



RoHS2

Version 4 April 2009

- 2 new product categories (8 & 9)
- 4 substances identified for priority risk assessment BBP, DBP, DEHP and HBCDD
- Former WEEE product categories moved to a new annex
- 1 new exemption
- 6 exemptions withdrawn
- CE marking directive

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As part of the RoHS (Restriction of Hazardous Substances) Directive, Article 6 requires that the directive is reviewed. So what is likely to happen?

ERA Technology looked at the viability of adding categories 8 (medical equipment) and 9 (monitoring and control instruments) to the scope of the RoHS Directive. RoHS originally covered 8 of the 10 categories of the WEEE (Waste Electrical and Electronic Equipment) Directive and categories 8 and 9 were omitted. This was due to the uncertainties, at that time, around the reliability of lead-free solder.

What is proposed?

- Categories 8 and 9 will fall within the scope of the RoHS Directive. Implementation will be from 2014, with vitro diagnostic medical devices in 2016 and industrial monitoring and control instruments in 2017. Details of supporting exemptions will feature in a new annex (annex 6) where substitution is not currently feasible.
- 4 hazardous substances are identified for priority assessment and possible future ban (annex 3).
- As part of a separate review of exemptions carried out by the Oko Institute to be announced during the first half of 2009:

Of the 29 exemptions, it is expected that 8 will be annulled and others will be re-worded.

Of the 5 proposed new exemptions under review, 1 is likely to be included. Implementation during 2010 with a period of grace of around 18 months prior to implementation.

So, we will all face a significant compliance data collection exercise as in 2006. Gathering compliance information was certainly a challenge before and this will become more complex, with new product categories falling within scope, as well as changes to exemptions.



What was "compliant by exemption" will become "non compliant" unless alternatives can be found.

RoHS2 will certainly have an impact on design and on industry.

Description of main measures

A. Clarification of the scope and definitions: What is proposed?

- Two new annexes describing the scope of the directive have been added, the first describing the broad product categories and the second, amendable by the European Commission, providing binding product lists within each category. Annex 1 and 2 moved from the WEEE Directive.
- Medical devices and monitoring and control instruments are included in the scope in a staged manner commencing 2014 through to 2017.
- The definitions for economic operators are aligned to the "Marketing of products" package and new definitions, such as for "medical devices" and "homogeneous material" are added.

Why is it being proposed?

- A harmonised scope improves implementation of the directive and provides clarity.
- Medical devices and control and monitoring instruments are included to reap the environmental and health benefits from the reduction of use of hazardous substances in such equipment but in a staged manner so that adverse socio-economic impacts are avoided.

B. Substance ban: What is proposed?

- The current directive's list of restricted substances and the maximum concentration values are moved to Annex 4.
- There is no change to the current list. However, 4 substances are identified for priority assessment in view of possible future inclusion in the list of restricted substances;
- Permission to use non-compliant spare parts is extended to equipment benefitting from an exemption when placed on the market;
- A new annex (6) with exemptions specific to the new product categories (medical devices and control and monitoring instruments) is added for cases where substitution is currently not feasible;

- A mechanism for introducing new substance bans in line with the REACH methodology is inserted to ensure coherence and maximise synergy with the work carried out under the chemicals' legislation. The 4 substances under RoHS review also feature on the 1st REACH SVHC "Candidate List" for authorisation.

Why is it being proposed?

- Four substances have been identified as presenting potential environmental risks when used in electrical and electronic equipment. These substances need to be kept under close scrutiny in view of a possible future inclusion in the list of banned substances;
- Permission to use non-compliant spare parts in equipment which benefitted from an exemption is necessary to prevent premature withdrawal of equipment from use.
- The exemptions for medical devices and control and monitoring instruments are justified as substitution is currently not feasible.

C. Exemption mechanism: What is proposed?

- **The 4-year review has been replaced with a 4-year maximum validity period for exemptions**, with a possibility of requesting renewals.
- New exemption criteria have been introduced covering the availability and reliability of substitutes and the inclusion of socio-economic impacts.
- The Commission now has a mandate to establish detailed rules for exemption requests to establish legal certainty for economic operators pending a Commission decision on a renewal request.

Why is it being proposed?

- The 4-year maximum validity period for the exemptions should stimulate substitution efforts, provide legal security and shift the burden of proof to the applicant, in line with REACH.

D. Product conformity assessment requirements and market surveillance mechanisms: What is proposed?

- Articles 7-17 are new and introduce product conformity assessment requirements and market surveillance mechanisms in line with the "Marketing of products" package (Commission decision 768/2008/EC on a common framework for the marketing of products).

Why is it being proposed?

- Reducing the number of non-compliant products through strengthened and harmonised market surveillance is a cost effective way for increasing the environmental benefits provided by the directive;
- Harmonised conformity assessment requirements increase legal certainty and reduce administrative cost for Member States and manufacturers.

Annex 1: 10 product categories
Annex 2: Indicative products
Annex 3: 4 priority (risk) substances

Annex 4: 6 original restricted substances
Annex 5: General exemptions
Annex 6: Exemptions for categories 8&9

Summary

Introduction

Article 6 of the RoHS directive requires the European Commission 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.

Background

RoHS substance restrictions will only 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 the two additional categories of Medical Devices and Monitoring and Control Instruments. **Equipment that is part of out-of-scope equipment is now specifically excluded from RoHS.** The term "military" is also clarified. Annex 2 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.

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 of medical and 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 European 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 4 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 6 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 5 and 6, 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).

The European Commission has published a review carried out by its contracted technical consultants on 29 existing exemptions. The recommendations are:

- 21 exemptions will continue with, in most cases, amended wording and proposed expiration dates between 2010 and 2014
- 5 exemptions will be withdrawn with a proposed transition period until mid 2011
- 1 exemption will be withdrawn with no transition period
- 1 new exemption proposed from a possible 5

These recommendations must be voted on by the Technical Adaptation Committee (TAC) and adopted by the Commission before becoming effective.

2 exemptions were already obsolete

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, applying to finished goods, with some typical implications shown below. Manufacturers, importers and distributors will be responsible for some, or all of these activities:

- Verify that products are CE marked and supplied with the required documentation.
- Audit manufacturers to ensure that they have, where appropriate, carried out sample testing.
- Audit importers and manufacturers located in the EU to ensure they keep registers of complaints, details of non-conforming equipment and product recalls. Distributors should be kept informed of this monitoring.
- Audits should be on a sample basis although new products could be checked upon receipt.
- Check products to ensure they are correctly labelled.
- Ensure that manufacturers label their equipment with the type, batch or serial number of the product. This may be placed on the packaging if there is insufficient space on the product. EU manufacturers are also obliged to label products with their name and address.

- Where products are manufactured outside the EU it is the importer who has to label with their name, or registered trademark, and address. However, where the distributor is the importer, thorough conformity assessment procedures will be required as the importer is legally responsible for ensuring compliance.
- Distributors need to ensure that product compliance is not jeopardised while under their control. This should be no issue where the equipment stays in its box.
- Distributors need to assess the compliance status of products they sell and not rely purely on declarations from suppliers. This implies that a sample testing process is required (obligated if the distributor is the importer). Corrective action must be taken to bring products into conformity if they suspect that they do not comply, or withdraw the product from sale.
- Distributors must inform the relevant national enforcement authorities if any non-compliant equipment "presents a risk". A risk assessment should be carried out and documented.
- Distributors will need to build "technical files" that include documentation such as supplier declarations of compliance, any data supplied by the manufacturer or importer, results of any distributor assessment etc, and keep for 10 years. This implies that obsolete or discontinued equipment, and the associated technical files, should not be removed from websites.
- Where distributors import equipment under their own name they are required to draw up technical documentation as specified in the recently published 768/2008/EC**. Where the product complies affix a CE mark, provide a declaration of conformity, affix labels with name and address and keep all documentation for 10 years.

In summary, good record keeping will be essential as most of the new obligations are to produce documentation that can be assessed by enforcement bodies.

**Regulation 768/2008/EC defines what manufacturers, importers and distributors need to do to demonstrate compliance with CE mark directives such as EMC, LVD and RoHS in the future. It describes conformity assessment procedures such as what should be included in technical files and declarations of conformity.

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.

Please note:

The information contained in this guide is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

The revised RoHS Directive is likely to enter into force during 2011-2012

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