***THE RoHS 2 DIRECTIVE***

***(Directive 2011/65/EU of 8 June 2011)***

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Directive 2011/65/Eu ( the recast of RoHS Directive ) was implemented by Italy by way of Legislative Decree 04.03.2014 No. 27 .

The purpose of this document it is to examine some practical and relevant issuesof particular interest to those who produce, import and market the products – now becoming increasingly numerous – involved by the restriction on the use of certain hazardous substances.

**FIELD OF APPLICATION OF THE DIRECTIVE (recast)**

While in t he previous Directive 2002/95/EC ( the RoHS 1 Directive ) there was an almost absolute equivalence between WEEE and RoHS (meaning that the products subject to the WEEE Regulations were also subject to the RoHS ones; since RoHS regulates hazardous substances in EEE, while WEEE regulates the disposal of the same equipment ), with t he new RoHS 2 t his is no longer t he case as, in fact, within its scope are now also included:

(1) monitoring and control instruments as well as medical devices (previously excluded) and, above all,

(2) all t hose products (classified as category 11 in Annex 1 of the new Directive) which even though not relying on electric current or electromagnetic fields for performing their main f unction, they depend on it for fulfilling at least one of their intended functions (e.g., a toy doll saying cute words was not previously included in the RoHS scope, since it fulfilled its entertaining f unction even without this feature; while now, instead, it falls under the Directive examined here); said new product category is intended at extending t he RoHS provisions also to those products which – in not being included among t he 10 large-scale categories listed in Annex 1 of t he WEEE Directive (now listed also in Annex 1 of t he new RoHS Directive) – were so far excluded from the scope of both WEEE or RoHS Regulations (as for instance: electric compressor, electric shutters, etc.). A careful scrutiny of the equipment/items marketed by t he economic operators in t he toys, consumer electronics, telecommunications and computer industry, will most likely result in identifying further “new” products (among those marketed) that are now subject to the RoHS Regulations. The ORGALIME RoHS 2 guide published in September 2012, considers that the expression “*one intended function*” has to be regarded as one of the functions intended by the manufacturer, as such inferable from the presentation (including websites), producers manuals and instructions accompanying the product as well as from the related technical standards (when they exist), thus excluding an “ex-post” analysis of how t he product is specifically used or intended by t he purchasers; ORGALIME also believes that if electricity is used only for starting up t he equipment, it cannot be considered t hat just for this it depends on it and consequently it does not fall within the scope of the RoHS Directive.

However, the products “newly” covered by the RoHS Directive, are only be subject to it as:

**(1)** with regard to those referred to in point (1) above (i.e. medical devices, monitoring and control instruments; categories 8 and 9 of Annex I of the Directive): from 22 July

2014, from 22 July 2016 or from 22 July 2017, depending on the case;

**(2)** with regard to all other "new" products referred to in point (2) above (category 11 of Annex I): from 22 July 2019, date by which also all products held in store by the retailers, producers, distributors and resellers shall have to be strictly and properly disposed of**.**

The RoHS 2 Directive does not apply to various types of products specified in a very articulated list, that will obviously have to be carefully examined by the industry operators in order to precisely identify the sphere of responsibilities placed upon them by the regulations examined here.

Eco legal Counsel currently deals with environmental legislation for the electrical and electronics industry and is able to deal with any legal assessment on applicability of the new RoHS Directive to products of interest to manufacturers and importers.

**RESTRICTED SUBSTANCES AND MAXIMUM CONCENTRATION VALUES**

The restricted substances (Annex II of the updated Directive) are: Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls an Polybrominated Diphenyl Ethers (the same as before), and they CANNOT be present in concentration greater than 0.1% (expect for CADMIUM which is 0.01%) by weight in *homogeneous material* (for which t he following definition – not dissimilar from the concept already expressed in the previous directive – is given:*“ ...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... “).*

New exemptions are specified, and confirmed t hose ( numerous) that have been progressively established under the previous directive (Annex III), while an “ad hoc” procedure for requesting new ones has been established (Annex IV).

**OBLIGATIONS FOR THE ASSESSMENT AND CERTIFICATION OF PRODUCT CONFORMITY**

Now we come to the most delicate point.

Since the RoHS 2 Directive recalls the procedures related to the assessment and certification of the conformity of the CE marking (as well as in part those on the general product safety), I would like, first of all, to remind that similarly to these, with reference to the main regulations concerning those who market toys (Directive 2009/48/EC); electrical equipment designed for use within certain voltage limits (low voltage Directive (LVD) 2014/35/EU; Electromagnetic compatibility or EMC: Directive 2014/30/EU; Radio Equipment Directive or RED : Directive 2014/53/EU), the Producer (or the importer, if he presents himself as the producer in having affixed to the product only his own brand name or, anyhow, modified it) shall :

**a.** Confirm and certify the compliance of the product ( according to a procedure that can be simple , by means of self-certification , or complex, by involving a Notified Body, according to the case);

**b.** Draw up the technical documentation to keep available for the Authority for 10 years;

**c.** Draw up a statement of compliance, to be show n to the Authority (if related to the.

R&TTE Directive, a summary of the same must accompany each product);

**d.** Affix the CE marking to the product (or, if not possible, on t he packaging and on the accompanying documentation);

**e.** Affix to the product or, as appropriate, includes in the accompanying documentation the specific information foreseen by the various sources (directives; Blue Guide on the CE marking; Decision No. 768/2008/EC, etc.), including:

- type - batch number - product’s serial number;

- name and address of the producer or of one of his

representative in the EU with an only point of contact;

- instructions and warnings in Italian.

In addition to the above , there are other obligations set out by the Consumer Code concerning the safety of the products (including: the obligation to withdraw/recall dangerous products from the market and the obligation to keep a register of complaints).

As regards the Importer (who in the case of not having affixed only his own brand name to the product presents himself as the Producer), pursuant to t he EC and general product safety regulations, he:

**a.** must ensure t hat the Producer has complied wit h all the obligations referred to above;

**b.** must not place on the market any non-compliant products and, if appropriate, take corrective measures as well as withdraw/recall the same; in any case he must cooperate with the Authority and supply any information t hat may requested;

**c.** must keep for 10 years a copy of the EU Declaration of Conformity (DoC) issued by the Producer;

**d.** must keep a register of any non-compliant equipment and of any product withdrawal/recall, taking care informing the distributors.

It must be noted t hat t he Decision No. 768/2008/EC – which as such is necessarily only a guidance laying down common principle and reference provisions with no legal force – foresees an obligation on t he part of the importers that to date is still not present (in lacking national laws making it effective), requiring to affix to t he product or, if t hat is not possible, on t he packaging or on the accompanying documentation his ow n name, company name and address.

However, the Directive 2011/65/EU extends all t he above obligations (referred to both Producer and Importer) also to the products’ assessment and certification of conformity with the RoHS Directive, although, for the latter one, only the self-certification is foreseen. Therefore, in practical terms, with t he implementation in Italy of the new RoHS Directive, taking into account the EC requirements already implemented by companies, w hat’s above will result, among others, in the following innovations:

(1) the technical documentation drawn up by t he Producer and to be show n to the Authority must also include the information permitting to verify the compliance of the product with the new RoHS Directive (Article 7.b of the same) ;

(2) the Producer must draw up (and t he importer shall request it from the Producer) an EU Declaration of Conformity with t he RoHS Directive (Article 7.c) containing the information specified in Annex VI of the same Directive;

(3) the economic operators must be able to ident ify to the Authority, for a period of 10 years, “*any economic operator who has supplied them with an EEE .. “ or “ .. to whom they have supplied an EEE*” (Article 12 of the new Directive);

(4) **the importer must indicate “ ....*on the EEE or, where that is not possible, on its packaging or in a document accompanying the product hi s own name, registered trade name or regi stered trade mark and the address at which he can be contacted* ”.**

This last requirement on the part of the importer – which as previously said is NOT currently specifically foreseen – would NOT however seem to apply according to what’s set out in the last paragraph of Article 9.d) of the new Directive: “*In cases 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* ”: in fact, the directives concerning Toys, EMC, LVD and RED already contain specific provisions in this regard .