

Summary

Introduction

Article 6 of the RoHS directive requires the European Commission (EC) to carry out a review of the RoHS directive and to consider any changes that are needed. The review started in 2005 and all aspects of the directive have been considered. There have been stakeholder consultations and studies by consultants into several aspects of RoHS. The Commission published its proposals on 3rd December 2008.

The main changes are as follows:

Background

Unlike in the original RoHS Directive, the EC now has to take into account the aims of the Lisbon strategy so that development of an environmental strategy also considers growth and employment. Another fundamental change is that RoHS substance restrictions would be imposed only if there is an unacceptable risk to human health and the environment, whereas previously it was based only on the precautionary principal.

Scope

The scope of RoHS is specified in Annex I and is no longer linked to the scope of the WEEE Directive. The new Annex I includes two additional categories: "8. Medical Devices" and "9. Monitoring and Control Instruments, including industrial monitoring and control instruments". Military equipment and equipment that is part of out-of-scope equipment are now specifically excluded from RoHS. Annex II has also been added and is a binding list of products that are included and the EC is able to amend this list.

All of these changes are helpful in making explicit the intended scope and avoiding the different interpretations that have occurred across the European Union (EU).

The RoHS directive has applied since 1 July 2006 but the amended directive now explicitly states, "placed on the Community market", the word "community" has been added to ensure that Member States do not interpret this as their national market. The two additional categories 8, medical and 9, monitoring and control instruments will be included in scope from the 1 January 2014 except for in vitro diagnostic medical devices (1 January 2016) and industrial monitoring and control instruments from 1 January 2017. The Commission will review whether to include active implantable medical devices by 1 January 2020.

Definitions

Many definitions are made explicit in particular those for homogeneous materials and the maximum concentration values. Although these definitions are the same as previously, their inclusion in the text reduces the risk of different interpretations. There are new definitions including "manufacturer", "importer", "distributor", "conformity assessment", the types of medical device and industrial monitoring and control instruments.

The spare parts exemption has been amended to adopt the "repair as produced" principle. Non compliant parts can be used in electrical and

electronic equipment that benefited from an exemption and was placed on the market before the exemption expired.

Additional Substances

Additional RoHS substances may be restricted if they pose an unacceptable risk. They would be reviewed by the REACH methodology and four additional substances are listed that will be assessed as a priority. These substances are hexabromocyclododecane (HBCDD), diethylhexyl phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP), all of which have been included in the REACH Candidate List as Substances of Very High Concern (SVHC).

HBCDD's main use is as a flame retardant in polystyrene and the other three are plasticisers used in PVC and some types of flexible adhesive and ink. It will be possible for the EC to add more substances to Annex IV in the future and so more substances could be restricted by RoHS.

Exemptions

The current exemptions are being reviewed and will change before the new directive comes into force. Exemptions required for categories 8 and 9 are listed in Annex VI and are identical to the list in ERA Technology's report on the possibility of including categories 8 and 9 within the scope of RoHS. The proposals state that materials and components may be included in Annex V and VI, i.e. "exempt" but expire after a maximum period of four years. Manufacturers may re-apply before they expire if no alternatives have been identified. This would entail submitting research results that had been obtained in the intervening period. The proposals also state that applications for renewal of exemptions should be at least 18 months before they expire and that the Commission will make a decision within the 18-month period. New criteria for allowing exemptions have been added which are "if the availability and reliability of substitutes is not ensured" or if there is a negative socio-economic impact.

The Commission will adopt rules for exemption applications that define the type of information required and this includes the need for a substitution plan, which the proposals state should be in line with REACH (these are required when applying for REACH authorisation to use substances).

Obligations

The proposals define who is responsible for compliance with RoHS and this will include manufacturers (including organisations that have products made by others), importers and distributors. The proposals also specify that sample testing is required and products must be labelled with specified information.

Demonstration of compliance

RoHS will become a CE marking directive. Manufacturers will need to carry out conformity assessment based on as-yet non-existent standards. The procedure will be based on the recently adopted EC Directive 768/2008/EC and Regulation 765/2008/EC. This directive and regulation are rather complex and explain how conformity assessment should be carried out as well as other aspects of compliance. Electrical equipment that has been assessed by tests

and measurements in line with as-yet non-existent harmonised standards will be presumed to comply with the requirements of this directive.

Enforcement

Enforcement will be carried out in accordance with Articles 15 – 29 of EC Regulation 765/2008. This formalises liaison between EU RoHS enforcement bodies and ensures that they exchange information.