European Commission Publishes New RoHS Directive 2011/65/EU

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On 1 July 2011, the European Commission (EC) published new RoHS Directive 2011/65/EU in the Official Journal of the European Union. The directive shall enter into force on July 21st, 2011. Member States must transpose Directive 2011/65/EU into national law by 2 January 2013.The old directive 2002/95/EC and its amendments is repealed with effect from January 3rd, 2013.

Compared to initial ROHS directive 2002/95/EC, the significant changes of new RoHS directive 2011/65/EU are as below:

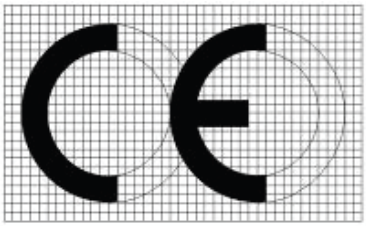
1. Under the revised Directive, the scope of application has been extended to all electrical and electronic equipment (including cables and spare parts). And give transitional period for new categories 8 medical devices, and categories 9 monitoring and control devices (include industrial monitoring and control devices). Annex I of the directive introduces a new, eleventh product category – 'other EEE not covered by any of the categories above (categories1–10)'. Detailed transitional period is as below.

- Control and monitoring devices and medical devices (placed on the market from 22 July 2014),
- in-vitro diagnostic medical devices (placed on the market from 22 July 2016),
- Industrial control and monitoring instruments (placed on the market from 22 July 2017).
- eleventh product category – 'other EEE not covered by any of the categories above (categories1–10)' (placed on the market from 22 July 2019).

2. New RoHS directive introduced no new substances in the restricted substance list which including six hazardous substances: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). While the EU commission will regularly review and adapt the list of restricted substances according to interrelated criteria in the future. Priority substances which should be considered for future inclusion in RoHS were: hexabromocyclododecane (HBCDD), phthalates (DEHP, BBP, DBP) and nanomaterials.

3. More specific obligations and requirements for "manufacturers", "importers", and "distributors"in new RoHS directive. Appointment of an "authorized representative" who performs the tasks specified by the manufacturers outside the EU to comply with the requirements of CE marking and RoHS directives.

4. New RoHS directive will become a CE Mark directive, which means that CE marking will be affixed to all finished products. Manufacturer should carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC. In addition, manufacturer /importer/distributor should keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market.



5. New RoHS directive introduced first legal definition of "homogeneous materials" which it states as being: 'One material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be mechanically disjointed into different materials, meaning that the materials cannot be separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes'.

11 categories of EEE covered by this new RoHS Directive :

- Large household appliances.
- Small household appliances.
- IT and telecommunications equipment.
- Consumer equipment.
- Lighting equipment.
- Electrical and electronic tools.
- Toys, leisure and sports equipment.
- Medical devices.
- Monitoring and control instruments including industrial monitoring and control instruments.
- Automatic dispensers.
- Other EEE not covered by any of the categories above.

Annex list of new RoHS Directive:

- ANNEX I : Categories of EEE covered by this Directive
- ANNEX II : Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials
- ANNEX III : Applications exempted from the restriction in Article 4(1)
- ANNEX IV :Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments
- ANNEX V :Applications for granting, renewing and revoking exemptions as referred to in Article 5
- ANNEX VI :EU DECLARATION OF CONFORMITY
- ANNEX VII :
- PART A : Repealed Directive with its successive amendments
- PART B : List of time-limits for transposition into national law
- ANNEX VIII : Correlation table

Additional information

View the revised Directive 2011/65/EU:

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF

How can TÜV SÜD support you?

TÜV SÜD can provide companies with cost-effective and comprehensive strategy for RoHS compliance. Equipped with strong expertise and a global network of laboratories, TÜV SÜD offers a wide range of RoHS testing service, include XRF scanning, chemical analysis, RoHS product certification, RoHS legislation consulting and training service.

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