

RELIABILITY AND FAILURE ANALYSIS

**Possible Compliance Approaches
for Directive 2002/95/EC
(The RoHS Directive)**

Executive Summary and Key Conclusions

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Executive Summary

This document constitutes the Executive Summary and Key Conclusions from the full ERA report 2004-0134, *“Possible Compliance Approaches for Directive 2002/95/EC (The RoHS directive)”*.

Electrical equipment that is placed on the EU market from the 1st July 2006 will be presumed to comply with the requirements of the RoHS Directive. Enforcement authorities in Member States will carry out market surveillance. Producers will need to be confident that there are no banned substances within any of their products that are covered by the RoHS directive but the Directive does not specify how this shall be done. Analysis of every component would be unacceptably expensive. Both producers and enforcement authorities need a simple low cost procedure to ensure that no banned substances are present.

ERA was requested to assess four potential approaches:

- Self-Declaration
- Standards for Compliance Testing
- Standards on Reporting Formats
- Information Exchange Networks

Underpinning whatever approach is eventually agreed is the requirement for a clear understanding of how the definition of the maximum concentration values will be interpreted. An early decision is essential to both the electronics industry and the enforcement authorities. At present, several different interpretations of “homogeneous material” are in circulation:

- **“Assemblies” such as modules and printed circuit boards.** If this interpretation is adopted, the use of the six banned substances will not decrease significantly as manufacturers will be able to continue using them in many products. Tin/lead solders could be used on PCBs including heavy PCBs.
- **“Components” such as semiconductor devices, capacitors and resistors.** Adopting this interpretation would significantly reduce the quantities of most of the six substances that can be used but their widespread use could continue legitimately. For example, component manufacturers would be able to continue using tin/lead termination coatings, in some cases by reduction of the lead concentration. Recent research has shown that using tin/lead termination coatings, rather than lead-free coatings, with lead-free solders can lower reliability.
- **“In materials” such as metals, plastic and ceramic.** Adopting this interpretation would permit the use of the least quantities of the six substances and would prevent manufacturers using them as thin coatings on parts and components. For example, tin/lead coatings could not be used as the concentration of lead in the component termination coating metal would be too high.

The correct interpretation must be clearly understood and the best approach for achieving this would be to provide a clear definition accompanied by clarifying examples - an approach adopted by the Packaging Directive.

Self-declaration

Self-declaration is used for many of the EC New Approach Directives and would be appropriate even though RoHS is not a New Approach Directive. Two main approaches are available to producers:

- **Obtain an assurance from suppliers that no banned substances are present.** These could take many formats but ideally a permanent record will need to be kept. If an enforcement authority finds a banned substance then the producer will need this information to show that he has taken reasonable steps to comply with legislation.
- **Carry out limited analysis to verify declarations.** In a survey carried out by Soldertec, 47% of manufacturers stated that they intend to carry out at least some analysis to check the accuracy of their suppliers' declarations. Analysis will be advisable to audit suppliers, where there are doubts over the reliability of declarations or if none can be obtained. Materials having a greater risk of containing a banned substance, for example PVC and red/orange plastics, could be analysed more frequently, ideally every batch.

The aim of the RoHS Directive is to protect the environment and human health. Efforts from producers must seek to achieve this aim but without excessive cost. In some cases, the erroneous use of a component containing a banned substance will have an insignificant effect on the environment. Analysis of every component by all producers is clearly unreasonable, would be hugely expensive and may even be harmful to the environment and human health. A balance is required between the need to protect the environment and the taking of "reasonable steps" to comply with the Directive. Circumstances when analysis is advisable to support this aim are discussed in this report.

Standards for Compliance Testing

A small number of Standards exist that are suitable for analysis of parts used for or within electrical equipment to determine the concentrations of the banned substances. There are many more Standards for analysis of other materials such as pollutants in air and water, which could be utilised to develop new standards, but these will not be available by the 1st July 2006 deadline. The presence of banned substances can be determined using well established analytical techniques so that producers and enforcement authorities will not need to rely on Standards. However, it is recommended that some new Standards are developed where sampling and analysis are difficult or where a technique has significant limitations that could lead to erroneous results.

Analysis technology

Several suitable analytical techniques exist that could be used for each of the banned substances and there is no need to specify a particular method for each. Analysis of some components will be

technically challenging (but to date no impossible analytical challenges have been identified). In many cases, the choice of procedure will depend on the interpretation of “homogeneous materials”.

Some analytical techniques have been proposed which have significant limitations that need to be understood. For example, energy dispersive x-ray fluorescence, available as a handheld instrument, has been proposed for screening with desktop instruments for more accurate analysis. Research has shown, however, that both have significant limitations which, if not fully appreciated, can result in the incorrect assessment of a product.

There will be issues over the analysis of certain components which are discussed in this report and in some cases, clear guidance would be beneficial.

Standards on Reporting Formats

As a first step, equipment producers will need to obtain an assurance from their suppliers that no banned substances are present except where these are exempt from the requirements. This can take many forms and various methods are being used. It would be simpler for both equipment producers and component manufacturers if only a small selection of formats were used.

Several materials declaration formats are being developed but these are not designed for the RoHS Directive (as data on many other substances is included). Nevertheless it may be possible to use some of these for this purpose. A standard format for Supplier Declaration of Conformity, being developed by the IEC provides another option. Several organisations are working on markings on components, assemblies and products which would show their RoHS status. Once agreed these could become internationally accepted standards that could be used as “materials declarations”.

Information Exchange Networks

Member State enforcement authorities rarely co-operate to enforce EU Directives. Information is passed between authorities via the Commission only when a safety risk is identified. The new General Product Safety Directive, however, encourages collaboration and an exchange network has been set up to ensure that Member States do co-operate.

This type of approach would be beneficial for those responsible for policing RoHS legislation in order to survey the huge variety of equipment in a systematic way and to avoid duplication of effort.

Guidance on Compliance

Producers require guidance on how to comply with the RoHS directive. Information in this report will enable producers to decide on which approach to use; there is no universal procedure for all producers. Procedures could be further clarified by the use of a checklist or a decision tree approach and illustrative examples of these are included. The Commission could consider sponsoring a simple guide such as was produced for the Packaging Directive. Input should be provided by all parts of the electronics industry and experts on analysis technology.

Executive Summary of Recommendations

Definition of Maximum Concentration Values

1. It is essential that the correct interpretation of the “Maximum Concentration Values” definition is clearly understood by all producers and the enforcement authorities in all Member States. The TAC should decide whether the correct interpretation for the concentration limits is in “materials”, “components” or “assemblies” as illustrated by the indicative examples given in this report. The wording of the Directive implies that the interpretation should be “materials”. In order to avoid misunderstandings, indicative examples should be used as part of the definition.

Self-Declaration

2. Electrical and electronic equipment placed on the market will be presumed to comply with the RoHS Directive and enforcement authorities will carry out market surveillance. Self-declaration is used for New Approach Directives and is suitable for the RoHS Directive even though RoHS is not a New Approach Directive.
3. The main approach used by producers should be to obtain assurances from all suppliers that materials, components and equipment do not contain the banned substances. Producers will need to maintain records to show enforcement authorities in the event that a banned substance is found in the course of market surveillance.
4. It would be unreasonable to expect producers to analyse every batch of incoming materials and components, as this would be prohibitively expensive. It is also unnecessary to specify what should be analysed, but producers will be expected to take “reasonable steps” to ensure that banned substances are not used. The extent to which analysis is used will depend on many factors including:
 - the relationship with suppliers,
 - the risk of a banned substance being present, and
 - the quantity of product put onto the market.
5. Enforcement authorities should take into account what is required to protect the environment and human health. Where a banned substance is identified but the effect on the environment and human health is negligible, then as long as the producer can show that reasonable steps were taken to comply, the part containing the banned substance could be modified for future production, but it may not be necessary to remove the product from the market.
6. It is unlikely that Standards will be available by the 1st July 2006 deadline. Producers require a simple guide showing how they can comply with the RoHS Directive. A checklist or decision tree approach could be used. The guide could be produced in collaboration by the TAC, representatives of the electronics industry and experts in analysis technology.
7. The approach used must be harmonised in all Member States.

Standards for compliance testing

8. Techniques for analysis of all six banned substances are available. As with the Packaging Directive, there is no need to specify any particular procedure or instrument as, in most cases, there are several sufficiently accurate analysis methods available. Producers would benefit, however, from a Standard defining what steps they should take to comply with the Directive. This could provide guidance on when analysis is advisable, appropriate sampling methods and records that should be maintained.
9. New Standards would be useful for certain analytical techniques, which could give inaccurate analysis of electrical products if their limitations are not understood. In particular these include ED-XRFA and SEM-EDX.
10. Analysts should be aware of the limitations of ED-XRFA. This is a very useful technique widely promoted for checking compliance, but research has shown that incorrect assessments can be obtained.
11. Consideration should also be given to modifying certain existing Standards, for example those that specify tin/lead solders.

Standards for reporting formats

12. Several approaches are being developed within the electronics industry. These are intended to provide equipment producers with an assurance that the material, component, etc. does not contain a banned substance. This is the minimum information that a producer needs.
13. Materials declarations that include all six banned substances, ideally explicitly stating that they are absent rather than simply not mentioning them, would be suitable. The standard "Substance Declaration of Conformity" (SDoC) being developed by IEC would also be suitable. (This requires records of analysis to be maintained which can be audited).
14. Markings on components providing a readily visible indication that the banned substances are absent would also be suitable. This approach would minimise the need to maintain paper or electronic compliance records. Any Marks used should be standardised.

Information exchange networks

15. A RoHS Network to co-ordinate market surveillance should be established. Enforcement authorities in all Member States would benefit from close collaboration. Benefits would include

- pooling of limited resources,
- sharing of market intelligence and
- transfer of expertise in analysis technology.

A formal Network similar to that set up by the European Commission for the New General Product Safety Directive appears a sensible approach. This would ensure that surveillance included all categories of equipment and all Member States, and that higher risk products could be targeted.

16. Clear guidelines for product assessment procedures are required. Producers could also use these.

17. Analysis should be sub-contracted to laboratories with the required skills and expertise.

18. A standard reporting format should be used. Results should be circulated to all Member States including data on products found to comply with RoHS legislation (i.e. not just those that fail).

Specific conclusions and recommendations on each approach

Key conclusions and recommendations concerning concentration limits and definitions

1. A clear interpretation of the definition of the maximum concentration values is essential. It is important that the same interpretation is understood in all Member States and by both producers and enforcement authorities. It is also important for deciding how equipment is analysed.
2. Three interpretations have been made within the electronics industry of the definition of a homogeneous material and this has been interpreted as:
 - Materials (metals, plastics, ceramics)
 - Components (semiconductor devices, resistors, capacitors, etc.)
 - Assemblies (PCBs, etc.).

Self-declaration

1. Self declaration is used as the basis for compliance for many other EU Directives and is suitable for the RoHS Directive.
2. Any product put onto the market would be presumed to comply with the RoHS Directive and enforcement authorities will carry out market surveillance to detect non-compliant products.
3. If the enforcement authority finds a non-compliant product, the action they take will depend on the extent to which the producer has taken reasonable steps to prevent non-compliant products from being put onto the market. Most producers will want to be able to provide evidence to show that they have taken reasonable steps although what is reasonable will not be defined and is open to interpretation.
4. Significant challenges face all equipment producers who will need clear guidance as to what they will be expected to do to ensure that their products comply with the Directive's requirements.
5. Most producers are conscientious and will endeavour to ensure that their products are RoHS compliant by using two complementary approaches:
 - Obtaining Declarations: Identifying components and materials that do not contain banned substances and obtain materials declarations from their suppliers. Some equipment producers prefer these as formal certificates, which can be shown to enforcement authorities if necessary. Some producers currently believe that these will be sufficient and that analysis is not necessary.
 - Supporting analysis: Many equipment producers plan to, and some already, check supplier materials declarations by analysis. This is a sensible precaution, especially where no declaration is available, but also as a random check to audit suppliers. The extent to which analysis is necessary will depend on the risk from a banned substance being used.

6. The criteria for analysis will depend on the quantity of product put onto the market (less for small producers than for large producers), the relationship with suppliers and the risk of a banned substance being present.
7. Producers and enforcers should be permitted to use any appropriate analytical technique (as with other EC Directives). However, they should be aware of the limitations of some of these, in particular the low cost screening analysis methods.
8. The extent to which analysis is carried out will depend on many variables. Producers will consider the financial implications but the potential impact on the environment should be another factor for both producers and enforcement authorities. The environmental impact of a non-compliant product being placed on the market is a complex issue affected by many different factors. The enforcement authorities could, for example relate penalties to environmental and health impact. If, for example, the producer has taken reasonable steps to comply with RoHS but a banned substance has been included inadvertently, and if the impact on the environment is insignificant, the authorities may not require these products be removed from sale, only that the defect is be corrected or taken into account in new products. **This policy, however, needs to be harmonised in all Member States.**

Standards for compliance testing

1. The exact meaning of the maximum concentration values is currently not clear and different interpretations are being assumed. This is in part due to some of the terms used in the proposed definition having been used in other Directives, some of which have different intended meanings (in particular “unit”). Difficulties with precise translation may also be a complicating factor.
2. The maximum concentration values must be clear, in particular it should be understood whether these values apply to “materials” such as metals, plastics and ceramics or to individual components. There will be some “grey areas” most of which can be clarified by use of a list of indicative examples.
3. The definition that is chosen will have a direct impact on the quantities of the banned substances manufacturers will be permitted to use.
4. A small number of standards exist that can be used for analysis of components and materials from electrical equipment but are not sufficient for equipment manufacturers or enforcement authorities to use to assess materials, components or products.
5. Analytical methods are available with sufficient accuracy for almost all materials and components used in electrical products. In many cases, there are several techniques that could be used. Some items will be difficult to analyse although this will depend in some cases on the precise interpretation of the maximum concentration values.
6. ED-XRFA has been widely promoted as a simple low cost analysis technique but research has shown that accuracy can be poor if the limitations are not understood and taken into account. It is

possible for these instruments to give the wrong assessment of products; that is passing a material containing >0.1% lead, or failing a material containing <0.1% lead.

7. Some components present difficulties for analysis, for example if one contains lead in an exempt form and in a banned form as discussed in section 6.5.2 of the full report.
8. New Standards would be helpful to the electronics industry as these will give guidance to how equipment should be tested and ensure that the same results are obtained in all Member States. However it is unlikely that these will be available in time for the 1st July 2006 deadline.
9. It is reasonable to allow component and material manufacturers and equipment producers to use any suitable analytical technique but they should be aware of the limitations.

Standards for reporting formats

1. An increasing number of electrical equipment manufacturers are asking their suppliers for details of a wide range of hazardous materials that might be either used in the production process or are components of products. This information is used to reduce the impact of their products on the environment by limiting or restricting the use of all hazardous materials and is part of Design for the Environment procedures.
2. This data will be important in the proposed Energy using Products Directive (EuP) but is not required for the RoHS Directive. The only requirements placed on equipment manufacturers by the RoHS Directive are that materials, components, assemblies or equipment contains do not contain any of the six banned substances at concentrations above the specified limits in homogeneous materials. A simple statement to this effect may be sufficient as a materials declaration.
3. A variety of materials declarations are being proposed. Most have not been developed specifically for the RoHS Directive and so include data on many more materials than is required for compliance with RoHS. Some, such as the IMDS system, are very complex and not ideally suited for RoHS compliance. The final format of the EICTA/EIA/JGPSSI materials declaration has not been agreed but should be suitable for RoHS. The format from ZVEI may also be suitable but the one being developed by IEC (SDoC) is the simplest requiring only a statement that the product conforms to specified Directives or Standards.
4. A standardised system for marking materials, components, PCBs, assemblies and products is being discussed by several organisations. If these become accepted as Standards, then these could be used to declare that the substances banned by RoHS are below the maximum concentration limits.
5. Various methods of disseminating RoHS data have been considered. Web-based databases are being developed for suppliers to publish their product's composition data. Some manufacturers already publish their data on company websites.

6. Many equipment manufacturers intend to carry out at least some analysis to check on their suppliers declarations. They could collaborate to share the cost of analysis but there are potential risks that need to be considered.

Information Exchange Networks

1. Collaboration between enforcement authorities in Member States is mainly limited to passing on information where a safety risk has been identified. Different approaches are used in each Member State and the resources available vary significantly.
2. The New General Product Safety Directive (2001/95/EC) contains measures to encourage collaboration and the pooling of resources and a has set up a Product Safety Network to co-ordinate market surveillance. This type of approach would be beneficial for the RoHS Directive as it would allow enforcement authorities to share analytical expertise, co-ordinate targeted campaigns to check the compliance of all types products and to avoid duplication of effort.
3. Most electrical equipment is sold in all EU Member States and if a procedures to ensure compliance is acceptable in one State then this must be recognised in all other States. Methods used by enforcement authorities for assessing products should be based on one standard procedure although any reliable and accurate analysis method could be used. Producers will also be permitted to use any reliable and accurate analysis procedure. This will be possible only if enforcement of RoHS Directive legislation by Member States is co-ordinated and enforcement authorities collaborate such as already occurring with the New GPSD.
4. Suggestions for enabling harmonisation and collaboration include:
 - Producing clear guidelines for product assessment procedures. These could also be used by producers.
 - Setting up a RoHS Network to co-ordinate market surveillance.
 - Sub-contracting analysis to laboratories with the required skills and expertise.
 - Using a standard reporting format and circulate results to all States including data on products found to comply with RoHS legislation.