18th July of 2011

DIRECTIVE 2011/65/EU (REVISED ROHS DIRECTIVE) - EEE

European Union adopts revised rules on the use of certain hazardous substances in electrical and electronic equipment

On July 1, Directive 2011/65/EU of June 8, 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) was published in the *Official Journal of the European Union*[1]. The new Directive will enter into force 20 days after its publication, i.e., on July 21, 2011. Member States must adopt the necessary implementing measures by January 2, 2013 at the latest.

Directive 2002/95/EC of January 27, 2003, currently applicable, is repealed with effect from 3 January 2013. As of this date, in order to make available or place EEE in the EU market all undertakings must abide by the new rules.

Some of the most relevant aspects of the new legislative framework are indicated below.

[1] Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF

Broader scope of application

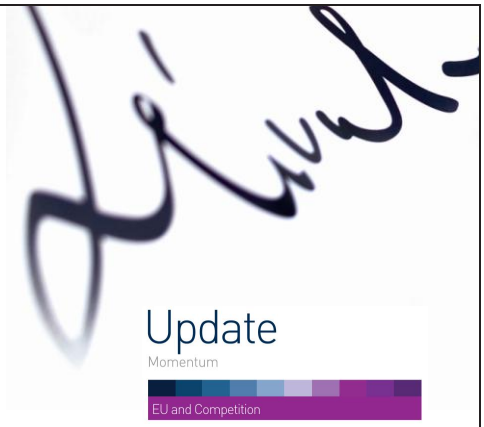
The scope of application of the new Directive is extended to all EEE (including medical devices and monitoring and control instruments; cf. article 2/1 and Annex I), subject to the exceptions provided for under article 2/ 4 (the Directive does not apply, for example, to active implantable medical devices, large-scale stationary industrial tools, etc.).

EEE presently outside the scope of Directive 2002/95/EC, and which is not in compliance with the new Directive, may continue to be made available on the market, i.e., may be supplied for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge, until July 22, 2019. Note that the revised Directive defines shorter time periods for placing on the market certain EEE. For example, as of July 22, 2014 medical devices and monitoring and control instruments must comply with the new requirements. The same holds in relation to *in vitro* diagnostic medical devices as of July 22, 2016.

New definitions

Some important definitions have been modified and others included. For example:

- EEE (is defined 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*"; where "Dependent" means "*needing electric currents or electromagnetic fields to fulfil at least one intended function*");
- Economic operators (includes the "manufacturer", the "authorised representative", the "importer" and the "distributor");
- Homogeneous material ("*means 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*").



More demanding requirements for economic operators

To be able to make available or place EEE in the EU market economic operators must ensure that a number of requirements are met.

Obligations upon *manufacturers* include:

- Draw up technical documentation to demonstrate compliance of EEE with the requirements set out in article 4.º and Annex II (restrictions on the use of lead, mercury, cadmium, hexavalent chromium, PBB and PBDE);
- Put in place internal production control procedures and procedures to ensure that series production remain in conformity;
- Draw up an EU declaration of conformity and affix the CE marking on the EEE as well as other information on the product and manufacturer identification.

Obligations upon *importers* include:

- Ensure that manufacturers have complied with their obligations, in particular, that the EEE bears the CE marking and the information on the product and manufacturer identification;
- Affix on the EEE information on the importer identification;

- Keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities.

Obligations upon *distributors* include:

- Ensure that that the EEE bears the CE marking, the information on the product, manufacturer and importer identification, and that it is accompanied by the required documents in a language

which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market;

- Provide competent national authorities with all the information and documentation necessary to demonstrate the conformity of EEE with the applicable requirements.

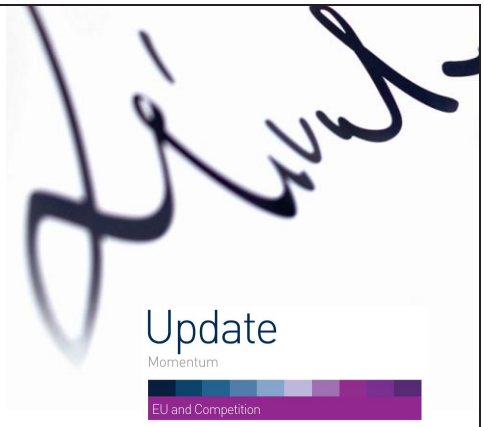
List of hazardous substances without changes

In addition to the substances already included in the existing Directive 2002/95/EC no new hazardous substance is listed in Annex II. Notwithstanding, recital (10) of the revised Directive points out that "*the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2- ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority*".

Nanomaterials

Even if no nanomaterial has been added to the list of hazardous substances in Annex II, recital (16) of the Directive notes that "*as soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure […] should be examined*."

Also, article 6 clearly indicates that in order to review Annex II, the European Commission will take special account of whether a substance, *including substances of very small size or with a very small internal or surface structure*, could have a negative impact during EEE waste management operations, could give rise to uncontrolled or diffuse release into the environment of the substance, could give rise to hazardous residues, or transformation or degradation products, or could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes.



Note: The information provided before is not exhaustive. For any additional queries or clarifications on the revised RoHS Directive or related matters please contact Miguel Gorjão-Henriques (mgh@servulo.com) or Carla Farinhas (caf@servulo.com).

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