

Best Practices for RoHS Compliance in support of CE Marking

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Abstract

In 2012, The European Directive on Reduction of Hazardous Substances was recast. The new version of the directive now requires products to be adequately validated as RoHS compliant in order to be eligible for CE marking and access to the EU market. Additionally, the recast also increased due diligence requirements for companies validating their products as compliant, including elevated documentation, data validation, risk analysis, and record keeping requirements. Methods used to address RoHS compliance before this change, such as simply collecting RoHS compliance statements from suppliers, may no longer be adequate. This paper starts by reviewing the evolution of the RoHS directive and how it has evolved. It then moves on to cover the requirements and scope of the directive, as well as which standards are used to demonstrate compliance, and how those standards must be referenced in internal company quality processes. Suggestions on best practices for building a comprehensive, efficient, and effective product environmental compliance process with a focus on risk mitigation and cost containment are provided, including real world examples. New specific requirements for classifying parts and materials according to risk will be addressed, as well as new requirements to rank all part and material suppliers by evaluating the trustworthiness of the data they provide. Marking requirements, declaration of conformity formatting and examples, and technical compliance files, will be covered with examples provided. The EU REACH law is also addressed briefly. Although the REACH law is not tied to the RoHS directive or CE-Marking, REACH validation is required for access to the EU market, and compliance validation techniques can be similar to RoHS compliance validation. References to standards and industry resources are provided.

Introduction

In July 2011, The European Commission published EU RoHS directive 2011/65/EU, replacing 2002/95/EC and adding new expectations and requirements onto manufacturers of electrical and electronic equipment (EEE.) Sometimes called “*RoHS-2*” or the “*RoHS Recast*”, the new re-worked directive placed new due diligence and documentation requirements onto manufactures, forcing companies to re-evaluate their strategies for ensuring compliance. In many cases, a complete overhaul of current RoHS validation procedures is warranted.

Evolution of the RoHS Directive

RoHS compliance is nothing new to many manufacturers of electronic devices. The original RoHS directive 2002/95/EC (Sometimes referred to as RoHS-1), along with WEEE directive 2002/96/EC, was adopted in February 2003 and came into force on July 1st, 2006. The RoHS directive required manufacturers to restrict the presence of six substances in their products; Lead, Mercury, Cadmium, Hexavalent Chromium, PBBs, and PBDEs. This directive applied to most consumer electronic and IT equipment. While the regulation was clear on the intent of the requirements, the expectations on how manufacturers go about validating their products to these requirements were not. This lack of specific guidance or standards lead to a wide variance in the level of due diligence being exercised by companies in meeting the stated requirements of the directive. The RoHS-2 directive (2011/65/EU) is an evolution of the original directive and became law on July 21st, 2011 and took effect January 2nd, 2013. This new directive implemented new administrative changes and an expanded scope which now includes medical and industrial control equipment. It also brought the RoHS validation requirements under the CE-Marking scheme – meaning applying CE marking is not allowed unless the product has been adequately validated to the RoHS-2 directive. In November 2012, to help remove the confusion on how to meet the regulation, a new harmonized standard was published in the Official journal – EN50581:2012 which will be discussed later in the paper.

CE Marking and the New Legislative Framework

The recast of the RoHS directive was one of the first in a list of directives being redefined as part of the EU’s New Legislative Framework (NLF). The NLF was implemented by Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products; Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised; and Regulation (EC) 764/2008 which provides procedures relating to the application of certain national technical rules to products lawfully

marketed in another EU country. This new framework provides a consistent CE-marking compliance strategy across all applicable directives. The EMC directive, Low Voltage directive, ATEX directive, and Measuring Instruments directive are just some of the other directives which have been recast to align with the new legislative framework. The inclusion of the RoHS-2 directive in the NLF, which brings the requirement under the CE-Marking scheme, has significantly increased the due diligence and documentation expectations directed at manufacturers, while also raising the stakes in enforcement.

EN 50581: The path to RoHS-2 Compliance

In order to provide companies with a consistent approach to applying the mandates of the EU directives, the EU publishes a list of “Harmonized Standards.” The list is maintained in the EU official journal. While manufacturers are not required to apply these standards, those who do not may be subject to additional scrutiny and may be taking on additional risk. As a result, most companies apply these standards when performing conformity assessment.

In November 2012, The EU Commission published such a standard for companies to reference when determining the expectations placed upon them in meeting the requirements of the new RoHS-2 directive. **EN 55081:2012, “Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances”** is currently the only standard listed in the official journal in support of the RoHS directive. The following sections of this paper will explore best practices in applying the requirements of this standard into a product RoHS compliance validation process. When designing an EN 50581 compliant procedure, the applicable clauses of the standard should be referenced throughout the internal procedure documents.

An EN50581 Compliant Process: Step 1 – Determine the information needed

Before one can collect and validate the required compliance data, one first needs to determine exactly what data is required. How is this done? Referring to **EN 50581:2012, clause 4.3.2**, we can see that this determination should be based on: (1) the probability of restricted substances being present in the materials, parts, or assemblies being evaluated, and (2) the trustworthiness of the supplier.

Regarding how to determine the likelihood of the presence of restricted substances, the manufacturer may apply technical judgement, based on technical information available via the electronics industry, or literature investigation of the products. Such investigations might include:

1. Material types typically used in the part or sub-assembly (or similar parts)
2. Historical record of substances being present in the part or sub-assembly (or similar parts)
3. Recently expired exemptions that may impact the part or sub-assembly

This is all good, but exactly how does one go about finding this information, and documenting the process of assigning risk?

This will vary depending on your type of product, position in the supply chain, and available data. For example, a Mylar insulation sheet may be deemed lower risk than a low voltage capacitor, based on the known properties of Mylar, and the high risk of the presence of lead in the ceramic matrix of the capacitor. As a result, one might require a full material declaration or test report to validate the capacitor, while only requiring a simple certificate of compliance for the Mylar sheet. The key is to define the metrics for assigning risk to types of parts and materials in your documented validation process, and to then collect the required data as determined by those metrics. In **Figure 1** below, parts are divided into three risk categories, each with different levels of data validation assigned. Please note in this example that while PCBs can be considered high risk due to potential surface finish variants (such as SnPb HASL), finished goods which carry the CE marking (such as PCs) are considered medium risk even though they contain high risk components within them. This is due to the CE marking indicates that the product has been validated by the manufacturer, thereby lowering the risk of non-compliance compared to components which have not been shown to have gone through such validation.

Component Class A Low Risk	Component Class B Medium Risk	Component Class C High Risk
Metal fasteners, screws, rivets, and standoffs	Mechanical Parts	Integrated Circuits (ICs)
Fabricated metal enclosures	Mounting Brackets	Resistors
Labels	Heatsinks	Capacitors
Packaging	Plastic chassis, bezels, plastics in fans	Inductors
Label ink, paints, dyes, pigments	Plastic knobs, buttons and handles	Semiconductors
Heat shrink tubing, electrical tape, plastic tape	Gaskets, rubbers	Diodes / Mosfets
	Cable assemblies, cords, wires	Printed Circuit Boards (PCBs)
	Speakers	Batteries
	Complete, finished goods devices such as PCs, etc.	Solder
		Power Supplies *
		Completed Sub-Assemblies (PCBAs) *

(Sample part ranking table example provided. Courtesy: RTF Compliance Corp)

Figure 1

Partnering with a compliance data collection provider can help assist in defining these metrics. A data collection provider would maintain and should be able to provide a historical record of data received from suppliers, so categorizing the parts and materials would not be an issue.

Regarding how to determine the trustworthiness of suppliers, the manufacturer may apply their own judgement. However, the EN 50581 standard does offer some suggestions on metrics that might be used for this purpose:

1. Historical experience with the supplier organization
2. Results of previous inspections or audits

While these sound great in theory, very few companies have documented, quantified data on historical experiences with suppliers. And, what exactly do we mean by “experience?” Additionally, most companies do not have the budget to audit their supply chain, with suppliers possibly numbering in the hundreds. So, “evaluating supplier trustworthiness” only sounds easy until you try and make it happen.

The key to this effort is reasonable due diligence. There is a reason the standard is vague about how this is done; it will be slightly different for each company, based on their products and supply chain. A couple key metrics that are often used in this capacity are:

1. How quickly does the supplier respond to requests for compliance data? A company which is aware of the regulations and has the data you requested ready for you may be more reliable than a supplier who takes three months to figure out your request and compile the data.
2. What percentage of data provided by the supplier failed validation and had to be sent back to the supplier for corrections?

However, this information is not always readily available. In some cases, this data won’t exist until the process is put in place and supplier requests start going out. Partnering with an established data collection supplier is one way to obtain the data you need to fulfill your due diligence requirements and quickly launch a new internal validation program. In Figures 2 and 3 below, one industry partner provided historical data and supplier risk analysis details at the beginning of a collection project. Regular updates of supplier response times and data validation cycles also provide real time metrics which can be easily fed into the “supplier trustworthiness” portion of any internal validation process. It is important to know that this kind of already-existing industry data is available when deploying a compliant validation process.

Number of parts	% by Total PMA	
428	52%	
26	3%	A: Suppliers that provide feedback within 15 days
141	17%	B: Suppliers that provide feedback within 30 days
116	14%	C: Suppliers that provide feedbacks within 60 days
79	10%	D: Suppliers that provide feedback in more than 60 days

Figure 2

Data Collection Status		
First Contact Date	No of times in Contact since Escalation Reset	Last Contact Date
2013-03-19	23	2014-03-24
2013-03-28	16	2014-03-20
2013-06-05	13	2014-02-17

Figure 3

An EN50581 Compliant Process: Step 2 – Collection of the Information

At this point the process is defined. Parts and materials are categorized according to risk of containing restricted substances. Suppliers are ranked according to trustworthiness. We have defined what information we need to collect based on our risk evaluations. Now, as required by **EN 50581:2012 clause 4.3.3**, it is time to collect the data.

The type of documentation being collected will vary depending on the assigned risk of the component containing restricted substances, the assigned supplier trustworthiness, your position in the supply chain, as well as your customer requirements. The various types of documents that should be compiled in this effort include some or all of the following:

1. Supplier declarations and contractual agreements, such as:
 - a. Supplier RoHS-2 Certificate of Compliance – a declaration which confirms the restricted substance content of the material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied. This document should be signed by an authorized representative of the supplier.
 - b. Supplier Proof of Compliance – Documents such as data sheets, technical specification declarations, and material data safety sheets which may provide some level of compliance validation and/or substance content. These types of documents are usually viewed as inadequate for compliance confirmation by themselves, but are sometimes combined with material declarations or test reports as part of an overall part validation documentation package.
 - c. Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.
2. Material Declarations:
 - a. Partial Declarations (not preferred): These are material declarations that list the amounts and worst-case concentrations of all restricted materials. The declaration must also identify exemptions used.
 - b. Full Material Declaration (FMD) (preferred): These are material declarations which disclosed all materials and substances present in the material, part, or sub-assembly. A valid FMD will provide the overall mass of the part or material, as well as a list of homogeneous materials and a list of substances in those materials.

The total mass of all disclosed substances must equal the disclosed mass of the part or material to which the FMD is reporting on.

- c. Industry standard reporting methods: To facilitate the transfer of information throughout the supply chain, the industry has developed several standards. The most common is the PDF-based IPC 1752-2 form, which is now obsolete. Many suppliers have transitioned to the latest data exchange XML-only based IPC 1752A, which allows for XML data transfer of material content data in both partial and FMD formats. EN 62474 is another global standard supporting this type of data exchange. However, with the exception of the obsolete IPC 1752-2 standard, these are machine readable XML data files, and users will need a software tool to review the data provided in these formats. Many such software tools exist and are readily available today.

3. Analytical Test Reports:

- a. In some cases, analytical test reports may be provided by suppliers. This is sometimes the case with suppliers who provide raw materials, or components based on simple raw materials. Supply chains with variable raw material sourcing may also need to provide periodic updated test results. Additionally, suppliers deemed untrustworthy may be asked to provide test data as an elevated validation step.
- b. Any analytical test reports collected from suppliers in support of RoHS compliance validation should reference the methods described and referenced in the EN 62321-x family of standards.

While the collection process may seem like the simplest step here, in truth it is quite the opposite. Finding a person within a supplier's organization who can provide the needed information is difficult, and working with suppliers who provided inadequate data is even more difficult. The constant communication needs of such a robust data exchange process can require significant time and resources. This is why many companies choose to partner with data collection and validation providers. These providers collect, validate, and reformat data from thousands of suppliers every month. In most cases, outsourcing the collection and validation effort to an industry partner provides a lower overall cost, shorter lead times, and a higher completion rate than efforts to perform the function internally.

An EN50581 Compliant Process: Step 3 – Evaluation of Information

Our process is defined and the parts and materials are categorized according to risk of containing restricted substances. The suppliers are ranked according to trustworthiness and we have defined what information we need to collect based on our risk evaluations, and collected the required data. Per **EN 50581:2012, Clause 4.3.4**, we now need to evaluate the data we collected. The standard tells us that the manufacturer must establish procedures that shall be used to evaluate the documents in order to determine their quality and trustworthiness. The expectation is that the supplier shall evaluate the content of the documents using their established procedures, along with the pre-determined part and supplier ranking, to determine if the material, part, or subassembly meets the specified substance restrictions.

If the documentation is considered to be of sufficient quality and trustworthiness, then it shall be included in the technical documentation. If not, then the manufacturer shall determine what action is needed. This may include:

- 1. Requesting additional or corrected information from the supplier
- 2. Undertaking a separate substance analysis (testing) of the part
- 3. Finding a new supplier who can meet the substance restriction reporting requirements.

This evaluation requires a certain level of subject matter expertise. This review should be performed by a group or individual with knowledge in the subject matter of RoHS compliance and substance reporting methodologies. Individuals with a working knowledge of inorganic and organic chemistry offer a huge plus in evaluating data. This need for expertise in this function, coupled with the large amount of data that may need to be processed, has placed a heavy burden on some companies. However, if the manpower or expertise is not available within the organization, there is always the option to partner with a data collection and validation company, or contract the services of an external consultant with expertise in the subject matter.

An EN50581 Compliant Process: Step 4 – Technical Documentation

Once the data has been collected and validated it must be included in the technical documentation for the product under validation. But what exactly does this mean? Taking a look at **Module A of Annex II to Decision No. 768/2008/EC**, we can see the following requirements defined:

“The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

- 1. A general description of the product*
- 2. Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.*
- 3. Descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product*
- 4. A list of the harmonized standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonized standards have not been applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied*
- 5. Results of design calculations made, examinations carried out, etc.*
- 6. Test reports*

This package is commonly referred to as a TCF, or “Technical Compliance File”. Because the EMC and Low Voltage directives have also been recast as part of the New Legislative Framework, many companies combine the technical documents from those directives into the same TCF as RoHS-2 documentation, as shown in the example in Figures 4 and 5. Please note the example provided is just that - an example. There is no pre-determined format for a technical compliance file.

While all of these elements are required as part of the technical documentation, they are not required to be in one place. For example, RoHS-2 data may be present in a substance tracking database, while the product drawings are present in a PLM database. A physical technical compliance file is not required, and no specific format for such a file is expected. However, all elements should be available if requested by the relevant authorities.

CE-MARK TECHNICAL COMPLIANCE FILE






	Prepared for:	John Doe			
		Anycompany			
	Prepared by:	AnyCompany Quality Group			
		1234 Main Street, USA			
	Name:	Jane Smith	Title:	QA Engineer	
	2/15/2016	Email:	J.smith@notreal.com	Phone:	123-456-7890
PRODUCT INFORMATION					
Product Name:	Ethernet Adapter				
Product Model:	Model01	Assembly No.:	123-123		
Product Description:	Ethernet Adapter – PCI express				
Product Information Documents:	Bill of Materials	Data/Spec Sheet	Assy. Drawing	Photos of Product	
	 Adobe Acrobat Document	 Adobe Acrobat Document	 Adobe Acrobat Document	 Adobe Acrobat Document	
EUROPEAN DIRECTIVES / NOTICES SUPPORTED BY THIS TECHNICAL COMPLIANCE FILE					
Directive / Notice		Description			
2011/65/EU		DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Recast)			
768/2008/EC		DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC			
2014/35/EU		DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (recast)			
2014/30/EU		DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (recast)			
EU HARMONIZED STANDARDS USED TO EVALUATE PRODUCT CONFORMANCE TO THE ABOVE DIRECTIVES					
Standard	Date	Description			
EN 50581	2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances			
EN 55022	2010	Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement.			
EN 55024	2010	Information technology equipment. Immunity characteristics. Limits and methods of measurement			
EN 60950-1	2006 +A11 +A1 +A12+A2	Information technology equipment. Safety. General requirements			
EN 60825-1	2007	Safety of laser products. Equipment classification and requirements			

Figure 4












DOCUMENTS AND TEST REPORTS DEMONSTRATING CONFORMANCE TO THE ABOVE STANDARDS				
DIRECTIVE / STANDARD	SUPPLIER REPORTS & DECLARATIONS	ONGOING FACTORY TEST DATA	RoHS CERT OF CONFORMANCE	MATERIAL DECLARATION
2011/65/EU 768/2008/EC	 Supplier Docs.zip	 Rohs Data_Updated on May 17'13.xls	 Adobe Acrobat Document	 Adobe Acrobat Document
	SUPPLIER RANKING & EVALUATIONS	CE DECLARATION OF CONFORMITY	(Other)	(Other)
	 Supplier Risk Assessment.xls	 Adobe Acrobat Document	N/A	N/A
2014/35/EU	EN 60950-1 Certificates	EN/IEC 60590-1 Test Report(s)	EN 60825-1 Certificates	(Other)
	 Adobe Acrobat Document	 Adobe Acrobat Document	 Adobe Acrobat Document	N/A
2014/30/EU	EN55022 Test Report(s)	EN 55024 Test Report(s)	(Other)	(Other)
	 Adobe Acrobat Document	 Adobe Acrobat Document	N/A	N/A
ADDITIONAL INFORMATION				
AnyCompany, Inc. has in place processes to ensure conformance with the relevant requirements of the referenced standards and directives as part of a certified ISO 9001 quality management system. All relevant procedures, quality control records, and relevant documents are available for review upon request.				
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AnyCompany gathered the information in this declaration using appropriate methods to ensure its accuracy and such information is true and correct to the best of its knowledge and belief. AnyCompany acknowledges that OEM customers may rely on this technical compliance file in determining the compliance of products with European Union member state laws that implement the referenced directives. AnyCompany may have relied on information provided by others in compiling this information, and Anycompany may not have independently verified such information. If Anycompany and the OEM customer have entered into a written agreement with respect to the identified model(s), the terms and conditions of that agreement, including any warranty rights and/or remedies provided as part of that agreement, are the sole and exclusive source of the EAnyCompany's liability and the OEM customer's remedies for issues that arise regarding information AnyCompany provides in this technical compliance file.				

Figure 5

Additionally, EN 50581:2012, Clause 4.3.5 specifically calls on the manufacturer to:

1. Perform a periodic review of the documents contained in the technical documentation to ensure that they are still valid. This means regularly updating your supplier data to ensure nothing has changed. Such a process should be incorporated, regardless if this is done using internal resources, or if a data maintenance service is employed to manage the ongoing data validation and refreshing.
2. Ensure that the technical documentation reflects any changes to materials, parts, or subassemblies. In other words, if you qualify a new alternate resistor to be used for your product, or change to a new plastic name plate, you need to update your compliance documentation accordingly.

3. Ensure that the documentation supports any changes to standards and requirements. For example, if an exemption is expiring soon, and you are not reviewing your technical documentation to ensure that this is not impacting the compliance status of your product, you are not fulfilling your due diligence obligations. Partnering with a data collection and validation partner can provide a way to quickly and easily track legislative changes and its impact to previously collected data.

CE Marking and Declaration of Conformity

Once all required directives have been adequately applied and compliance has been validated per the standards, the CE marking can now be applied to the product. Please note that no additional RoHS compliance markings are specified – only the CE mark can be used to officially declare compliance to any CE marking directives. Any additional RoHS compliance markings are considered un-official. Most companies are familiar with the CE marking and the requirements for its application. Many resources exist on the internet detailing such requirements, so those are not detailed in this paper.

In addition to the CE marking, the manufacturer of a CE-marked product is required to draft and make available an EU Declaration of Conformity. Most companies are familiar with this concept, and like the CE Marking details, there are many resources available to assist in drafting such a document. However, it should be noted that the following specific wording is now required to be present on the DoC:

“The object of this declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment”

An example of a standard Declaration of Conformity is shown below in **Figure 6**.


DECLARATION OF CONFORMITY	
Manufacturer:	AnyComany, Inc. 1234 Main Street Anytown, Anystate 12345 USA
declares under sole responsibility that the product:	
Product Name:	Ethernet Adapter
Model:	Model01
Assembly Number:	1234-1234
To which this Declaration relates is in conformity with the following standards or other documents for Information Technology Equipment (ITE):	
<u>Product Safety:</u>	<u>Electromagnetic Compatibility (Class A):</u>
EN 60950-1:2006 +A11 +A1 +A12 +A2	EN55022:2010 / CISPR 22:2008
	EN55024:2010 / CISPR 24:2010
	EN61000-3-2:2006+A1+A2
	EN61000-3-3:2008
<u>Hazardous Substances:</u>	<div style="border: 2px solid red; padding: 5px; color: red; text-align: center;"> Wording required to be added to CE DoC per Annex IV of RoHS Directive 2011/65/EU </div>
<p><u>The object of this declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment</u>, and has been validated per EN 50581:2012.</p>	
Supplementary Information:	<ol style="list-style-type: none"> 1. The product was tested in a typical configuration. 2. The product is in compliance with the following directives: <ul style="list-style-type: none"> • European Union Low Voltage Directive 2014/35/EU • European Union EMC Directive 2014/30/EU • European Union RoHS Directive 2011/65/EU
March 5, 2015 Anytown, CA	 John Doe President and Chief Executive Officer
European Contact:	AnyCompany, Inc Europe Plaza 123, Fake Corporate Park 2, Someplace, SomeTown, Ireland
	+353 (0)1 655 5555 www.xxxxxxxx.com

Figure 6

REACH SVHC Compliance

The EU REACH law is beyond the scope of this paper. However, although determination of regulated substance concentration for REACH is at the component level, which is very different from homogeneous level determinations, REACH SVHC validation can be accomplished using the processes and approaches described above. Manufacturers are required to evaluate their products for the presence of substances listed on the European Chemical Agency's "Substance of very high concern" (SVHC) candidate list. This list contains over 160 substances, with new substances added to the list twice per year. Keeping up with the growing list presents challenges to manufacturers faced with validating compliance of their products. The ongoing data collection and validation processes described above work well for such an effort, and most companies will build their process to meet the data collection and validation requirements of both the RoHS directive and REACH law. A recent EU Court of Justice ruling that SVHC thresholds should be applied at the component and not product level makes a robust data collection, validation, and management system even more critical than ever.

Conclusions

The recast of the European Union's "Reduction of Hazardous Substances" (RoHS) directive has placed new, more stringent due diligence and documentation requirements on manufacturers and importers of electronic products. To assist manufacturers in understanding the requirements, EN 50581 was published in the EU official journal. Per this standard, manufacturers should be ranking their parts and materials based on risk, their suppliers based on trustworthiness, and executing a data collection and validation process based on such analysis. Companies should be evaluating and communicating with their supply chain on an ongoing basis to ensure continued compliance, while compiling all the necessary documentation. Documentation should be reviewed and updated on a regular basis. While some companies choose to deploy a large staff to handle the significant workload associated with meeting these requirements, many have chosen to reduce costs and risks by partnering with data collection and validation providers. Any company looking at creating an internal RoHS compliance validation process in support of CE Marking might consider incorporating the capabilities of an outside data collection and validation provider.

General References/ Resources

Below is a list of online resources that may provide additional information:

EU RoHS Directive 2011/65/EU:

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/restriction-of-hazardous-substances/index_en.htm

EU Commission Decision 768/2008/EC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF>

IPC 175x Standards:

<http://www.ipc.org/ContentPage.aspx?pageid=Materials-Declaration>

Purchase EN 50581:2012 from BSI:

<http://shop.bsigroup.com/ProductDetail/?pid=000000000030261478>

How to place the CE Mark on your product:

<http://ec.europa.eu/enterprise/faq/ce-mark.htm>

New Legislative Framework:

http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

REACH SVHC Candidate List:

<http://echa.europa.eu/web/guest/candidate-list-table>