The Challenges of Collecting Product Compliance Data:

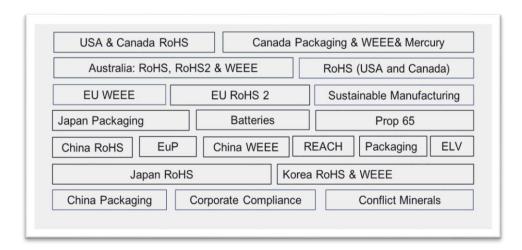## 6 Critical Decisions

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Introduction

Today's material regulations and compliance are focused on the health, wellness, and the safety of humans, animals and the environment.

Product regulations from around the globe are enforcing stricter standards and requirements on companies to manufacture products that fall within the specified allowable tolerances for materials and substances or are sourced from specific countries and regions. In order to meet these requirements, companies must implement efficient and effective compliance programs which include collecting data from all levels of their supply chains.

In order to understand data collection requirements, it is important to study each regulation for material requirements and to get interpretations from a variety of sources.

Internal and external legal counsel, industry working groups, and compliance solution and service providers help fill the knowledge and tools gap, needed to meet compliance.

Below is a sample of the common regulations manufacturing companies are building programs for:

USA & Canada RoHS	Canada Packaging & WEEE& Mercury	
Australia: RoHS, RoHS2 & WEEE	RoHS (USA and Canada)	
EU WEEE	EU RoHS 2	Sustainable Manufacturing
Japan Packaging	Batteries	Prop 65
China RoHS	EuP	China WEEE	REACH	Packaging	ELV
Japan RoHS	Korea RoHS & WEEE	
China Packaging	Corporate Compliance	Conflict Minerals

Materials play an important role throughout the product development lifecycle. Suppliers must be approved and meet compliance conditions before products are released to manufacturing.

In order to prove that all regulation requirements have been met, suppliers need to provide declarations that verify compliance and provide a documented level of material composition. This documentation is the proof for compliance. Each company needs to collect, store, analyze, and report the data.

Risk Analysis

Every company needs to be aware of the potential regulatory risks and requirements of their products.

Regulations may refer to the sourcing of materials and the determination of responsible and ethical sourcing conditions.

Product landscapes continue to change. New global regulations, manufacturer updates, and new markets all demand companies build relevant compliance programs.

Data collection, validations and maintenance need to be implemented at all stages of the compliance process.

Data integrity ensures accuracy of compliance statements.

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Understanding the 6 critical decision points in every compliance program that guide you to success.

There are 6 critical decision points to consider when developing product compliance programs:

1. Product data
2. Processes and standards
3. Software
4. Data collection
5. Handling non-compliance
6. Compliance maintenance

The 6 Decision Points

Let's look at how these 6 critical decision points can affect your compliance status.

Product Data

It is important for companies to have the latest Bill of Materials (BOM) in order to get accurate information on the composition used in manufacturing their products. Determining if a part is considered "off the shelf" or has been developed as a custom part is the first step in deciding where to look for data. Understanding the type of product data needed to meet compliance requirements is a precursor to building efficient and effective data collection programs.

Processes and Standards

Data standards enable a swift exchange of data from one party to another and minimize the need to parse through Word, Excel, or PDF documents looking for compliance data. Standards like IPC-1752 and IEC 62474 enable the process of collecting full material disclosure and enable data to be exchanged between internal and external systems. These standards provide an XML schema or rather a path for data to move between systems easily.

Software

It is necessary to understand how much automation will be needed to quickly process compliance requests and requirements in a timely manner. Determining if your company can manually process and report on the volume of data collected and the required level of complexity is critical.

In the case of regulations like the European Union's RoHS and REACH, and the United States' Dodd-Frank Conflict Minerals regulation, rolling up data to the product level for thousands of products and suppliers is resource-intensive and prone to error.

Understanding your company's IT landscape and security requirements will make it easier to implement the right tools. Consider the cost and speed of the implementation, along with the possibility of purchasing data from a third party in order to speed up the process.

Data collection

Data collection requires a series of decisions that define a go forward plan for how your company will commnuicate with your suppliers and customers. The process of collecting data can be resource-intensive and expensive if alternatives are not considered. Leveraging internal resources can be costly, and internal systems may not be configured to store compliance data. Manual processing of compliance data creates overhead on existing resources and may cause confusion in the supply chain with continual requests. When collecting data, it is also important to consider the duration of collection data and how frequently compliance statements must be updated.

Handling non-compliance

As companies expect that all parts and products will meet compliance requirements often there are exceptions. Non-compliant parts must be managed and a process implemented to work with suppliers to replace or remove the part or product in question. Compliance is mandatory and all suppliers must meet government regulations.

In addition, non-compliance may be the result of a supplier who has not provided data on a part or product. This process requires that outside sources of data are used or new sourcing requirements are implemented.

Compliance maintenance

Compliance is the snapping of a chalk line at any given moment. If a regulation changes, if parts are altered in any way, if new part numbers are assigned, or substitute materials used, all trigger an event to check that compliance is maintained.

Companies need to implement policies, procedures and tools that maintain the latest data on all parts and products they buy and sell. This ensures that at any given moment, all products are in compliance with regulations.

Data Collection Standards

Current compliance practices include *Full Material Disclosure* (FMD) whenever possible. This means collecting product data at the material composition level from suppliers.

FMD provides comprehensive data about product chemical compositions. This enables the data collected to be used for all product compliance regulations and minimizes the number of times needed to request information from suppliers.

Collecting FMD lowers the overall cost of data and manages the overall risk to companies by easing handling of new regulations and changes.

When FMD is not available, supplier declaration based data or *Certificates of Compliance* (CoCs) can be collected to provide a due diligence trail to authorities.
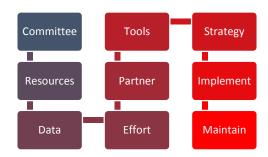
Over a 24 month period, FMD is 50% more cost-effective than CoCs.

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Solutions

Getting started with data collection is simple if you implement basic processes, standards, and tools.

Start by setting up a compliance committee which includes members from Engineering, Quality, Supply Chain, Purchasing, Manufacturing, Legal, and Compliance. Meeting product compliance requirements will require input from teams across the organization.

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Committee    Tools      Strategy

Resources    Partner    Implement

Data         Effort     Maintain
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Next, assess the internal resources available to you. Determine the number of people needed for the tasks associated, the knowledge that is required from each discipline, the systems and methods for data collection to be used, and the budget required to implement compliance.

Plan out how your company will leverage automation to get compliance answers quickly. Use software to rapidly determine if your products meet global regulations.

When evaluating software keep in mind that tools must provide visibility to the *Bill of Material* (BOM), provide visibility to the substances and materials contained in the product, and have comprehensive knowledge of global product compliance requirements.

Determine the level of data you will collect, declarations or full material disclosure. It is better to find tools that enable your company to collect full material disclosure in order to meet ever changing regulations in a timely manner.

Collecting data can be expensive. Evaluate data collection solution providers that minimize the overall cost of collecting data and speed up the process, e.g. by automation or data collection services. Leverage part databases that already contain thousands of declarations. This minimizes the need to contact every supplier for compliance data.

Build an audit trail that can demonstrate to customers, government, and state agencies that your products meet all applicable product regulations and demonstrate due diligence with a documented process.

Finally, having compliant products requires continual updates and maintenance. It requires keeping up with global regulations, finding the most accurate data, and being able to report to customers and authorities. Make sure to build in a maintenance plan to assure your company's compliance performance and data accuracy.

Manufacturers must understand and control the material content in their products. They must ask, "is my product safe and can I prove it?"

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