The new RoHS Directive 2011/65/EU: interpretation and application problems for who produces and/or markets electrical and electronic equipment, or similar products, in Italy

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The new RoHS Directive 2011/65/EU (also known as "*RoHS 2*"), has not yet been implemented in Italy. Although the deadline for its implementation expired on 02/01/2013 and, while the majority of other EU countries have already implemented it, to date it is not known when it will be implemented. This - besides the interpretation and application problems affecting all European operators - poses further peculiar problems to the Italian operators, which are added to those created by an already very difficult economic situation. With this article I will try to throw some light on this subject.

The purpose of this article is to illustrate, in a nutshell, the main innovations introduced by the new RoHS regulation (Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and "the like", as better explained later) and to provide an answer to some interpretive problems already affecting the operators who are facing this new and complex regulation, among which:

- ***Which products fall within the scope of the new directive?***
- ***What are the costs borne by the producers or importers for the certification, conformity assessment and CE marking of the products?***
- ***What will happen to all non-compliant products held in stock?***
- ***What is the current Italian situation as a result of not having implemented the directive by the prescribed date of 2 January 2013?***

But let's proceed in order.

What products are covered by the RoHS 2 Directive?

While in the previous directive there was almost absolute equality between EEE and RoHS (meaning that products subject to the waste electrical and electronic equipment regulation or "WEEE" referred to in the Directive 2002/96/EC, were also subject to the RoHS one), with the new directive this in longer the case as, in fact, now fall within the scope of the RoHS regulation also:

- **medical devices** (e.g.: electronic devices for measuring blood pressure) - Category 8 of Annex I (which were previously excluded);
- **monitoring and control instruments** (e.g.: domestic gas detectors; industrial automatic door opening sensors) - Category 9 of Annex I (both previously excluded) and, in particular,
- all those products - classified as Category 11 in Annex I, which, **although not dependent on electric currents or electromagnetic fields for performing their main function, they depend on them for fulfilling at least one of their intended functions.** It is worth reminding that the

RoHS 2 Guide published by ORGALIME in September 2012, considers, quite correctly, that the definition given in Article 3.2 to "*one intended function*" should be regarded as meaning one of the functions intended by the manufacturer, clearly deducible from the presentation (including websites), manuals and instructions accompanying the product and as well as from their related technical specifications (when they exist), thus excluding the further need of an ex-post analysis on how the product is specifically used or intended by the purchasers.

As is apparent from recital 12 of the RoHS 2 Directive, among others, the following two points apply:

(a) - although those are mostly products intended by the manufacturer as multifunctional products (e.g.: a doll that says cute words has a primary entertaining function which can still be enjoyed even without any sound, and a secondary entertaining function consisting, in fact, in the possibility of producing sounds similar to words: consequently, it will never be a WEEE but it does nonetheless fall within the new Category 11 of the RoHS 2 Directive), they include, anyhow, also products that are not multifunctional (e.g., a Schuko plug adapter does not fall under the WEEE regulation but it is included in the RoHS 2 one);

(b) - such products must in any case have one function which, although not primary, is dependent on electric currents/electromagnetic fields (just as a negative example: DOES NOT fall in Category 11 a petrol lawn mower: the engine spark plug is not, in fact, a service provided by the device, i.e. a "function", but a mere internal operation mode).

A careful analysis of the equipment/products marketed by economic operators in the toys, consumer electronics, telecommunications or computer industry, will certainly lead to the identification, among those marketed, of many "new" products now subject to the RoHS 2 regulation. I point out that my firm specializes in the area of environmental legislation for the electrical and electronics industry and can deal with any legal issue or evaluation on the applicability or otherwise of the new RoHS Directive to products marketed by producers and importers.

When will the provisions regarding the new products in Category 8, 9 and 11 come into effect?

The products "newly" covered by the RoHS Directive, shall only be subject to it:

- as regards to those listed in Category 8 (medical devices): after 22 July 2014 (after 22 July 2016 in the specific case of in vitro equipment);
- as regards to those in Category 9 (monitoring and control instruments): after 22 July 2014 (domestic equipment) or after 22 July 2017 (industrial equipment);
- as regards to all other "new" products in Category 11: after 22 July 2019.

What will happen to the stocks of non-compliant products referred to in Category 8, 9 and 11?

The regulation is very different depending on the type of product, as follows:

- Products of Category 11 that are not RoHS 2 compliant: cannot be "*made available on the market*" (i.e. marketed) after 22 July 2019 (Article 2.2 and 3.11): consequently, there is not any "*grace period*" foreseen for clearing the stocks;
- whereas products of Category 8 and 9 that are not RoHS 2 compliant, but that are placed on the EU market before the above specified dates (22 July 2014, 2016 and 2017), may continue to be marketed also after (Article 4.3 and 3.12): it is therefore possible to clear the stocks of non-compliant products.

When is a product made available on the EU market?

As said, the products of the "residual" Category 11 made available on the EU market before 22 July 2019 can no longer be marketed after such date.

Therefore, the question arising is: when is a product "made available on the EU market"?

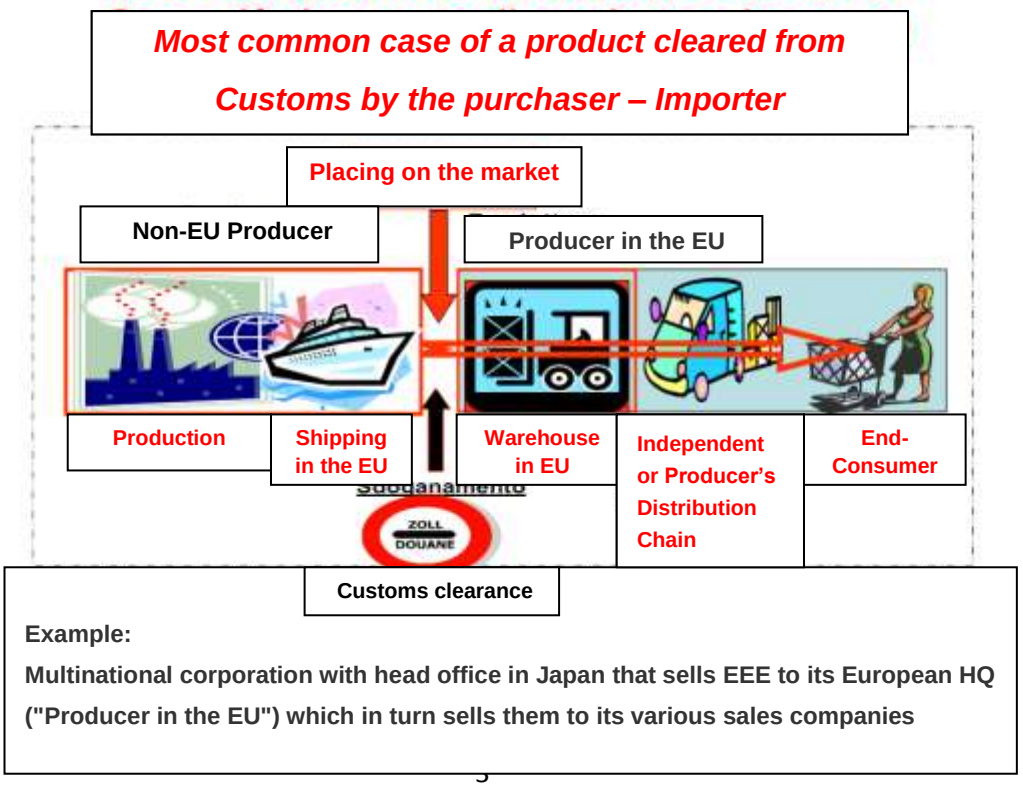
It must first be said that **when a product comes from a non-EU country**, according to the consistent interpretation of the European Commission, its placement on the market occurs once it has cleared customs in the EU, i.e. released into free circulation, provided that such time coincides:

(a) with its physical transfer to the importer/distributor's warehouse and/or

(b) with the transfer of ownership, possession or retention, for valuable consideration or free of charge, to the above importer/distributor or end-consumer;

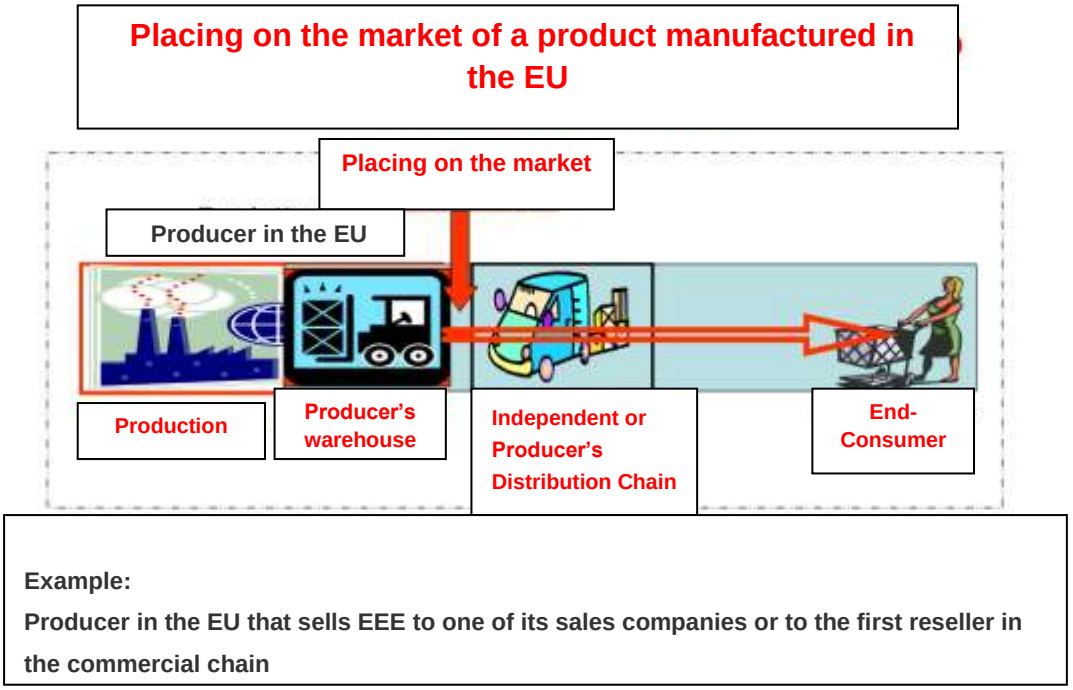
(c) provided, of course, that this is a finished product, i.e. ready for delivery. All as shown in Scheme 1 below.

Scheme 1



When a product is manufactured in the EU, its placement on the market occurs **at the time when the producer transfers the same, intended as a finished product (by way of a physical transfer and/or transfer of ownership, possession or retention, for valuable consideration or free of charge**) to the first commercial intermediary (whether it is controlled by the producer or not) or to the end-consumer. All as shown in the following Scheme 2.

Scheme 2



What are the maximum concentration values permitted for the restricted substances?

The restricted substances (Annex II of the RoHS 2 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 for the first time 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 established, 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 set up (Annex IV).

What are the new requirements for assessing and certifying the RoHS 2 compliance of the

products?

We now come to the most delicate point.

Given that the new RoHS Directive recalls the procedures relating to the assessment and certification for the CE conformity marking (and partly also 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 who market toys (Directive 2009/48/EC) or domestic electronic equipment (Low Voltage Directive 2006/95/EC or LVD; Electromagnetic Compatibility Directive 2004/108/EC or EMC; Radio and Telecommunications Terminal Equipment Directive 1999/5/EC or R&TTE), the Producer (or the importer, if he presents himself as the producer in having affixed only his own label to the product or in having anyhow modified it) must:

a. assess and certify the conformity of the product (according to a procedure which can be simple, by means of self-certification, or complex, by involving a Notified Body, according to the case);
b. prepare the technical documentation which must be kept available for the Authority for 10 years;
c. prepare a declaration of conformity, to be shown to the Authority (in the case of the R&TTE Directive, a summary of the same must accompany each product);
d. affix the CE marking to the product (or, when not possible, on the packaging and on the accompanying documentation);
e. affix to the product or, as appropriate, include in the accompanying documentation, specific information and indications in accordance with the various requirements (directives; Blue Guide on CE marking; Decision No. 768/2008/EC, etc.), including:
   - type, batch and serial number plus any other identifying information on the product;
   - name and address of the producer or of one of his representative in the EU with a single point of contact;
   - instructions and warnings in Italian.

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

As for the Importer (who, in the case of having affixed only his own label to the product, presents himself as the Producer), pursuant to the EC and general product safety regulations, he:

a. must ascertain that the Producer has complied with all the requirements 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 products; he must in any case cooperate with the Authority and supply any information that may be requested;

c. must keep for 10 years a copy of the EU Declaration of Conformity issued by the Producer;
d. must keep a register of any non-compliant equipment and of any withdrawal/recall of products, as well as notifying the distributors.

However, the RoHS 2 Directive extends **all the requirements seen above** (referring to both Producers and Importers) **also to the assessment and certification of conformity of the products with the RoHS Directive**, for which only the self-certification is required.

Therefore, in practical terms, with the implementation of the new RoHS Directive in Italy, taking into account the EC requirements already implemented by Italian companies, all the above will result, among others, in the following innovations:

- the technical documentation prepared by the Producer and to be shown to the Authority, must also include information permitting to assess the compliance of the product with the RoHS Directive: in this regard there is an EU-harmonized standard (EN 50581:2012) setting out the requirements to be met with the specific activities for this purpose, with the aim of reducing, as far as possible, the technical inspections and tests on the product;
- the Producer must prepare an EU Declaration of Conformity with the RoHS Directive (that the importer must request from the Producer) containing the information specified in Annex VI of the new Directive;
- 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* ";
- 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, registered trade name or registered trade mark and the address at which he can be contacted* ". This last requirement shall NOT however apply "*In cases where other applicable EU legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply* ", as, in our case, are the various product provisions (Toys, EMC, LVD and R&TTE) that apply to the majority of electrical and electronic products.

What is the current Italian situation as a result of not having implemented the directive within the prescribed period of 02/01/2013?

The European Court of Justice, and as well as the Supreme Court, has ruled that in the case of non-implementation by a Member State of a EU directive which provisions, as far as their subject-matter is concerned, appear to be unconditional and sufficiently precise, the following three principles shall apply:

(a) - it is aimed at the States, and not to their individual citizens;

(b) - when the Directive confers rights to individual citizens which cannot be exercised as a result of its non-implementation, the State (understood in the broadest sense, and hence also National Courts, Ministries, Public Bodies, etc.) is required to "... *interpret its national law in the light of the wording and the purpose of the directive in order to achieve the result pursued by the latter*...." (ECJ case C-106/89; ruling of 13 Nov 1990);

(c) - if that interpretation is not sufficient to achieve the same end-result pursued by the non-implemented directive, the individual may exercise the rights deriving from the directive against the State (but no other individuals) to seek compensation for possible damages suffered by him as a result of its non-implementation.

In our case, however, while points (b) and (c) seem to confirm - with reference to the new exemptions contained in the RoHS 2 Directive - that although not yet implemented it must in effect be considered as already operating, point (a) results in the absence of any obligation for the Italian operators to comply with the new requirements imposed by the RoHS 2 Directive, including those for CE marking and products conformity certification. It goes without saying that anyone wanting to market products imported or manufactured in Italy also in the other EU countries where the RoHS 2 Directive has already been implemented will unavoidably have to comply with its requirements.

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