



## **Key Elements of a RoHS Due Diligence Plan**

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## Introduction

With the RoHS deadline upon us as of July 1, 2006, most companies should be well on their way towards RoHS compliance as of the date of this white paper. The tasks are many and include bill-of-material (BOM) conversion, supply chain notification and evaluation, establishing designs that can withstand the new lead free soldering processes, performing pilot runs of new RoHS compliant product and grappling with the various reliability concerns created by RoHS conversion. Amidst this flurry of activity, companies should not ignore the key task of establishing a compliance assurance system and an extensive, well organized collection of due diligence documentation. Such a system and records act similarly to the “Quality Management System” and “Quality Records” required as part of the ISO 9000. Due Diligence activities provides visible evidence that a company is taking all reasonable steps to assure that their products conform to RoHS.

## Self Declaration

The European Union (EU) concept of self-declaration may be somewhat unfamiliar to those who have not been deeply involved in satisfying other regulatory compliance issues for the EU countries such as CE marking. The EU self-declaration concept is based on the presumption of conformity. By placing its products on the market, a company is declaring that its product conforms to the applicable EU regulations. Enforcement is expected to be carried out through marketplace surveillance where various products are selected for further investigation rather than mass customs inspections.

If selected, the “producer” may be asked to present evidence of conformance in the form of an engineering documentation file. The file may be referred to by names such as “Technical Information File” (TIF), “Technical Conformance File” (TCF) or simply the “Technical File”. These files should contain a description of the product and all the information necessary to establish that it conforms to the appropriate EU Directive(s). The Technical File usually contains formal descriptions of process controls, risk assessments, product evaluations and test results pertaining to the product. There are typically requirements that these documents be available to the authorities within a few days or weeks of request and that they be available for a several years after shipment. For example, the British RoHS law states:

“.....A producer shall prepare and, at the request of the Secretary of State, submit to him within 28 days of the date of the request, technical documentation or other information showing that electrical and electronic equipment which he has put on the market complies with the requirements of regulation.... A producer shall retain the technical documentation or other information in respect of electrical and electronic equipment ... for a period of four years from the date that he puts the equipment on the market....”

*British SI 2005 No. 2748*

The quality of the Technical File may well determine whether the authorities decide to further investigate a company’s products. If the Technical File gives the impression that the company has expended all *reasonable* efforts to ensure compliance, no further action may be taken. On the

other hand, if the company's responses to requests from an enforcement body for information are met with delays and scattered, disorganized, and inconclusive information, the enforcement agency is likely to further investigate the product. The key goal then is to be able to clearly demonstrate product conformance by having a documented and functional RoHS compliance system that includes official policies, decision-making procedures, compliance risk assessments and evidence that these procedures have been successfully implemented. For many companies, this evidence will be dominated by large collections of Certificates of Compliance and test data from suppliers but it is also important to demonstrate that the OEM is exercising active control of the components and processes used to make the product.

### **Compliance Assurance System**

There must be substance to the compliance assurance system described in a company's documentation. The system should answer a number of key questions such as: What policies has management put in place regarding conformance to RoHS and other environmental directives? How have these policies been communicated to employees and suppliers? What steps have been taken to evaluate products for compliance? What procedures and standards have been established to ensure conformance? Do drawings and purchase orders require compliance to the RoHS Directive? Has the system's performance been audited to ensure that employees and suppliers understand and are following these policies and procedures? Are compliance test data and records organized in such a fashion to facilitate control? Is management actively controlling these processes to assure conformance to RoHS and WEEE requirements? While perfection is neither practical nor hopefully required, efforts towards designing an adequate compliance assurance system may prove very worthwhile if your company's products are challenged.

### **Compliance Documentation**

Most original equipment manufacturers (OEMs) are dependent on a wide array of suppliers and outside contract manufacturers to provide components and subassemblies for their products. While much of the OEM's added value may be in designs and software, it is the physical features of the product that is of interest in RoHS. Because of this, the RoHS compliance system must focus on the OEM's contract manufacturers and suppliers that are making the physical product. Since most companies don't have the luxury of extensive supplier communication programs and onsite audits of their suppliers, they must depend heavily on more remote measures for assessing suppliers' RoHS compliance systems. This is typically done by collecting and evaluating various documents from suppliers and then following up with chemical testing audits of selected batches of incoming components.

For supplier designed purchased parts, requests for Certificates of Compliance, Materials Declarations and RoHS test data are typically sent to suppliers, followed in some cases by chemical / process surveys to assess suppliers' internal controls and understanding of the RoHS requirements. The quality of these documents can provide insight into how well the supplier understands the RoHS regulations and whether sufficient effort has been expended to be able to use components without further testing. For example would a particular supplier's Certificate of Compliance be useful as evidence in a court of law? If it clearly states that the specific component in question has been manufactured and tested in accordance with European Directive

2002/95/EC and meets all the requirements of the Directive and is signed by an officer of the company, it probably would be useful. However, if the Certificate of Compliance uses vague, non-committal language and is signed by someone with no authority in the company, then more investigation will probably be needed. A supplier that sends detailed, layer-by-layer chemical descriptions of the component – even if a few items are labeled “proprietary ingredient” – indicates that they have thoroughly evaluated their own product for potential RoHS violations. Third party chemical lab test data are further proof that the supplier has made a serious attempt to find and eliminate chemicals forbidden in the RoHS Directive.

Care should be taken to seek this information uniformly throughout the entire Bill of Materials. Most OEMs have the tendency to focus on high value items such as ASICs and Printed Circuit Boards and ignore things such as garden-variety fasteners. After expending millions in RoHS compliance efforts, a product can be in violation of the directive over a free stock, five-cent plated screw that contains hexavalent chromium corrosion preventative.

Consideration should also be given to subcontractors who are manufacturing OEM designed components such as mechanical and sheet metal parts. Since the OEM’s drawings are providing the specifications, it is critical that drawings contain statements requiring manufacturing to be done in conformance with the RoHS Directive. During routine supplier audits, special attention should be paid to the supplier’s feedstock and free stock materials, plating subcontractors’ processes, etc. to ensure that RoHS substances are not being accidentally introduced into the OEM’s designs.

### **Auditing and Testing: A Supplement to Certificates of Compliance**

Most of the official guidance available for RoHS cautions that stockpiling supplier Certificates of Compliance will probably not constitute sufficient “due diligence” for most products. The guidance documents are careful to point out that chemical testing is not mandated by the RoHS Directive and *may not* be necessary but it is probably a good idea to conduct some verification and analysis on selected components through product testing. While it is neither practical nor necessary for companies to analyze every batch of components at receiving inspection, testing should be considered for new suppliers or when there is doubt about a supplier’s controls and thoroughness. There will also be cases where you must use aging inventory, which was purchased long before suppliers were paying any attention to control for RoHS conformance.

Several chemical testing methods have risen to prominence based on studies done by consulting groups sponsored by the RoHS Technical Adaptation Committee, which has been commissioned by the EU to oversee the technical details of RoHS implementation. Both ASTM and IEC have working committees pursuing standardization of methods for RoHS compliance testing.

Generally, these protocols start by using XRF (X-ray Fluorescence) to conduct gross screening of components at relatively low cost. Components that are found to have elevated levels of the RoHS elements are then further tested using a variety of wet chemical testing methods. Methods such as ICP-AES are used to analyze for lead, cadmium, and mercury. A special dye is used in conjunction with a UV-Vis spectrometer to assess levels of hexavalent chromium. Specialized GC-Mass Spectrometer methods are required to distinguish and measure the various forms of

Polybrominated biphenyl ethers (PBDE) and Polybrominated biphenyls (PBB). Because of the \$300,000 plus price tag and the chemical expertise required, all but the largest companies will probably rely on an outside testing lab to perform the wet chemical analysis.

While it should be a simple matter of sending samples to any major chemical laboratory and receiving the answers, the heterogeneous construction of many electronic components makes analysis by inexperienced laboratories a tricky and unreliable prospect. RoHS requires that the levels of Pb, Hg, Cr+6, PBB, and PBDE be below 0.1% and Cd be below 0.01% in each homogeneous layer of each material. While most labs have procedures for dissolving and accurately testing homogeneous substances, many are not accustomed to dealing with highly heterogeneous electronic components. Available EU guidance documents clearly describe the term “homogeneous” to mean each plating layer, each adhesive, each encapsulating plastic, etc. must be below the official limits. This means that the lab should be prepared to use specialized analysis methods to determine the lead (Pb) content of the component leads, while perhaps grinding up the plastic encapsulant to look for PBDE. Regrettably, a number of labs are grinding up components and sometimes entire printed circuit boards for one bulk chemical analysis of all six RoHS elements. While this strategy is perhaps defensible for extremely small components, European RoHS guidance documents indicate that it is not considered as a good testing strategy for most components and certainly not for entire printed circuit board assemblies or products.

The long list of exemptions also adds a great deal of confusion. While the industry is highly grateful for the many exempt items, it does mean that one must be very careful in assessing lab results. For example, lead is banned in component terminations but is exempt in the glass layers used inside and on the surface of some components. If you grind up the entire component and analyze it for lead (Pb), where did the lead originate: the termination (where it is illegal) or the passivation glass layer (where it is exempt)? These dilemma point out the need to seek a chemical testing laboratory that is prepared to offer sound guidance in addition to chemical testing. Companies are well advised to carefully interview lab personnel to understand the depth of their knowledge about RoHS and work with them on the strategies for disassembly.

While it would be cost prohibitive to analyze every layer of every product, there are clues as to which materials have a tendency to contain specific RoHS substances. For example, some electroless plating baths are known to contain cadmium. Some component manufacturers used ECO (Engineering Change Order) effectivity dates rather than changing part numbers during conversion to lead free terminations. Therefore, it would be prudent to check component terminations for lead (Pb) until such time as no more lead containing components are left in distribution inventories.

Certain plastics are known to frequently contain banned flame-retardants while others are naturally flame retardant and require no flame retardant additions. Certain types of metals are notorious for containing hexavalent chromium preservative coatings. Based on this type of knowledge, it is possible for experienced testing houses to do intelligent, selective testing for certain elements rather than generically testing all materials for all six RoHS substances.

## Conclusions

A company's RoHS preparation efforts are not complete until they have organized their conformance efforts into a Technical File for each product. The Technical file should contain a general product description, details about the company's compliance assurance policies and procedures, documentation showing that requirements for RoHS compliance have been passed down to subcontractors and suppliers. The file should also contain vital evidence of compliance such as supplier's Certificates of Compliance, third party test data and most importantly, the OEM's efforts to audit and monitor suppliers, contract manufacturers and their own internal assembly operations for RoHS compliance.

Although there are no specific checklists or methodologies that companies can apply towards due diligence, one thing is for certain: frantic collection of Certificates of Compliance without validation and the absence of a robust data management strategy is far from *due diligence* and perhaps closer to *negligence*.

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