



ORGALIME

Position Paper

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INDUSTRY'S COMMON UNDERSTANDING OF THE SCOPE PROVISIONS OF DIRECTIVE 2011/65/EU ("RoHS2")

Following Orgalime's recent participation in the RoHS2 FAQ Working Group meeting, our industry provides this outline of its common understanding of the scope provisions of Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment ("RoHS2").

The background to this paper is twofold:

- 1. It substantiates the initial understanding expressed in Orgalime's RoHS2 Guide of July 2011 and aims at particularly clarifying the background to the position of the affected industry**
 - that the compliance obligations with the substance restrictions and CE marking obligations established by RoHS2 arise for manufacturers and importers of EEE, however not for installers,
 - that the definition of "electrical and electronic equipment" cannot be interpreted as targeting anything and everything with the slightest connection to electrical or electronic,
 - that any interpretative criteria in the context of RoHS2, and article 2.4 in particular, requires full respect of the legal text of the Directive and an "ex ante" approach in the light of the alignment of the RoHS Directive with the New Legislative Framework (NLF) and in view of preparing for RoHS2 compliance and for effective market surveillance and enforcement.
- 2. The draft FAQs are in our view built on a number of significant flaws, misunderstandings and erroneous starting points, including for example:**
 - accepting that Member States have different interpretations of the existing RoHS Directive, despite the fact that it represents a fully harmonised product legislation and the existence of a Commission Guidance Document on the existing RoHS Directive, and accepting that they plan to perpetuate those differences in the implementation of RoHS2.
 - charging responsibilities and obligations on market operators regardless of the New Legislative Framework and of the official text of RoHS 2 itself, or
 - proposing unclear interpretations of the New Legislative Framework, which result in conflicting answers and misleading indications.

Orgalime, the European Engineering Industries Association, speaks for 34 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 9.7 million people in the EU and in 2010 accounted for some €1,510 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.

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1. THE SYSTEM OF THE SCOPE PROVISIONS OF RoHS2

- According to article 2.1, RoHS2 applies to EEE falling within the **categories** set out in annex I. Recital 3, art. 2.1, art. 5.2, annex I and entry 29 of annex III of RoHS2 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.¹
- The recast has extended this systematic 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 11.²
- **Article 3.1 defines “EEE”** as *“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”*.
 - The **IEC International Electrotechnical Vocabulary 60050** defines “equipment” as follows, which is appropriate for the understanding of the RoHS2 scope provisions, too: “*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. Examples of equipment are a power transformer, the equipment of a substation, measuring equipment.*”

The IEC International Electrotechnical Vocabulary 60050 defines “apparatus” as follows: “*device or assembly of devices which can be used as an independent unit for specific functions.*”

NOTE – In English, the term "apparatus" sometimes implies use by skilled persons for professional purposes.”

 - Article 3.2 RoHS2 states that “*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 “**ECHA Guidance on substances in articles**” developed under the REACH Regulation to which RoHS2 has been aligned, states that:

“the term “function of an object” ...should be interpreted as meaning the basic principle determining the use of the object rather than the degree of technical sophistication determining the quality of the result.”

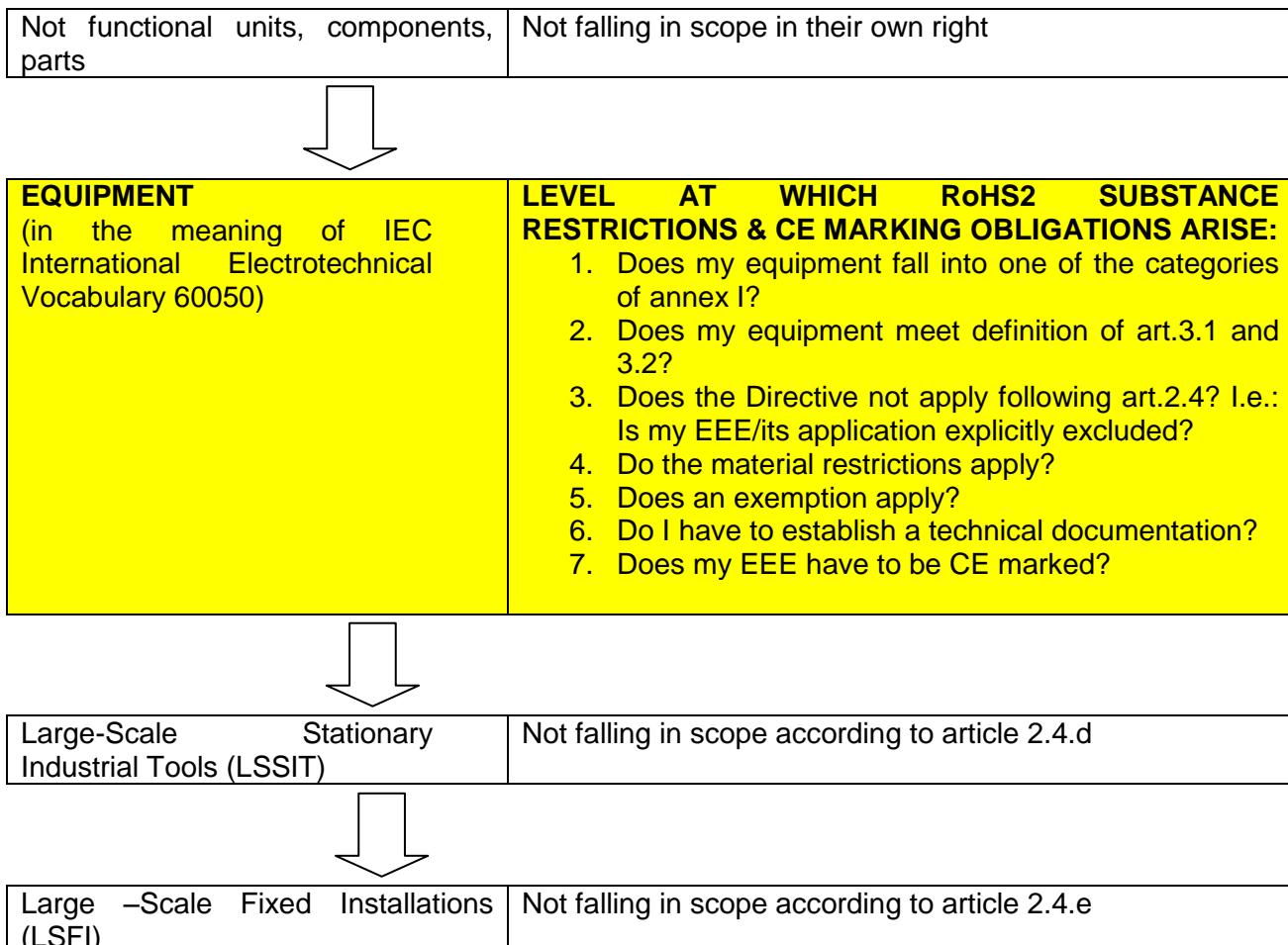
Note: Recital 12 states that the definition of “dependent” is to “complement” the definition of EEE, however, it is not supposed to overrule or go beyond the definition of “EEE”, which would result from considering the term “dependent” the only relevant criterion for assessing whether or not an equipment represent an EEE under RoHS2. Instead, all criteria of the definition of “EEE” given in art. 2.1 need to be assessed in order for the manufacturer to conclude if his equipment represents an EEE under RoHS2 or not. This includes in particular also an assessment of the notion dependent “to work properly”.

¹ See 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

² 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.”

- Article 3(27) of the recast RoHS Directive defines a "spare part" as: "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 only a (spare) part or component, which by Art. 3.27 is something below the level of "equipment".
- 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.
- **Any EEE newly included in scope benefits from an 8 years transition period:** The Commission has clarified in its Declaration to the adopted Recast Directive that article 2.2 means "*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*".
- RoHS2 recognises the following cases of **equipment not in scope** and/or **Non-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
 - b) Any other product that does not depend on electric current and electromagnetic fields to work properly (e.g.: textiles, furniture)
 - **Equipment and their applications on which the Directive does not apply according to article 2.4 ("scope exclusions")**
 - 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.

Summary of RoHS2 Scope Decision Flow Chart:



2. WHAT DOES THIS DECISION FLOW CHART MEAN FOR “LARGE-SCALE FIXED INSTALLATIONS” and “LARGE SCALE STATIONARY INDUSTRIAL TOOLS”?

- 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 above flow chart).
- 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 (according to above decision flow chart) not meet the definition of EEE under RoHS2, however, they may comprise various contiguous subsystems that represent EEE under RoHS2 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 RoHS2. 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. It is an indicator if the equipment is readily displaced to another location and if it is intended for use at one single location during its life time.
- **For LARGE SCALE FIXED INSTALLATIONS, the affected industry has the following position:**

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, physical volume of the combination, 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".
- **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.”*

- **For LARGE SCALE STATIONARY INDUSTRIAL TOOLS, the affected industry has the following position:**

- Article 3.3 defines **“large scale stationary industrial tools” as follows:** *“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.*

- The Guidelines of the Machinery Directive provide a common understanding of the notion “**assembly of machines**”, which should also be used for the purpose of RoHS2.
- “**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.*”

3. WHAT DOES THIS DECISION FLOW CHART MEAN FOR COMPONENTS, PARTS AND CONSUMABLES?

It is particularly relevant to stick to the concept of “equipment” as defined in the IEC International Electrotechnical Vocabulary 60050 in order to preserve the logic of the RoHS2 Directive:

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 requirements for its parts (material, components, sub-assemblies) unless an exemption applies that is listed in Annexes III and IV of the Directive or in finally adopted and published amendments to it.

Consumables, such as CDs, DVDs, floppy disks, badges, etc. do not fall in the scope of the RoHS recast as they are not electric or electronic equipment, since they do not meet the definition of “EEE” provided in Article 3(1) in combination with 3(2).

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.

For more information, please see Orgalime guide, page 13 (chapter 1.3.5) and page 25 (chapter 1.7).

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