RoHS Enforcement

Guidance Document

Version 1 – issued May 2006

This Guidance Document has been developed through discussions within the "EU RoHS Enforcement Authorities Informal Network".

It should be noted that the document is informative and advisory, but has no legal authority.

Individual Member State RoHS enforcement authorities are bound by their own national legal structures and can only apply this guidance within the confines of those structures.

OVERVIEW

This guidance document contains three sections:

1. Introduction: Aims & Objectives, Principles and the Enforcement Process
2. RoHS Compliance Documentation
3. Sampling & Testing Issues

Key issues addressed within the Guidance include:

- The underlying principles that might be used to guide RoHS enforcement
- The type of documentation that 'producers' (*within the specific definition given in Article 3 of the Directive*[1]) might be advised to keep
- The ways in which Member State enforcement authorities might use such documentation to check for RoHS compliance
- The ways in which sample preparation and analytical testing might be employed to avoid inconsistent enforcement decisions between Member States

[1] The RoHS Directive defines a 'producer' as any person who (a) manufactures and sells electrical and electronic equipment under his own brand; (ii) resells under his own brand equipment produced by other suppliers, (*but for these purposes a reseller shall not be regarded as the producer if the brand of the producer appears on the equipment, as provided for in (a)*); or (c) imports or exports electrical and electronic equipment on a professional basis into a Member State.

SECTION 1: Introduction

Aims & Objectives of this Guidance

The RoHS Directive (2002/95/EC) does not prescribe any requirements in respect of compliance documentation that needs to be maintained or enforcement procedures that need to be undertaken. As a result, this document has been developed to provide ***non-binding guidance*** on these issues.

This document has two primary intentions: -

- to assist Member States with national enforcement of the RoHS Directive; and

- to provide clarity to industry on how producers may demonstrate compliance with its requirements.

This document is also intended to become part of a wider, voluntary initiative to develop administrative co-operation between those Member State enforcement authorities that have responsibility for the implementation of the RoHS Directive.

Principles

An effective RoHS compliance and enforcement regime should be based on the following underlying principles:

- a consistently applied and **common interpretation** across Member States regarding those products which are considered to fall within the scope of the RoHS Directive

- a **presumption that products** falling within the scope of the Directive **conform** with its requirements; and

- **self-declaration by producers**.

These principles will provide an effective and cost-effective approach for both Member States and ‘producers’ (within the terms of Article 3 of the Directive), who place electrical and electronic equipment on the EU market after 1 July 2006.

Enforcement Process

Faced with the very wide range of products covered by the RoHS Directive, Member State enforcement authorities must - in the first instance - decide which EEE (electrical and electronic equipment) categories and products they wish to select for further investigation. These decisions will be made following market surveillance activities and could involve one or more of the following criteria:

- Market intelligence;
- Random selection;
- Products known to contain materials of high concern;
- High volume products;
- Short life products;
- Consumer products unlikely to be recycled;
- Notification of concern from external parties;
- Notification of concern from other Member States.

If concerns arise (*for whatever reason*) the Member State enforcement authority may, at this stage, decide to submit a formal request to the producer. This second stage of the enforcement process is described in Section 2.

Although a sequential step process is envisaged, enforcement authorities may take whatever actions are appropriate to the circumstances and to the powers assigned to them in national legislation, including removal of goods from the market where this is deemed to be necessary.

Indicative non-destructive testing (e.g. XRF analyser) for example can be used at each step of the inspection process, and notably before the documentation check. The results of this should not be used as proof of infringement, but some enforcement authorities may proceed from this to direct sampling without previous examination of the documentation, (see next section – *Sampling and Testing Issues*). In addition in cases of very high suspicion, direct sampling may be carried out without any previous documentation check.

SECTION 2: RoHS Compliance Documentation

Figures 1 and 2 show a common market surveillance methodology that has been designed to assist Member States with their national enforcement of the RoHS Directive.

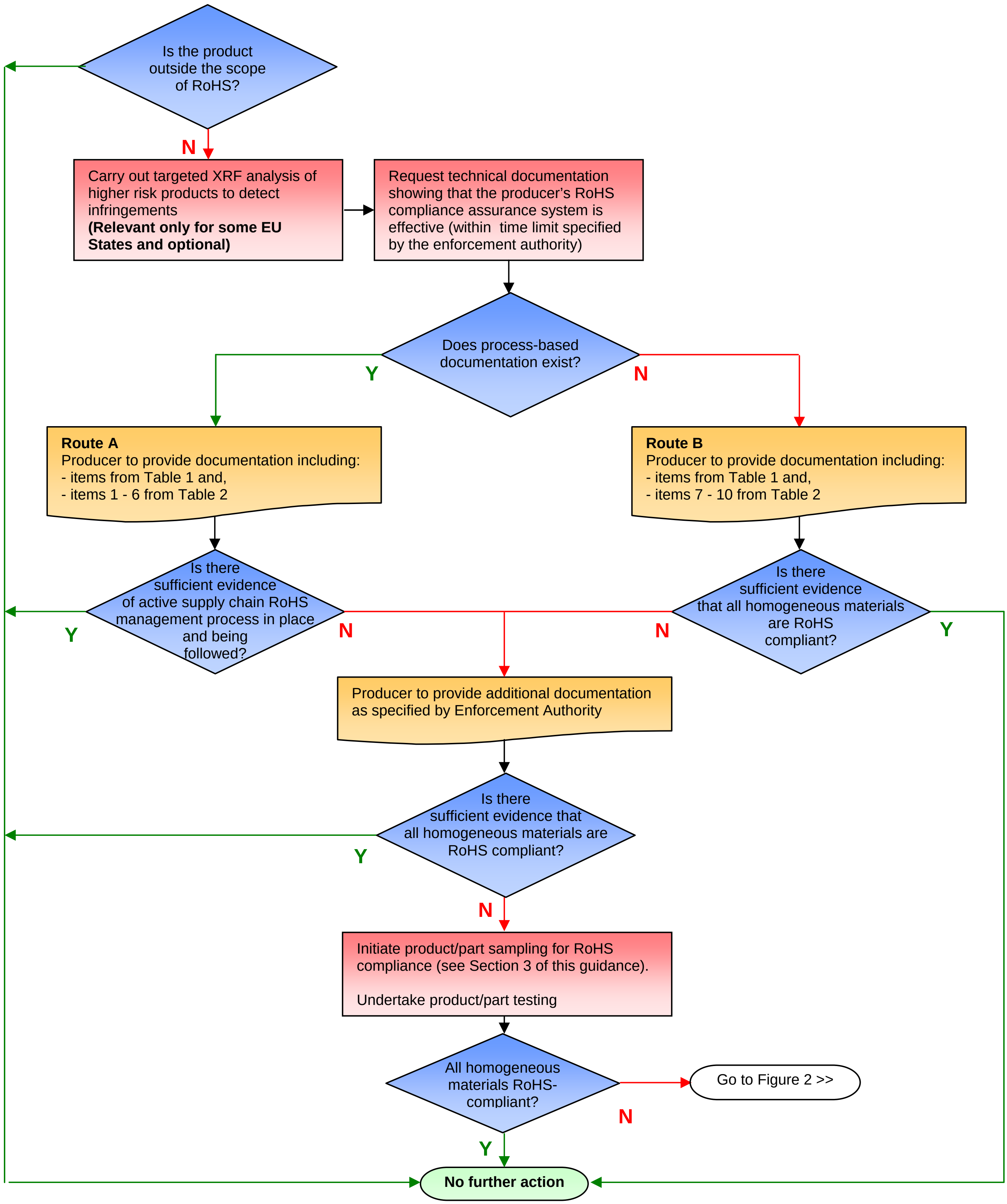
Whilst the overall approach to RoHS compliance is based on a *Presumption of Conformity*, it is recognised that national authorities will require self-declaration from producers as the key principle underlying the enforcement process.

Figure 1 demonstrates a step-by-step approach to RoHS compliance investigations - initial self-declaration; followed by a more detailed assessment in those cases where evidence from producers does not assure compliance. In cases of concern, detailed sampling and testing may or could be required.

The proposed enforcement process provides two initial routes to self-declaration, taking into account that for some organisations (small and medium-sized enterprises in particular), the process may be facilitated by the initial provision of compliance documentation for homogeneous materials in products/parts (Route B in Figure 1). However documentary evidence of more structured internal systems (based on quality assurance processes) could be the initial step in assessing a producer's ability to manage RoHS compliance for those companies or organisations that have such systems in place. This is shown as Route A.

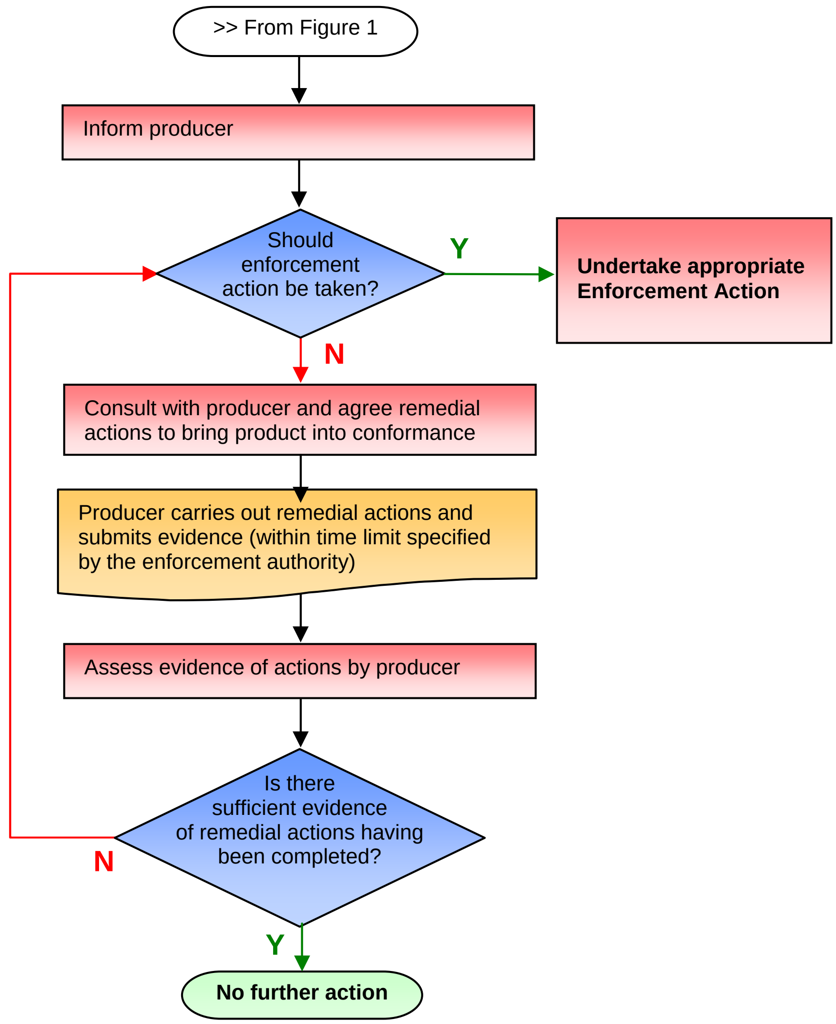
Figure 2 shows a step-by-step approach to enforcement action should this become necessary.

Figure 1 - Flow chart for RoHS Compliance Assessment Using Documentation



Note - This flow-chart should not be viewed in isolation from the main enforcement guidance document.

Figure 2 - Flow Chart for RoHS Enforcement Action



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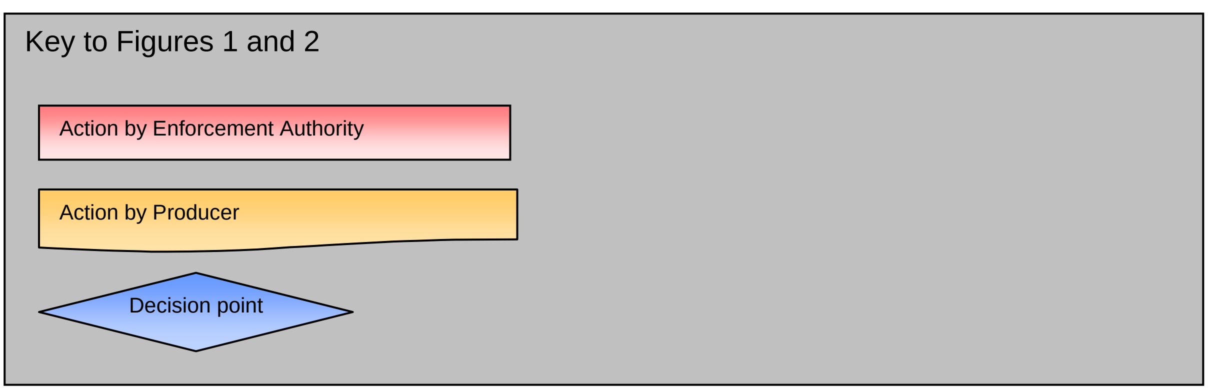

Note - Enforcement Authorities may take whatever action they deem necessary and is appropriate to the circumstances.

Table 1 - Typical List of Overview Documentation
Contact information *Point of contact within the organization that will deal with the RoHS enforcement request.*
Company information *This should include the size of the organization, product range and approximate levels of sales.*
Approach to compliance *This should be a general overview of any compliance systems that the company has in place and which are suitable for assisting compliance with the RoHS Directive.*
An overview of the data quality systems, (in those cases where the producer relies significantly upon supplier information to demonstrate compliance) *This could include risk assessments, acceptance criteria, purchasing procedures and any other relevant documentation and may be a combination of both process-based and product/part-based documentation.*

Table 2 - Typical Compliance Documentation List

Route A	Route B
Process-based **Technical Documentation** *(Typical information relating to the producer's internal system to ensure RoHS compliance)*	**Product/Part-based** **Technical Documentation** *(Typical information relating to a product's/part's physical attributes that ensures RoHS compliance of a specific product)*
Compliance Assurance System (CAS)	
1) A definition of the purpose of the system, its essential requirements and specification. This specification should cover compliance both within the company and within the supply chain	7) Producers' or suppliers' warranties /certificates declaring that the use of the restricted substances is within the permitted levels
2) A formally defined process which implements the requirements of the system and is integrated within the organisation's quality and management systems	8) Producers' or suppliers' completed materials declaration for each part (including revision for revised parts) and justification of RoHS categorisation and use of exemptions. These declarations would be limited to the list of RoHS substances, not full materials declarations
3) A technical documentation system (paper and/or electronic) to support the process and measures to assure conformity with the requirements of the system together with necessary training, tools and infrastructure.	9) Analysis report for homogeneous materials in parts/components, (which could be the producers or suppliers own internal or external test results). The test results should refer to homogenous materials in parts/components.
Evidence of Active Control of the CAS	10) Those who use approach B only (SMEs) must also provide evidence that procedures are being followed to show that materials declarations have been assessed to determine if they can be trusted. Enforcement authorities will also need to see documented compliance procedures
4) Results of internal and supplier audits to validate Compliance Assurance System and/or processes. i.e. the supplier's ability to assure compliance.	
5) Evidence that the system is being followed including results of product specific conformance assessments comprising items such as product assessments (including justification of RoHS categorisation and use of exemptions), materials declarations, procurement, inventory and production controls and substance analysis where appropriate	
6) Overview of any internal data system used for the management of RoHS compliance data	

SECTION 3: Sampling and Testing Issues

Harmonized Approach for Sample Preparation and Analytical Testing

Generally speaking, the employment of testing (which could be either non-destructive or destructive) to verify compliance with the requirements of the RoHS Directive will usually be seen as a last resort. In order to obtain conclusive proof of a product's compliance the RoHS Directive, producers may however choose to carry out analytical testing of homogeneous materials in their products and/or specific components. Enforcement authorities may also choose to carry out such testing to verify the claims of producers in relation to equipment placed on the EU market.

A variety of recommended testing approaches and standards are being established by international standards organisations and (in the absence of European harmonised standards related to compliance with the RoHS Directive) producers may wish to adopt these. An Annex listing test standard procedures and guidelines that might be considered for use in RoHS analysis may be included in later editions of this Document.

One specific example of a standard procedure for analytical testing (which is being widely promoted for use by the IT, telecoms and consumer electronics sector) is IEC 62321.Ed.1, 111/54/CD. The IEC standard is currently available as a draft and it includes an Annex of guidance on disassembly, sample selection and the application of test methods. Other standards are being discussed and are being prepared by other organisations (ASTM, IPC and others) so both producers and enforcement authorities will need to keep abreast of the latest developments.

Certified Reference Materials for RoHS Testing

In order to ensure the quality of test results and limit discrepancies between analytical methods, a comparison with reference materials can be utilised. A reference material is a material with an accurately known concentration of specific substance(s). While standard procedures are useful, certified reference materials are often the best tool to prove that the standard is being applied correctly and should therefore be considered as a part of the enforcement strategy.

The Institute of Reference Materials and Measurements of the European Commission (www.irmm.jrc.be) and other reference material producers are developing specific reference materials suitable for this purpose.

Sampling

The Challenge for Electronic Products

A typical electronic product is made up of hundreds of individual components, such as integrated circuits (ICs), discrete components (resistors, capacitors, diodes, etc), wires, cables, printed circuit boards, connectors, fasteners, sensors, enclosures etc. Each of these components has a unique mix of materials that makes up its composition. An integrated circuit, for example, may consist of a silicon die, die attach material, epoxy underfill, mould compound, leads, and lead plating materials. These materials are often heterogeneous, being themselves made up from a range of materials. Obtaining a representative sample of such a device for testing purposes can be challenging.

Screening

As a first step, producers and enforcement authorities may choose to use a screening tool, such as energy dispersive x -ray fluorescence (ED-XRF) analysis. This tool has been widely promoted as a simple low cost analysis technique, but the results may only give an indication that a particular product/component may or may not present a potential compliance problem. It may not, for example, be sufficient to discount the possibility of an infringement of the RoHS requirements where one or more of the substances are present in both an exempted and restricted application. It will also not differentiate different types of brominated flame-retardants or identify the valence state of chromium.

The limitations of XRF techniques must be understood and taken into account. In general bench-top laboratory systems provide greater accuracy and the ability to analyse smaller areas ($<0.5\ mm^2$) than handheld units. In either case the use of a standardised protocol based on suitable test procedures (and using certified reference materials to show correct application where possible) by a trained operator is essential. Further guidance is not provided here as both standards and instrumentation are developing rapidly.

It is important that ED-XRF analysis is carried out correctly as misleading results can be produced if the limitations of this technique are not understood. Producers and enforcement authorities might wish to follow any adopted industry standards. The sort of screening analysis described above should be used to establish a “pass”, “fail” or ”borderline” result. No further analysis by producers should be required if a clear pass or fail is obtained, but additional more accurate analysis might be needed if enforcement authorities are considering further enforcement action. Additional analysis will be needed, however, if a borderline result is obtained.

Sampling Strategies

As a typical electronic product may be made up of hundreds or thousands of homogeneous materials, complete testing of the product is usually impractical - due to cost, time and sample preparation constraints. To address this challenge, the following three practical sampling strategies are recommended:

1. Focus on samples from known “high concern” materials and applications. It is generally not worth either the time or resource to analyse materials for substances that are not likely to be present.

2. Focus on samples that can be separated from the equipment using those ordinary tools that would be typically found in an analytical and testing laboratory or by techniques such as sectioning.

3. Where it can be demonstrated that it is not possible to mechanically disjoint a particular component or part due to its very small size or some other constraint **and** analysis of individual homogeneous materials is not possible, then this component or part is to be regarded as one homogeneous material. In such cases, the use of homogenizing techniques for components and parts that are composed of two or more homogeneous materials might be considered.

Additional analysis should only be undertaken if screening analysis gives a “borderline” concentration, where bromine is detected in a high risk plastic or where chromium is detected in a metal coating. Further analysis may also be required in cases where a “fail” result has been obtained but it is suspected that this is due to the presence of the restricted substance in an exempt application. Enforcement authorities may carry out further more accurate analysis to obtain evidence for prosecutions even where screening analysis gives a “fail” result.

1. Focus on samples from known “high concern” materials and applications

   Most historical uses for restricted substances are known, so that “high concern” materials or applications can be targeted for sampling. This first sampling strategy focuses on taking samples from applications where restricted substances have been used historically.

   Some current examples of high concern materials and applications include:

   - PVC (Cadmium and Lead; as stabilizer and colorant);
   - Polystyrene (PS) and Acrylonitrile/Butadiene/ Styrene (ABS) (PBDE; as flame retardant);
   - Red/orange/yellow plastics (Cadmium, Lead and Chromium VI *as lead chromate*; as colorant);

- Plated metal enclosures, fasteners, clips, and screws (Hexavalent Chromium; as chromate finish);
- Populated Printed Wiring Boards (PWBs) and their components (Lead; as solder and terminal finish);
- Decorative name plates, buttons (Mercury; as additive, colorant, curing agent);
- Switches, relays (Mercury; as component of switch/relay);
- Lead solder used inside components;
- Cadmium used in thick film circuits.

Please note that this is **not** an exhaustive list.

2. Focus on samples that can be separated from the equipment using ordinary tools

   This strategy will be required if screening analysis does not give a clear result. A negative result in some circumstances may not, however, confirm RoHS compliance and if this is suspected then additional testing may be required.

   The currently agreed definition of homogeneous material introduces the concept of "mechanically disjointing". This, however, is not the only sampling method that might be considered.

   As a proposed second sampling strategy, the only samples that are tested are those that have been separated from the equipment using ordinary tools. 'Ordinary tools' means those tools that would be typically found and used in a testing laboratory. Note that there may be more advanced analysis techniques that could be used for 'in-situ' RoHS analysis but at present there are no reference standards for these techniques.

   Please note that the definition of homogeneous materials is a guide to interpretation of the RoHS Directive, it is not a guide to analysis methods. The definition of homogenous material does not imply that a sample for testing has to be mechanically disjointed - any suitable analysis method may be used. It may be possible to separate some types of coatings for analysis purposes using chemical methods, (for example, water extraction of hexavalent chromium from coatings and selective dissolution of tin alloy coatings from components by BS 6534; 2003).

   Commission Guidance on homogeneous material:

   The Commission's guidance in respect to homogeneous materials is as follows -

‘Homogeneous material’ means a material that cannot be mechanically disjointed into different materials.

The term ‘homogeneous’ means "of uniform composition throughout". Examples of "homogeneous materials" are individual types of plastics, ceramics, glass, metals, alloys, paper, board, resins and coatings.

The term “mechanically disjointed” means that the materials can, in principle, be separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

Mechanical disjointing by abrasive processes is used as an example of a method that illustrates the intended definition of the maximum concentration value, but it may not always be feasible to use these techniques to obtain a clean separation for analytical purposes. New standard procedures will be required for the separation of materials from electrical equipment for analysis purposes. IEC Technical Committee TC111 is working on an informal document on sample disjointing, which takes requirements on mechanical disjointing for sampling into account.

For abrasive processes, the size of the part/component should be taken into account. For large parts (like a coated housing), it should be possible to remove a coating by abrasive processes. However for small components that consist of a number of layers and/or a number of homogeneous materials, the separation of homogeneous materials by abrasive processes will often not be possible for routine checks although in-situ screening methods will be suitable for some types of metal coatings. The third sampling strategy, (outlined below), might be considered for components where an analysis of the constituent homogeneous materials is impossible.

Commission examples of the application of this guidance:

A plastic cover is a ‘homogeneous material’ if it consists of one type of plastic that is not coated with or has attached to it or inside it any other kinds of materials. In this case, the limit values of the Directive would apply to the plastic.

An electric cable that consisted of metal wires surrounded by non-metallic insulation materials is an example of a ‘non-homogeneous material’ because the different materials could be separated by mechanical processes. In this case the limit values of the Directive would apply to each of the separated materials individually.

A semi-conductor package contains many homogeneous materials, which include plastic moulding material, tin-electroplating coatings on the lead frame, the lead frame alloy and gold-bonding wires.

For many components, knowledge of where the restricted substances are likely to be found simplifies the analysis procedure. In a semiconductor package for example, the only location where a restricted substance is likely to be present is lead in the tin plated termination coating. This can be analysed using ED-XRF, so it will not usually be necessary to analyse any of the other materials, (note, however, that lead, cadmium or hexavalent chromium may be used in inks used to mark components but this is very unusual).

In the case of something like small passive components such as chip capacitors, consideration might be given to proceeding to the third sampling strategy (outlined below) as the clean separation of homogeneous materials from these types of parts may often not be possible for routine checks using the standard techniques currently available <u>**and**</u> analysis of individual homogeneous materials may not be possible. Sample sectioning or other techniques may be considered to allow analysis of coatings or other layers

The sampling strategy outlined above ensures that complete products (such as TV sets, mobile phones, washing machines, etc.) or individual parts (such as populated printed circuit boards or complete cables) are not considered as a homogeneous material.

It should also be noted that when testing for restricted substances, detailed disassembly would often not improve the end results. One of the most common uses of lead in electronics, for example, is within the solder that is used to attach components to a printed wiring board (a PWB). Although relatively small amounts of solder are used, the lead content of the solder (if this is deliberately added) is high enough to highlight its presence during screening testing, although lead as an impurity at >0.1% may be present in equipment (possibly giving a borderline result by ED-XRF). As a result, it might not be necessary to destructively disassemble the printed circuit board to test the solder material. Detailed disassembly can, nevertheless, have a significant impact when it comes to comparing the level of hazardous substance in a material to the relevant limit value.

3. <u>Use homogenizing techniques for components and parts that are both composed of many homogeneous materials and cannot be mechanically disjointed **and** analysis of individual homogeneous materials is not possible</u>

Where it can be demonstrated that it is not physically possible to mechanically disjoint a particular component or part due to size constraints and/or lack of adequate techniques for such disjointing or any other feasible sampling/analysis methods, <u>**and**</u> analysis of individual homogeneous materials is not possible, it may be necessary to convert it into one homogenised sample for testing.

For components and parts which; -

(i) either give indecisive borderline results by screening methods or are unsuitable for these techniques; and

(ii) are composed of multiple homogeneous materials; and

(iii) cannot be further mechanically disjointed or where selective chemical analysis procedure are unsuitable

In these exceptional cases *(where the three criteria above are met)*, Member State enforcement authorities may carry out analysis of the **homogenised** materials.

Note that the maximum component and/or size for homogenising would be limited to the minimum sample size of Best Available Techniques (BAT) for analysis in these circumstances.