RoHS2 – Obligations for distributors

The European Commission (EC) proposals for amending the RoHS directive introduce new obligations for the electronics industry. Originally, compliance was the responsibility of the “producer” who has to ensure that he supplies compliant equipment. Producer is defined by the directive, but interpretation of who is responsible has not always been straightforward. The EC’s proposals remove all references to producers and introduce four new Articles that clearly define the responsibilities of manufacturers (Article 7), authorised representatives (Article 8), importers (Article 9) and distributors (Article 10). This report describes the new responsibilities of distributors as described by the “RoHS2” proposals.

Main changes

Before describing the obligations of distributors, it is worth summarising the main changes proposed in RoHS2 that affect all of the electronics industry:

- Inclusion of Medical Devices (Category 8) and Monitoring and Control Instruments (Category 9) in the scope of RoHS from 1 January 2014, except for in vitro diagnostic (IVD) from 2016 and industrial monitoring and control instruments from 2017. Implanted medical devices will be reviewed before 2020 to determine if these can be included.

- No additional substances are restricted but the original list of six restricted substances has been transferred to a new Annex IV. The EC will be able to adapt this Annex and so can restrict more substances although this must be based on the REACH SVHC (Substance of Very High Concern) criteria and demonstration of an unacceptable risk. The EC will consider a priority four substances that are listed in new Annex III. These are the three phthalate plasticisers BBP, DBP, DEHP and brominated flame retardant hexabromocyclododecane (HBCDD) that are included in the REACH “Candidate List” and are likely to require authorisation under REACH. It seems likely therefore that RoHS will restrict these substances.

- Changes have been made to clarify the scope of RoHS. Previously, the scope was eight categories listed in the related WEEE directive. These lists will be transferred to Annex I and II in the new RoHS directive. The reason for this is to ensure that the scope is the same in all EU
Member States. Several definitions have also been changed to ensure greater clarity and consistency.

- Previously, no specific approach to compliance was required. RoHS2 requires the manufacturer to CE mark for RoHS and provide declarations of conformity. Harmonised standards will be published and if products are tested using these standards, they will be presumed to comply.

**New responsibilities for distributors.**

RoHS2 provides details of the obligations on distributors. However, if a distributor is also an importer, supply products under their own name or trademark, or products that are modified before placing on the market, then there are additional obligations as importers or as manufacturers.

**Distributor obligations**

- Before placing on the market, distributors must verify that products are CE marked and are accompanied by the required documentation in a language easily understood by the end-user.

- Distributors must ensure that the manufacturer has, where appropriate, carried out sample testing to ensure compliance.

- Distributors must also ensure that the manufacturers keep registers of complaints, of non-conforming equipment and product recalls and that they keep distributors informed of this monitoring.

- Distributors must 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, or in a document accompanying the product. Note that EU based manufacturers are obliged to label their products with their name and address by Article 7.7. Where products are manufactured outside the EU, it is the EU importer who has to label with their details. Importers are required to label products with their name or registered trademark and address in the EU. Again, this may be on the packaging if there is insufficient space on the product.

- Distributors need to ensure that product compliance is not jeopardised while under their control (storage, transportation etc).

- The proposals require distributors to ensure that corrective action is taken to bring products into conformity if they suspect that they do not...
comply (or withdraw them from the market). This requirement implies that distributors need to assess the compliance status of products they sell and that they should not rely on declarations from their suppliers.

- Distributors must inform the relevant national enforcement authorities if non-compliant equipment “presents a risk”. This implies that where the distributor discovers that a product is not compliant, they then need to determine if this poses a risk to the environment or human health. Most examples of non-compliance clearly do not pose a risk as the amounts of RoHS substances are usually very small, and the way that equipment is used should not harm the user. However the risk assessment needs to be carried out and documented.

- Enforcement bodies may ask distributors for documentation that demonstrates product conformity and the distributor is expected to be able to provide this. This would include the manufacturer’s declaration of conformity, the results of the distributor’s assessment and any data supplied by the manufacturer or importer.

**Where distributors supply equipment under their own trademark**

Under these circumstances, the distributor is required to comply with the manufacturer’s obligations as listed in Article 7 in addition to those required of distributors, these are:

- Ensure that the product complies

- Draw up technical documentation and carry out internal production control procedures (as in module A of Annex II of 768/2008/EC). Technical files will be needed and include as a minimum the information specified in 768/2008/EC.

- Determine if the product complies with RoHS and all other relevant CE mark directives using the harmonised standards where available (as yet non existent for RoHS). If they comply then affix the CE mark and provide a declaration of conformity as specified in 768/2008/EC. This new legislation is applicable to all CE mark directives including LVD, EMC and machinery.

- Keep technical files and the declaration of conformity for 10 years.

- Affix labels with name and address in the EU

- If a manufacturer believes that they have placed a non-compliant product on the market, they need to take corrective action immediately.
Where distributors are also the importer

Under these circumstances, the distributor is required to comply with the importer obligations as listed in Article 8 in addition to those required of distributors, these are:

- Importers need to ensure that the manufacturer has carried out the correct conformity assessment procedure before the equipment is placed on the EU market.
- Importers must label products with their name or trademark and address in the EU
- Importers need to carry out sample testing where appropriate (as do distributors).
- If an importer believes that they have placed a non-compliant product on the market, they need to take corrective action immediately.
- Importers must keep the EC declaration of conformity for ten years and ensure that the technical documentation is available to enforcement authorities on request.

Implications for distributors

The RoHS2 proposals formally make distributors legally responsible for compliance with RoHS. Previously only producers were responsible and in most EU States, distributors that were not importers had no legal obligations. The UK may be an exception as suppliers (that are not manufacturers or importers) could in principal be prosecuted under UK law but, in practice, legal action has been taken only on manufactures and importers.

Most responsible distributors already assess the products that they supply, carry out sample testing and they maintain documentation that could be supplied to enforcement bodies. Therefore they are already carrying out many of the activities that RoHS2 will require. However additional activities will be necessary such as:

- Verification that products are CE marked and ensure that any required documentation is in a language easily understood by the end-user.
- Distributors will need to audit manufacturers to ensure that they have, where appropriate, carried out sample testing to ensure compliance.
Distributors will need to ensure that importers and manufacturers located in the EU keep registers of complaints, details of non-conforming equipment and of product recalls, and that they keep distributors updated on this monitoring.

Check products to ensure that they are correctly labelled (i.e. with the type, batch or serial number of the product).

Check that imported products are labelled with the importer’s name or registered trade name / trademark and address in the EU. The names and addresses of manufacturer's located in the EU are also required and so distributors will need to check that products are correctly labelled.

When non-compliant products are discovered, distributors need to decide if this poses a risk. If there is a risk, then they should inform the relevant national enforcement authorities. The risk assessment should be documented, even if there is no risk and the enforcement body is not informed.

Distributors will need to be able to supply additional documentation to enforcement bodies such as copies of manufacturers’ technical files that demonstrate product conformity, the manufacturer’s declaration of conformity, the results of the distributors own assessment of products and any data supplied by the manufacturer or importer.

It may be necessary to translate technical documentation from manufacturers into the national language so that it can be understood by the enforcement body.

Where the distributor is also the importer, then the following additional activities will be required.

More thorough conformity assessment procedures will be required as the importer is legally responsible for ensuring compliance.

Affix a label with their name and address in the EU

Where the distributor supplies the equipment under their own trade name or trademark, they will have the obligations of the manufacturer and this will require:

Thorough conformity assessment procedures will be required as manufactures in the EU are legally responsible for ensuring compliance.
- Affix a label with their name and address in the EU

Many of the new obligations formalise what many distributors already do but there are several new requirements that distributors will need to carry out. Good record keeping will be essential and most of the new obligations are to produce documentation that can be assessed by enforcement bodies.

**Timescale**

RoHS2 is likely to come into force in 2011 – 2012, which leaves 2 – 3 years to set up procedures for RoHS compliance. This is not a long time. When manufacturers had to comply with RoHS originally, they found that this took much longer and was more costly than had been predicted.

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