

A review of data collection methods in product compliance

FMD vs. absence declaration

White Paper

This paper examines two approaches used to determine if there are restricted or controlled substances in components purchased from suppliers: full material declaration and absence declaration. The advantages and disadvantages of each are discussed in the context of data collection for regulatory compliance.

www.siemens.com/plm

Contents

Executive summary	3
Introduction	4
Absence declaration	5
Advantages of absence declaration	6
Disadvantages of absence declaration	6
Full material declaration	7
Advantages of FMD	7
Disadvantages of FMD	7
Summary	8
About WSP	8

Executive summary

One of the biggest challenges of a manufacturer's product compliance team is to determine if there are restricted or controlled substances in components purchased from suppliers. There are two major schools of thought when it comes to obtaining material declarations from component suppliers. One is to get a full material declaration (FMD): require the supplier to disclose the entire breakdown of the component. The other is to get an absence or negative declaration:

give the supplier a list of substances and require a declaration if any of these substances exist in the component. The objective of this paper is to examine these two methods in the context of data collection for RoHS¹, REACH², and Conflict Minerals³ and provide a few ideas that companies can employ to make the process a bit easier.



1. RoHS – Restriction of Hazardous Substances in Electrical and Electronic Equipment
http://ec.europa.eu/environment/waste/rohs_eee/events_rohs3_en.htm
2. REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm
3. Section 1502 of the Dodd-Frank Act
<http://www.sec.gov/News/Article/Detail/Article/1365171562058>

Introduction

There are a number of substance compliance regulations and directives that target the use of specific substances in manufactured products. Environmental compliance regulations such as the RoHS and REACH directives from the European Union (EU) restrict the use of substances that are known to pose a hazard to humans. Social compliance regulations such as the conflict mineral law of the United States (formally known as Section 1502 of the Dodd–Frank Wall Street Reform and Consumer Protection Act) are an attempt to uncover the origin of certain substances and discourage sourcing resources from unscrupulous mines.

To put a product for sale on the market, manufacturers must first conduct a thorough review of the prevailing regulations to determine their applicability to the product and the compliance requirements. The next step is to define a compliance policy (that is, what will and will not be allowed) and communicate it to the supply chain. Finally, manufacturers must tackle the large task of determining whether their supplier's components are compliant.

Most suppliers are not materials experts. They excel in building a quality component to specification at the best cost, in a timely manner. As part of their design process, suppliers will specify the performance properties (e.g. color, strength, stiffness) and source materials from a materials provider. Sometimes these materials providers willingly provide a materials safety data sheet (MSDS) that gives guidance concerning how to safely handle materials. But more often than not, the supplier will have to request a detailed material breakdown; if they can't obtain one, they must send the component or a material sample to a laboratory to be evaluated. The lab report is a resource that the supplier can use to create a material declaration to deliver to the manufacturer. The electrical and electronics industry has converged on standard formats for component and product material declarations in an effort to make it easier for everyone to understand the substance breakdown.

Absence declaration

Absence or negative declaration is the method of requiring a supplier to declare if they use a substance of concern. One of the best examples of this is Directive 2002/95/EC (RoHS) of the European Union (EU) commonly known as the RoHS directive. This regulation targets the use of six substances in the manufacture of various types of electronic and electrical equipment:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent chromium (Cr6+)
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ether (PBDE)

It seems a simple task to provide this list (or a list of substance and/or material categories) to a supplier and ask explicitly whether the component being supplied uses a particular substance on this list. This typically takes the form of

a Declaration of Compliance (DoC) or Certificate of Compliance (CoC) with Yes/No answers. The IPC-1752-2 standard was an attempt by the electronics industry to create a set of common questions that all suppliers could use to declare how a particular component complied against the RoHS directive (this standard has been superseded by the IPC-1752A standard). However, a DoC may not enable a company to easily take advantage of exemptions to these rules, which also requires adherence to an allowable threshold.

Another form of absence declaration is to send the supplier a checklist of substances along with a means for them to state if each substance used is above or below a threshold, and if there is an applicable exemption. The downside is that substances exist as compounds in combination with other substances, and a list of compounds such as the six from the RoHS directive can quickly balloon into more than 200 unique entities. Such a large list presents a daunting task for the supplier to sift through, searching for the handful of substances that may apply to their components.

1 - Item(s) does not contain RoHS restricted substances per the definition above
2 - Item(s) contains RoHS restricted substances above the limits per the definition and is not under exemption
3 - Item(s) does not contain RoHS restricted substances per the definition above except for lead in solders and selected exemptions, if any
4 - Item(s) does not contain RoHS restricted substances per the definition above except for selected exemptions
5 - Item(s) is obsolete, no information is available
6 - Item(s) is unknown, no information is available

Figure 1: RoHS Declaration from the IPC-1752-2 v1.1 pdf form.

Y/N	Substance Category	CAS #	PPM	Exemption Number	Expiration Date
	((4-((4-(ANILINO)PHENYL)(4-(PHENYLIMINO)-2,5-	1324-76-1			
	((BUTOXYMETHYLETHOXY)METHYLETHOXY)PROPAN-1-OL	55934-93-5			
	(TETRAHYDROFURFURYL(R)-2-[4-[6-CHLOROQUINOXALIN-2-	119738-06-6			
	(1-METHYL-4-(1-METHYLVINYL)CYCLOHEXENE	7705-14-8			
	(-)-EPHEDRINE	299-42-3			
	(-)-3-((5-((2,4-DIHYDROXY-5-((2-HYDROXY-3-NITRO-5-	85392-59-2			
	(+)-TARTARIC ACID	87-69-4			
	(+)-TARTARIC ACID	133-37-9			
	(1)-1,5-DIMETHYL-1-VINYLBUT-4-ENYL ACETATE	115-95-7			
	(1)-3,7-DIMETHYL-1,6-OCTADIEN-3-OL	78-70-6			
	(1)-3,7-DIMETHYLOCT-6-ENYL ACETATE	150-84-5			
	(1,1,3,3-TETRAMETHYLBUTYL)PHENOL	27193-28-8			
	(1,1'-BIPHENYL)-2,2'-DISULFONIC ACID, 4,4'-BIS((2-HYDROXY-1-	10169-02-5			
	(1,1'-Biphenyl)-4,4'-diol	92-88-6			
	(1,1'-BIPHENYL)-4,4'-DIOL POLYMER WITH 1,1'-SULFONYLBIS(4-	25608-64-4			
	(1,1'-BIPHENYL)-4-CARBONITRILE, 4'-PENTYL-	40817-08-1			
	(1,1'-Biphenyl)-4-ol, 3,4',5'-tris(1,1-dimethylethyl)-	6257-39-2			
	(1,1'-Biphenyl)-4-ol, 3,5-bis(1,1-dimethylethyl)-	2668-47-5			
	(1,2-DIBROMOETHYL)-1,2-DIBROMOCYCLOHEXANE	3322-93-8			
	(1,3-DIHYDRO-5,6-BIS((2-HYDROXY-1-	42844-93-9			
	(3ALPHA,2ALPHA,3ALPHA,4BETA,5ALPHA,6BETA)-1,2,3,4,5,6-	319-86-8			
	(3ALPHA,2BETA,3ALPHA,4BETA,5ALPHA,6BETA)-1,2,3,4,5,6-	319-85-7			
	(3ALPHA,4ALPHA,4ABETA,5BETA,8BETA&8BETA)-1,2,3,4,10,10-	465-73-6			
	(1E,5E,9Z)-CYCLODODECA-1,5,9-TRIENE	706-31-0			
	(1-METHYL-1,2-ETHANEDIYL)BIS(OXY[METHYL-2,1-ETHANEDIYL])	42978-66-5			
	(1-METHYLDODECYL)-BENZENE	4534-53-6			

Figure 2: A sample absence declaration checklist.

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

Advantages of absence declaration

- **Possibly quicker supplier response than FMD**
Some substances are clearly not present in a product so the supplier can easily respond to a Yes/No inquiry.
- **Responsibility is on the supplier to determine compliance of the component**
The burden of responsibility is on the supplier to determine if the component is compliant or not. This may be seen by manufacturers as an advantage, but the compliance status of the component does not always determine the compliance status of the final product.
- **It may be cheaper for the supplier than doing an FMD**
Many substances are obviously present or not applicable to certain components (and industries) and therefore do not require a lab evaluation or deep investigation. Therefore the length of time to complete and return a DoC may be significantly shorter than that of an FMD.

Disadvantages of absence declaration

- **Frequent supplier contact when regulation changes**
If the supplier is required to review and respond to a specific list of substances, then each time a substance is added to a list the supplier must review it and resubmit it. For example, the REACH regulation is updated with five or more substances every six months, requiring another response from every supplier.
- **May be more costly to a manufacturer**
When a regulation changes, the supplier may be unaware of the presence of the new substances in a component and be slow to respond, prompting the manufacturer to send it to a lab for evaluation.
- **Less visibility of restricted substance risk**
Because the supplier only indicates which substances are not in the component, the manufacturer cannot proactively anticipate how an upcoming addition to a regulation will affect the product.

- **Difficult to roll up risk across a product structure**
Some regulations enable the presence of a restricted substance below a certain threshold. A Yes/No DoC may not enable a manufacturer to use a substance that is restricted because the total quantity in the final product is unknown.
- **Less visibility into exemptions**
Exemptions are typically driven by thresholds and a Yes/No DoC may not enable a manufacturer to use a substance that is restricted because the total quantity in the final product is unknown.
- **More costly and time consuming for suppliers**
Manufacturers may have their own lists of restricted substances (and exemptions) and a supplier may get bogged down responding to several different checklists from each manufacturer to which they sell components.
- **Choose answer "D"**
When faced with an unpleasant task such as a reading through a checklist, people quickly choose the most convenient answer (which may not be the correct one) just to get the job done.
- **Selling into a new market**
Because absence declarations are a snapshot in time against a specific set of requirements, entering a new market requires resending declarations to all suppliers to review their previous responses against a new or different set of substance criteria.

Full material declaration

Another popular data collection method is to request full material disclosure (FMD) from suppliers. In this process a manufacturer requests that the supplier report the name and mass of all the substances and materials in a component. The supplier can also report if any exemptions to known regulations are applicable, but generally the FMD is regulation-agnostic. There are several industry standard formats for FMD, but typically they can all easily be completed by a supplier using a lab report as reference.

With the FMD the manufacturer has the responsibility to search through the list for restricted substances. Typically a software tool is used for this purpose because it can quickly aggregate the component substances across a product's structure, roll up masses, and determine compliance against one or many regulations.

Advantages of FMD

- **Less supplier fatigue**
The FMD is typically regulation-agnostic and therefore can be shared with all of a supplier's clients. It is generally only necessary to be completed once per component unless there is a change to the material.
- **Faster response to changing regulations**
As regulations change, the manufacturer can re-query the product structure to determine whether a product is still in compliance without having to re-contact suppliers. Suppliers have the responsibility to notify the manufacturer if the material composition of a component changes.
- **Thresholds**
Some regulations have thresholds based on the total amount of a substance in a product. With FMD a manufacturer can roll up the total amount of a substance across the product structure and determine if they can continue using it as long as the threshold has not been exceeded.
- **Proactive product compliance**
Manufacturers have good visibility into the material and substance makeup of their products. They can anticipate the event that a particular substance may be restricted in the future and make plans to phase it out of their supply chain ahead of the regulation. This data is also valuable for other corporate sustainability initiatives.

Disadvantages of FMD

- **Requires leverage over suppliers**
In order to make FMD work, the manufacturer must be in a position to source from another supplier if one refuses to cooperate. In most cases the supplier will agree to divulge this information because if the manufacturer can't sell a product, the supplier loses business.
- **The responsibility is on the manufacturer to determine compliance**
The manufacturer receives a list of substances for every component in the product and has to aggregate them and roll up their quantity to determine compliance. There are many commercially available software tools on the market that do this very well.
- **Supplier resistance to divulge propriety information**
Typically suppliers are reluctant to divulge the ingredients of their components out of fear of losing competitive advantage, but in today's market "no information" frequently means "no market" as entities such as the EU enforce stricter rules on the disclosure and use of hazardous substances. Non-compete and non-disclosure agreements between manufacturers and suppliers help to preserve the confidentiality and integrity of the business relationship.

Summary

Product environmental compliance is a fact of life for today's manufacturers and suppliers. It is a necessary cost of doing business because more governments are taking a firmer stance at protecting their populace from hazardous materials and substances. It is the duty of manufacturers to understand the regulations that are applicable to their products, to develop a plan and process to ensure their products are compliant, and to communicate this policy to their supply chain. As part of this process a decision must be made on how data will be received and analyzed for compliance. Both methods we have discussed have advantages and disadvantages which must be carefully considered and adapted for a manufacturer's particular business processes.

From our professional experience we highly recommend implementation of a well-planned FMD process from the very beginning. Starting with absence declaration and switching later to FMD pits a manufacturer against formidable internal and external inertia which can cost more than starting with FMD. Most companies that have started with absence declaration have gradually moved to FMD. We know of no cases where the reverse is true. And more "good" data is a valuable commodity. If your objectives are simply to check the box on compliance, then absence declaration will suffice. If you anticipate growing to support broader sustainability initiatives, then FMD is the best start.

Additionally, many manufacturers choose to use an FMD process that is integrated with a product lifecycle management (PLM) solution and create a product sustainability framework in order to realize even greater benefits. With PLM technology companies can:

1. Automate the communication process with suppliers to request, receive, and analyze the FMDs of sourced components
2. Automate the process of aggregating supplier data into an engineering BOM, rolling up quantities of substances across a product structure, and identifying areas of concern
3. Get a holistic picture of compliance by "grading" the complete product structure with internal and external (component) material and substance data
4. Archive supplier information and track useful metrics (or build scorecards) on suppliers and their communication history
5. Leverage core PLM capabilities (for example, requirements management, workflow and notification process, BOM management, document management, visual reporting) as part of a comprehensive product compliance process.

Our next white paper will explore the value of an integrated PLM & FMD process in greater depth.

In conclusion, regardless of the method a manufacturer chooses, it is important to:

- Clearly communicate the substance compliance policy and material declaration process to suppliers
- Build the substance compliance policy requirements into supplier contracts
- Train the suppliers on how to complete and return the material declaration document
- Remain vigilant for changes to existing regulations and the effect it will have on the supply chain
- Evaluate and chose the right commercial software to support your product compliance initiatives

Siemens PLM Software

Headquarters

Granite Park One
5800 Granite Parkway
Suite 600
Plano, TX 75024
USA
+1 972 987 3000

Americas

Granite Park One
5800 Granite Parkway
Suite 600
Plano, TX 75024
USA
+1 314 264 8499

Europe

Stephenson House
Sir William Siemens Square
Frimley, Camberley
Surrey, GU16 8QD
+44 (0) 1276 413200

Asia-Pacific

Suites 4301-4302, 43/F
AIA Kowloon Tower, Landmark East
100 How Ming Street
Kwun Tong, Kowloon
Hong Kong
+852 2230 3308

www.siemens.com/plm

© 2015 Siemens Product Lifecycle Management Software Inc. Siemens and the Siemens logo are registered trademarks of Siemens AG. D-Cubed, Femap, Fibersim, Geolus, GO PLM, I-deas, JT, NX, Parasolid, Solid Edge, Syncrofit, Teamcenter and Tecnomatix are trademarks or registered trademarks of Siemens Product Lifecycle Management Software Inc. or its subsidiaries in the United States and in other countries. All other logos, trademarks, registered trademarks or service marks belong to their respective holders.

45625-Y8 5/15 H

About Siemens PLM Software

Siemens PLM Software, a business unit of the Siemens Digital Factory Division, is a leading global provider of product lifecycle management (PLM) and manufacturing operations management (MOM) software, systems and services with over nine million licensed seats and more than 77,000 customers worldwide. Headquartered in Plano, Texas, Siemens PLM Software works collaboratively with its customers to provide industry software solutions that help companies everywhere achieve a sustainable competitive advantage by making real the innovations that matter. For more information on Siemens PLM Software products and services, visit www.siemens.com/plm.

“A review of data collection methods in product compliance” was authored by Tord Dennis, Practice Leader, WSP.

Tord Dennis is a Practice Leader in WSP's Integrated Product Compliance Management practice. Based in Los Angeles, CA, Mr. Dennis has over twenty years of technical and marketing experience for multinational entities in North America, with projects related to product development, supply chain management, and business collaboration; governance, risk management and compliance; and process analysis, re-engineering, improvement and documentation. Previously, Mr. Dennis worked as a product manager at Siemens, where he built and managed strategy for embedding environmental compliance into the PLM process and integrated new solutions into the software portfolio. Mr. Dennis holds an MBA and an M.S. in mechanical engineering from the Georgia Institute of Technology in Atlanta, GA.

About WSP

WSP and Parsons Brinckerhoff have combined and are now one of the world's leading professional services consulting firms. Together we provide services to transform the built environment and restore the natural environment, and our expertise ranges from environmental remediation to urban planning, from engineering iconic buildings to designing sustainable transport networks, and from developing the energy sources of the future to enabling new ways of extracting essential resources. We have approximately 32,000 employees, including engineers, technicians, scientists, architects, planners, surveyors, program and construction management professionals, and various environmental experts. We are based in more than 500 offices across 39 countries worldwide.