THE NEW RoHS DIRECTIVE (Directive 2011/65/EU of 8 June 2011)

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By 2 January 2013, Italy will have to implement the new RoHS Directive, which is rather articulated and complex. ***The purpose of this document it is to simply examine, in view of the forthcoming entry into force of the new legislation, some practical, relevant and immediate issues*** of 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 the previous 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 the new RoHS 2 this is no longer the 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 those 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 function, 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 function even without this feature; while now, instead, it falls under the Directive examined here); said new product category is intended at extending the RoHS provisions also to those products which – in not being included among the 10 large-scale categories listed in Annex 1 of the WEEE Directive (now listed also in Annex 1 of the 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

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of the equipment/items marketed by the economic operators in the 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 the product is specifically used or intended by the purchasers; ORGALIME also believes that if electricity is used only for starting up the equipment, it cannot be considered that 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, shall 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 be strictly and properly disposed of**.**

The new Directive does not apply to various types of products specified in a very articulated list, which examination is unsuitable with the practical and summary purposes of this article, but 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.

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My law firm provides expert legal advice and representation on matters of environmental legislation to the electrical and electronics industry as well as dealing with any legal assessment on the applicability of the new RoHS Directive to products marketed by manufacturers and importers alike

RESTRICTED SUBSTANCES AND MAXIMUM CONCENTRATION VALUES

The restricted substances (Annex II of the updated Directive) are: Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls and 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 the 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 those (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 new RoHS 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) 2006/95/EC; Electromagnetic compatibility or EMC: Directive 2004/108/EC; Radio and telecommunications terminal equipment or R&TTE: Directive 1999/5/EC), the Producer (or

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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 shown 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 the 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 the EC and general product safety regulations, he:

a. must ensure that the Producer has complied with 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 that may requested;

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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 of informing the distributors.

It must be noted that the 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 the part of the importers that to date is still not present (in lacking national laws making it effective), requiring to affix to the product or, if that is not possible, on the packaging or on the accompanying documentation his own name, company name and address.

However, the Directive 2011/65/EU extends all the 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 the implementation in Italy of the new RoHS Directive, taking into account the EC requirements already implemented by companies, what's above will result, among others, in the following innovations:

(1) the technical documentation drawn up by the Producer and to be shown 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) [1] ;
(2) the Producer must draw up (and the importer shall request it from the Producer) an EU Declaration of Conformity with the RoHS Directive (Article 7.c) containing the information specified in Annex VI of the same Directive;
(3) the economic operators must be able to identify 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 his own name,***

[1] See in this regard Article 16 no. 2 of the Directive. 2011/65/EU .

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***registered trade name or registered 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 R&TTE already contain specific provisions in this regard [2] , which, however, do not require that these information be affixed to the product, but in its accompanying documentation. It will therefore be important to ascertain how Italy will implement this Directive, since if such obligation was to be put into effect and immediately applied, for the importers who did not anticipate the implementation of the new RoHS Directive entailing to affix the requested information to the products, its immediate compliance would be obviously impossible.

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[2] Directive 2009/48/EC (Toys): Article 4, points 5-6-7 ; Directive 2004/104/EC (EMC) : Article 9.2 and Annex IV No. 2; Directive 2006/95/EC (LVD) Annex IIIB; R&TTE Article 12.4 (the procedures pursuant to Annexes II-III-IV-V do necessarily entail affixing the manufacturer's name and address)

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