E** | **Large-scale stationary industrial tools (‘LSSIT’)**<sup>7</sup> | **Purpose:**
|   | The idea is that large-scale industrial tools/machines that are installed, maintained, used and removed by professionals should be excluded from the new WEEE Directive. | **Example of misinterpretation:**
|   | The exclusion from the scope of any industrial tool. | Only those which meet the definition if LSSIT shall be excluded from the scope of the Directive. |
| **F** | **Large-scale fixed installations, except any equipment which is not specifically designed and installed as part of these installations (‘LSFI’)**<sup>8</sup> | **Purpose:**
|   | The idea is that professional EEE which is of large size and fixed but not an industrial tool, can be exempted if it fulfils the criteria in the definition of ‘large-scale fixed installation’. | **Example of misinterpretation:**
|   | In recital 9, oil platforms, airport luggage transport systems and elevators are mentioned as examples of large-scale fixed installations. | To argue that a streetlamp or stadium lamp bolted to a pole or a TV set mounted on the wall is a fixed installation. |
|   | To argue that equipment is out of scope as part of a LSFI even though the equipment is not specifically designed and installed as part of the installation. |   |

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<sup>7</sup> **Definition of LSSIT according to Article 2(1)(b):** ‘Large-scale stationary industrial tools’ means a large size 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;

<sup>8</sup> **Definition of LSFI according to Article 2(1)(c):** ‘large-scale fixed installation’ means a large size combination of several types of apparatus and, where applicable, other devices, which:
(i) are assembled, installed and de-installed by professionals,
(ii) are intended to be used permanently as part of a building or a structure at a pre-defined and dedicated location, and
(iii) can only be replaced by the same specifically designed equipment.
<table>
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<tr>
<th><strong>G</strong></th>
<th><strong>Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>To exclude lorries, cars, motorbikes, trains, boats, airplanes and other means of transport. The intention is to differentiate between means of transport that are type approved and these that are not type approved.</td>
</tr>
<tr>
<td><strong>Example of misinterpretation:</strong></td>
<td>The exclusion of electric toy cars where 1 or 2 children can sit inside. Such a toy vehicle is regarded as a toy first and foremost and it is not excluded from scope of the Directive. The exclusion of an electric bike or an electric roller which is not type-approved.</td>
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<th><strong>H</strong></th>
<th><strong>Non-road mobile machinery made available exclusively for professional use⁹</strong></th>
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<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>To exclude electric driven transport equipment and mobile machinery solely intended for professional use, which while working also moves around. Examples are forklifts, lawn movers, an electric wheelbarrow, street sweepers and mobile cranes.</td>
</tr>
<tr>
<td><strong>Example of misinterpretation:</strong></td>
<td>The exclusion of a machine designed to mix dough for bread professional production, with the argument that it can be moved around in the bakery. The exclusion of a concrete mixer, with the argument that it is moved from one construction site to another. The exclusion of a (non-fixed) water pump with the argument that it is not fixed and therefore mobile. The prerequisite to exclude the pump from scope is that it has got wheels or similar and while pumping water (working) it is moving around on these wheels.</td>
</tr>
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<tr>
<th><strong>I</strong></th>
<th><strong>Equipment specifically designed solely for the purposes of research and development (R&amp;D) that is only made available on a business to business basis.</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Purpose:</strong></td>
<td>Some R&amp;D equipment can be so specialised that the producer does not wish to make its means of construction publicly known. Thus, it is essential that the equipment is only available for research and development and it is excluded in order not to place a burden on research, scientific advancement, development and innovation in the EU.</td>
</tr>
<tr>
<td><strong>Example of misinterpretation:</strong></td>
<td>The boundaries between R&amp;D equipment for private households and R&amp;D equipment for users other than private households can be hard to define. To argue that equipment is still covered by this exclusion when it has become more widely available is a misinterpretation of the exclusion. The exclusion of equipment such as a centrifuge or blood gasses measuring devices if the equipment is both used for R&amp;D but also for ordinary caretaking in e.g. hospitals or for education purposes.</td>
</tr>
</tbody>
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⁹ Definition of ‘Non-road mobile machinery’ according to Article 2(1)(d): ‘Non-road mobile machinery’ means machinery, with 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;
<table>
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<tr>
<th><strong>J</strong></th>
<th><strong>Medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices</strong>¹⁰.</th>
</tr>
</thead>
</table>
| **Purpose:** | To avoid removing electrical equipment from deceased persons.  
To avoid that infected equipment ends up in the waste stream, causing risks to human health. |
| **Example of misinterpretation:** | The exclusion of anything having been in contact with body liquids, including, thermometers, medical reusable equipment, where the infected minor parts of the equipment (tubes) are disposed each time the equipment is used, whereas the key equipment may be disinfected.  
Example: an automatic insulin control and infusion device consists of a re-use electric product, a valve through the human skin and a pipe between the electric device and the valve. The re-use electric product is not expected to be infected. A misinterpretation would therefore be to exclude the electric control and infusion device. |

¹⁰ **Definition of ‘Medical device’ according to Article 2(1)(m):** ‘Medical device’ means a medical device or accessory within the meaning of, respectively, points (a) or (b) of Article 1(2) of Directive 93/42/EEC of 14 June 1993 concerning medical devices(24) which is EEE;  

**Definition of ‘in vitro diagnostic medical device’ according to Article 2(1)(n):** ‘in vitro diagnostic medical device’ means an in vitro diagnostic device or accessory within the meaning of, respectively, points (b) or (c) of Article 1(2) of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices(25) which is EEE;  

**Definition of ‘active implantable medical device’ according to Article 2(1)(o):** ‘active implantable medical device’ means an active implantable medical device within the meaning of point © 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(26) which is EEE.