

SOURCEINTELLIGENCE

PRODUCT COMPLIANCE FOR INDUSTRIAL MANUFACTURING

A Complete Industry Guide

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TABLE OF CONTENTS

3 Introduction

4 Product Compliance Regulations Related to Industrial Manufacturing

7 Common Challenges of Product Compliance

9 Managing Product Compliance In-House

13 Leveraging Product Compliance Management Software

14 Source Intelligence's Product Compliance Solutions

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INTRODUCTION

Achieving regulatory product compliance in the industrial manufacturing industry requires a deep understanding of the complex regulations and standards that govern the sector. Complicating matters is the sheer volume of regulations, totaling more than 800 worldwide (including REACH, RoHS, and SCIP). Staying current with regulatory obligations, conducting due diligence, and correctly applying documentation are only a few of the many common challenges. Without the proper tools, expertise, or resources, the process is daunting.

Whether a company manages its compliance program in-house or outsources it, the challenges faced across the industry are consistent. Utilizing product compliance best practices can help companies more effectively manage their programs while partnering with a supply chain solution provider streamlines the compliance process and allows companies to focus on their core competencies. Regardless of the approach, finding a solution that helps your business remain compliant and reduce risk is imperative.

In this e-book, we will explore:

- Product compliance regulations related to industrial manufacturing
- Common challenges of product compliance management
- Best practices for managing product compliance in-house
- Levering product compliance software to streamline compliance
- How Source Intelligence's product compliance solutions can help

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1 PRODUCT COMPLIANCE REGULATIONS RELATED TO INDUSTRIAL MANUFACTURING

Achieving regulatory product compliance in the industrial manufacturing industry requires a deep understanding of the complex regulations and standards that govern the sector. The most common regulations companies in the industrial manufacturing space must comply with are REACH, RoHS, PFAS, SCIP, and TSCA.

REACH

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) is a regulatory framework intended to protect human health and the environment from risks posed by exposure to chemical substances. Generally, REACH regulations apply to all chemical substances, including those used in industrial processes, the workplace, and everyday household items. REACH compliance typically requires manufacturers to register and provide detailed information about the chemicals they use in their products, as well as to assess and manage any risks associated with these chemicals.

Several countries across the globe have enacted REACH regulations, including the European Union (EU), the United Kingdom, and China. The primary difference between worldwide REACH regulations is data collection and reporting requirements. By complying with REACH regulations, companies can demonstrate their commitment to product safety and environmental responsibility, while meeting their legal obligations for the markets in which they sell products.

RoHS

The Restriction of Hazardous Substances (RoHS) is another regulatory framework that aims to protect human health and the environment by restricting the use of certain hazardous substances in electrical and electronic equipment. These harmful substances include lead, mercury, cadmium, and certain flame retardants and plasticizers. RoHS requirements typically apply to companies that manufacture or import electrical and electronic equipment. The compliance process involves conducting material testing, implementing control measures, and providing documentation to demonstrate compliance.

Many countries have recognized the value of minimizing hazardous materials in electrical and electronic equipment, and as a result, have implemented their own RoHS regulatory frameworks. Some notable examples include the EU, China, Japan, South Korea, the UAE, Saudia Arabia and India. By adhering to RoHS, manufacturers from these countries contribute to a global effort towards a greener future and demonstrate their commitment to responsible manufacturing practices.

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PFAS

PFAS, or per- and polyfluoroalkyl substances, have become a major concern on a global scale in recent years. These chemicals, commonly found in products like firefighting foam, non-stick cookware, waterproof fabrics, PCB laminates, and semiconductor device manufacturing, have been linked to a range of health issues, including cancer and immune system dysfunction. As a result, governments around the world have been working to implement PFAS compliance measures to limit their use and protect public health.

These regulations vary from country to country, with some nations taking a more proactive approach than others. In the United States (U.S.), for example, the Environmental Protection Agency has established guidelines and standards for PFAS in drinking water and reporting requirements for PFAS manufacturing, importing, and PFAS-containing products. In Europe, the European Chemicals Agency has classified certain types of PFAS as substances of very high concern and is considering restricting PFAS use under the REACH regulation. Companies that manufacture products containing PFAS must be aware of which regulations they must comply with and the associated requirements.

SCIP

EU manufacturers, assemblers, distributors, and importers of products into the EU must adhere to the Substances of Concern in Products (SCIP) database reporting requirements as established by the Waste Framework Directive and the European Chemicals Agency (ECHA). The SCIP database serves as a catalog of potentially harmful substances in products manufactured, distributed, or imported within the EU member states. The database is intended to help waste operators sort and recycle articles containing Substances of Very High Concern (SVHCs) and inform consumers on how to use and dispose of such articles properly.

European Union product manufacturers, assemblers, and distributors, as well as importers of products into the EU, must submit information into the SCIP database if their products contain SVHCs above a 0.1% weight over weight (w/w) threshold at the article level. The candidate list of SVHCs is based on REACH. By complying with SCIP requirements, companies can contribute to the overall reduction of hazardous substances in the environment and promote a more sustainable and responsible approach to product manufacturing.

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TSCA

The U.S. Toxic Substances Control Act (TSCA) is a crucial aspect of ensuring the safety and well-being of both humans and the environment. This federal law, enacted by the U.S. Environmental Protection Agency (EPA), regulates the manufacturing, importing, processing, and distribution of chemicals in the country. The main objective of TSCA compliance is to assess and manage the potential risks posed by chemicals, making sure that they do not harm public health or the environment.

Under TSCA, companies must comply with various reporting and testing requirements, as well as maintain accurate records of the chemicals they produce or import. TSCA has also added some chemical restrictions, for example, certain persistent bioaccumulative toxic substances (PBTs), for products sold in the U.S. TSCA compliance not only protects people from hazardous substances but also encourages innovation in chemical research and development, as it promotes the use of safer alternatives.

With more than 800 product compliance regulations worldwide, understanding and adhering to compliance requirements is crucial for any business. Manufacturers must stay informed about the specific regulatory requirements that apply to their products and markets to effectively fulfill their compliance obligations and reduce risk in their supply chain.

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2 COMMON CHALLENGES OF PRODUCT COMPLIANCE

When it comes to managing product compliance, companies often encounter challenges that can hinder their success in adhering to reporting requirements and reducing risk in their supply chains. Whether a company manages its compliance program in-house or outsources it, these obstacles remain consistent. Our regulatory experts have narrowed the list to four primary challenges companies face.



MAINTAINING CURRENT DATA

Regulations are often updated to reflect scientific and technological advancements. Substances and chemicals are added at the request of member states, non-governmental organizations, and other interested parties, and scopes are narrowed as new alternatives are discovered. It is imperative that companies track the latest versions of any relevant regulations to ensure their product data is current and they aren't exposing themselves to risk; however, keeping up with regulatory changes quickly becomes overwhelming without dedicated resources.

TRACKING UPCOMING NEW REGULATIONS

In addition to staying up to date with the latest versions of regulations, companies must also monitor upcoming new regulations. New regulations and legislation are announced frequently, and companies must be prepared to comply with any new reporting requirements once they take effect. Finding information regarding new regulations or legislation is challenging, as the information is typically published in a variety of locations and often dependent upon the country and responsible government agency.

UNDERSTANDING & CORRECTLY APPLYING DOCUMENTATION

Product compliance documentation is available in a wide range of formats. Accepting documentation in any format a supplier has available is good practice when gathering compliance evidence documentation. However, having the technical expertise to interpret and apply an assortment of evidentiary documents can be burdensome and costly.

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To be efficient with data collection and accurate with evidentiary analysis, a company's compliance team must be able to accept data in any format available, identify and analyze potentially contradictory information, and understand whether collected documentation is sufficient to support a regulatory requirement.

COMBATING SUPPLIER FATIGUE

Supplier fatigue is another common issue that can create challenges when building your compliance database. Language barriers, supplier education, and low response rates are common obstacles companies face, but these obstacles can be overcome by building and sustaining good relationships with suppliers. As suppliers are likely to receive compliance documentation requests from all their customers, certain best practices can help reduce supplier fatigue. This includes seeking documentation online before reaching out to suppliers, accepting data in whatever format a supplier has available, and building a well-organized database for accessing and storing supplier-provided documentation.

Despite these common challenges, product compliance is mandatory. Companies must find a solution that works for their business, as even a minor oversight can have severe consequences, including stopped shipments, hefty fines, and reputational damage.

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3 MANAGING PRODUCT COMPLIANCE IN-HOUSE

Managing product compliance in-house can be daunting, requiring a significant investment of internal resources and regulatory compliance expertise. However, with the right approach and dedication, it is possible to successfully meet your product compliance obligations. Companies must be prepared to allocate the necessary resources to their compliance program and utilize best practices to ensure its success. By taking control of product compliance in-house, companies can comprehensively understand their obligations and maintain a high level of control over the process. This helps companies ensure compliance with applicable regulations, enhances their reputation, and builds trust with customers.

BEST PRACTICES FOR SUCCESSFUL PRODUCT COMPLIANCE MANAGEMENT

The complexities and challenges of managing product compliance in-house can be simplified by following industry best practices. The regulatory experts at Source Intelligence have identified six key best practices that can help companies successfully manage their product compliance programs.

1 Save time by finding documentation online

Being as self-sufficient as possible regarding data collection is an effective way to reduce supplier fatigue, starting with understanding how to find the appropriate documentation online to fulfill your data requests. Compliance documentation is often available on supplier websites, so it's best practice to thoroughly search for the required data online before reaching out to suppliers. Requesting supplier data via phone or email can frustrate and fatigue suppliers when the information is publicly available.

Obtaining compliance information online will vary depending on the supplier. Some suppliers may require creating an account to access the information. Other suppliers may provide part-specific details on their website's product pages or have a specific webpage dedicated to compliance data. If the compliance information is not available on the supplier's website (or the data on the website is insufficient), further research to identify the appropriate contact to request the information is required.

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Reaching out to the most relevant department with information requests helps save time. For example, contacting the supplier via the purchasing or sales department may not be the most effective route. Quality, compliance, and engineering departments are better suited to fulfill the request in a timely manner. Suppliers may also have a specific email address for compliance requests.

2 Accept data in multiple formats



Accepting evidentiary compliance data in any format available greatly reduces the supplier's effort, yielding a higher response rate and lower turnaround time. Some suppliers may have company policies that prohibit them from completing customer-submitted forms, while others may not have adequate internal capabilities to complete custom forms.

Examples of commonly used formats for compliance information include:

- ***Company level declarations*** *– One of the most common forms of compliance information that typically states something like "All products are PFAS free"*
- ***IPC-175x declarations*** *– An industry standard format for providing product compliance information*
- ***Certificates of compliance*** *– Product-level declarations, often provided in PDF format*
- ***Excel spreadsheets*** *– Used to organize information for material declarations*
- ***Test reports*** *– Generated by 3rd party laboratories to show the presence or absence of specific substances*
- ***Material specifications*** *– Standard specifications of grade materials like metals, useful when dealing with metal hardware and fabricated components; metal grades and compositions allow for analyzing the presence of any regulated substances*

3 Compile and organize compliance data



Evidentiary documentation accumulates quickly during a robust compliance effort. Once the necessary compliance information has been collected and analyzed, it should be compiled and organized. To effectively utilize documentation already on file, it is necessary to have a compliance system in place that can house documentation and associate the documentation to specific purchased parts. In some cases, previously provided supplier documentation can be applied to newly procured components if they are similar, or if the previous documentation was provided at the company level. Making use of company documentation and product family declarations decreases the need to request new data from suppliers, which helps avoid fatigue.

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4 Know your products

Knowing your products and any product type-specific requirements is critical to implementing a successful product compliance program. Many product requirements are specific to the type of product, so you must fully understand your products and their uses to ensure that you are meeting all the product compliance requirements.

Understanding all the components and materials used to manufacture your products is also essential. This can be accomplished by developing and maintaining a well-defined Bill of Materials (BOM) for your products. A BOM should include all the components used to make a product, along with any consumables that will remain on the final product, such as solders, adhesives, or other materials used during the manufacturing process that become part of the product.

Another critical aspect of understanding your products is reviewing BOMs for obsolete parts. Given that product compliance requirements are updated anywhere from several times a year to once a year, suppliers typically do not update compliance documentation for obsolete parts. This means that as you continue to use obsolete parts in your products, you will not be able to verify that they meet the most current compliance requirements. Understanding where you are using obsolete parts will help you identify where you may have missing compliance data. If you made a large last-time purchase and need to continue using obsolete parts, you may have to send out a sample for 3rd party testing to keep compliance documentation current.

Finally, accurately tracking all engineering changes (ECs) and drawing reviews (DRs) also helps make managing product compliance much easier. It's beneficial to try and verify the compliance of new product components before introducing them through an engineering change or new part addition.

5 Understand your markets

Once you thoroughly know your products and their requirements for product compliance, the next step is understanding the requirements for each region in which you are placing products on the market. Although product compliance regulations, directives, and laws may be similar in nature, there are usually differences in the requirements from region to region.

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6 Have a data management system



Another critical component to managing product compliance is having a system in place to organize the data. Verifying that your products meet compliance requirements in each market you sell in means gathering, evaluating, and storing substantial amounts of data in various formats. Using a system to collect and store product compliance data will allow you to do the following:

- *Confirm that all documentation can be tied back to your product*
- *Ensure that the gathered documentation can be maintained long-term*
- *Verify that all documentation is current and up to date with regulations*
- *Collect information in a way that allows quick reactions to compliance requirement changes*
- *Organize and roll up your compliance data at the product level for simplified product compliance reporting*

Allocating the necessary resources, utilizing online documentation, accepting data in multiple formats, compiling and organizing compliance data, understanding product requirements and markets, and implementing a data management system are key steps to success. By following these industry best practices, in-house product compliance programs are much more manageable.

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4 LEVERAGING PRODUCT COMPLIANCE MANAGEMENT SOFTWARE



Although managing product compliance in-house may be a feasible solution for some companies, other companies may face several roadblocks that hinder the success of their product compliance programs – even when following best practices. From the complex and ever-changing regulations to a lack of specialized knowledge and resources, companies often find themselves overwhelmed and struggling to keep up. Moreover, the time and effort required to stay updated with the latest regulations and ensure compliance can drain valuable resources that could be better utilized elsewhere.

To navigate these challenges effectively, many companies are partnering with supply chain solution providers that have the expertise and the technology to streamline compliance processes and mitigate risks. By outsourcing compliance management, businesses can focus on their core competencies while ensuring adherence to regulations and safeguarding themselves from supply chain disruptions.

FINDING THE RIGHT SOFTWARE FOR YOUR BUSINESS

Choosing the right product compliance and ESG management partner is crucial for any business. With supply chain compliance not being a one-size-fits-all solution, it can be challenging to find the perfect fit. When speaking to compliance professionals, they all agree that the selection process is tough. That's why investing time and effort into finding the right product compliance software for your company is essential. With so many features to consider, choosing a partner that aligns with your business goals and values is imperative.

We created a buyer's guide to choosing a supply chain compliance partner to help equip companies with essential questions to ask during their decision-making process, including questions related to:

- *Where your company is on its compliance journey*
- *Which type of compliance program will best fit your company's needs*
- *What value potential supply chain compliance partners are offering beyond the basics*

Download the guide to get a head start on vetting providers and finding the right product compliance software for your business.

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5 SOURCE INTELLIGENCE'S PRODUCT COMPLIANCE SOLUTIONS

Source Intelligence offers the largest scope of regulatory program coverage in the industry, including REACH, RoHS, PFAS, SCIP, Prop 65, and more. Our spectrum of solutions facilitates supplier engagement, data analysis, and documentation generation through powerful compliance software with fully managed service options. Regardless of the level of support required, we deliver peace of mind knowing that every part of each product is in line with regulatory standards.

Our Product Compliance solutions will allow your company to:

Reduce internal resource burdens

Streamline due diligence efforts, such as supplier engagement, data collection, and report generation, and refocus internal resources on managing other parts of your business.

Minimize business risk

Easily provide documentation on demand. Your compliance data is housed in a centralized location, so you can efficiently generate reports and declarations to fulfill customer requests.

Gain supply chain visibility

Quickly identify issues with a complete view of your compliance and product data. Our configurable dashboards and BOM rollups display compliance verdicts for every part and component.

Increase risk foresight

Our regulatory experts guide our solution development, ensuring you have the right tools to anticipate changes to your compliance obligations and setting you up for compliance success.

SCHEDULE A DEMO

Take the complexities out of product compliance. Schedule a demo to discover how our software and services can help you achieve your compliance goals.

>> Visit us to get started.

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