IDC Manufacturing Insights

Raising Confidence and Driving Business Value with Product and REACH Compliance

WHITE PAPER

Sponsored by: SAP

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IDC MANUFACTURING INSIGHTS OPINION

This IDC Manufacturing Insights White Paper examines product and REACH compliance and how a comprehensive, IT-supported process goes well beyond regulatory compliance to drive business value through revenue and brand protection, cost savings, process efficiencies, faster product introduction, access to existing and new markets, and competitive advantage.

- Manufacturers often underestimate the risks associated with an ineffective product compliance management system and the limitations such a system places on supply chain continuity, revenue growth, customer service, and margins.
- Manufacturers are looking for ways to prevent and eliminate "compliance gaps," reduce risk, and build confidence in their product quality and safety as they pursue new opportunities.
- As manufacturers seek to operate in a more global marketplace, with increasing supply chain complexity, the number and depth of compliance issues will also continue to grow considerably, and any product compliance management system must be able to adapt to new regulations easily and quickly.
- Product and REACH compliance is the foundation for important strategic objectives such as improving the company's reputation and reducing its environmental footprint.
- It's not enough to merely define a product compliance management process; an IT-based system must be in place to ensure compliance management is consistent, yet flexible and auditable across the company.

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IN THIS WHITE PAPER

This IDC Manufacturing Insights White Paper details the business case for an integrated and comprehensive view of product and REACH compliance processes. We also provide examples of how manufacturers have benefited from product and REACH compliance investments to drive business value. We define how information technology can play an important role in standardizing and automating the product compliance management process, as well as providing an audit trail. We expect that if "done right," these improvements to the compliance process can not only provide time and cost savings but also open doors to new markets, lower risks associated with complex supply chains, protect the reputation of the brand, and create a foundation for environmental sustainability.

SITUATION OVERVIEW

A Complex, Changing Regulatory Environment

Over the past 10 years, manufacturers have faced an increasing number of compliance and product quality challenges, ranging from the introduction of new regulations around the globe to product recalls that result in fines and lost sales in the short term. Less certain but still worth noting are the unquantifiable impacts on a company's reputation and sales over the long term. Regulation and other compliance requirements aren't likely to decrease, and IDC Manufacturing Insights' survey research consistently confirms manufacturers' expectations of more regulations to come.

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A few years ago, an outgoing executive in a U.S. chemical association said that the challenges in the regulatory environment over the past eight years would seem like a "walk in the park" compared with what is coming in the future. Given the increasingly complex global nature of our manufacturers' markets and our supply chains and the increasing interest in our environment and sustainability, we think this statement applies to all types of manufacturers today.

The most common of these regulations include:

- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Restriction of Hazardous Substances Directive (RoHS)
- Waste Electrical and Electronic Equipment Directive (WEEE)

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Similar regulatory initiatives are visible across the globe — for example, China RoHS and Korea RoHS — emphasizing the fact that manufacturers must comply with regulation variations from country to country. And regulations may be stricter within specific regions or even states, such as California, Washington, and Maine.

Regulations also extend beyond the initial product design and product use case scenarios to issues such as package or product recycling and disposal; this widening scope of regulations is forcing manufacturers to document and expose more data about their products and their processes than ever before. On top of the resulting requirements for added visibility and tracking, manufacturers have to be ready to respond to change. Basically, more regulations to come create a moving target for product compliance; manufacturers are in serious need of rigorous compliance processes that can be updated quickly to conform to inevitable regulatory changes.

The Burden of Compliance and the Risks of Noncompliance

Product compliance — or noncompliance — greatly impacts manufacturers, and it's easy to point out instances of compliance gone wrong over the past few years, from tainted pet food and milk to hazardous toys and counterfeit pharmaceutical drugs. This awareness of mistakes is very visible in the results from the 2010 IDC Manufacturing Insights and IDC Retail Insights *Supply Chain Survey*: The most highly rated supply chain initiative across all United States–based manufacturers is "product quality." We attribute these results to the "compliance gaps" so visibly profiled in the media.

Compliance isn't just about product quality though. Among process manufacturers, noncompliance means "no data, no market." In other words, without ready access to accurate and up-to-date compliance data, manufacturers are limiting the markets in which they can sell and even closing themselves out of markets they have served in the past. For a large global chemicals manufacturing company, REACH compliance protects $2 billion in annual revenue — the revenue generated by ensuring its products can be sold into European markets.

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Escalating Requirements; Compliance Gaps; and No Data, No Market

But the burden of compliance is staggering. Before December 1, 2008, BASF submitted 40,000 REACH pre-registrations for several thousand substances. Even smaller manufacturers are facing significant data challenges related to compliance. Consider this example: If a company produces just one substance, but that substance goes into 100 products, and each product has 100 customers, the company potentially could have 10,000 (100 x 100) use cases to document.

REACH very quickly creates an avalanche of data and a data management challenge beginning with knowing what substances must be tracked and continuing through tracking substance volumes and complying with the requirements at various thresholds.

EU regulatory authorities recently released the results of almost 1,600 REACH inspections carried out between May and December 2009, with the following findings:

- 24% failed to comply with the legislation.
- 2.6% had infringements of Article 5 of the REACH regulation, the "no data, no market" provision, meaning products were removed from the market.
- 5.6% had incorrect content in their pre-registrations.
- 11% did not have the required safety data sheets.
- 20% did not have safety data sheets in compliance with the language and format requirements.
- 15% of the safety data sheets needed for the verified products were incorrect.

REACH compliance inspections are continuing through spring 2011 to assess compliance following the first registration deadline of November 30, 2010. Clearly, compliance gaps are a challenge for many, and the impact can be significant. We can easily project the direct impact of noncompliance with REACH's Article 5; infringements could lead to as much as 47 billion euros of lost revenue, based on 2.6% of the chemical industry's 2007 revenue of 1.8 trillion euros (Cefic Chemdata International).

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We define process manufacturers broadly to include segments such as chemicals, pulp and paper, metals, building materials, food and beverage, health and beauty, and footwear and apparel. Obviously, the market and regulatory requirements vary greatly among those segments, but most must create the equivalent of the chemical industry's material safety data sheet, often linking product and substance, composite, or component information. This also means ensuring product compliance for each market, including the market where the product ends up in the hands of the consumer.

Supply Chain Disruption, Lost Sales, Worthless Inventory

For discrete manufacturers, including segments such as aerospace, automotive, industrial equipment, and high tech, compliance is a foundational requirement in the supply chain. In the 2010 IDC Manufacturing Insights and IDC Retail Insights *Supply Chain Survey*,

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manufacturers ranked *introducing new or improved products more quickly* as a key business objective, right after the financial basics — improving profits, increasing sales, and reducing non-IT operating costs.

Noncompliance basically breaks the new product development and introduction process and causes a serious supply chain disruption. In some cases, discrete manufacturers have only a short window of opportunity to sell products, whether because of competitive reasons or seasonal cycles. Losing sales isn't necessarily the only financial impact. Manufacturers can end up having to write off or replace component inventory that doesn't meet their markets' compliance requirements.

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What's disconcerting is that often these situations can be avoided. Consider the 2001 case of a major consumer electronics company using cables that contained well over the acceptable limits of cadmium as defined by REACH. Replacing these cables cost $110 million, and the sales lost to competitors and the damage to the company's reputation are difficult to calculate. We haven't even considered the cost of possible fines. And this example could just as easily be related to other regulations besides REACH, such as RoHS or FIFRA.

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Although our consumer electronics example is somewhat dated, we can easily find evidence of companies introducing products into the market with ingredients or components well over acceptable thresholds. A search on the U.S. Consumer Product Safety Commission's Web site (cpsc.gov) quickly yields four recalls for unacceptable levels of cadmium and 17 recalls for unacceptable levels of lead, just in the first five months of 2010 and looking at only consumer products sold in the United States.

DRIVING BUSINESS VALUE WITH PRODUCT AND REACH COMPLIANCE

Justifying 100% Compliance for the Business

These scenarios in both process and discrete manufacturing underscore the fact that product and REACH compliance must be a best practice, not just for compliance efficiency or avoiding fines or lawsuits but also for reasons that are more proactive and have broader business context, such as:

- Keeping opportunities in current markets and opening the door to new markets
- Gaining visibility into and mitigating the risks of a broad and changing supply chain

- Protecting the brand
- *Doing the right thing* to ensure products are safe for the customer and the consumer
- Satisfying a company's environmental and social sustainability requirements
- Raising customer service levels

Compliance isn't simple in real life — collecting and integrating data can be cumbersome and error prone. Done correctly, compliance processes must be repeatable and easily reviewed and audited, with outcomes that go beyond safety data sheets and regulatory reporting.

IDC Manufacturing Insights believes that the right product compliance process should provide a manufacturer with the confidence in the quality, safety, and compliance of its products and in the integrity of its supply chain on an ongoing basis. To achieve this, manufacturers must improve their existing compliance processes and incorporate audit trails to prove there are no "compliance gaps," yet prepare to update those processes quickly and easily as the business and regulations change.

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Achieving Returns on Compliance Investments: Productivity

Few manufacturers prioritize meeting compliance requirements or industry regulations as a driver for IT investments — just 5.9% of discrete manufacturers and 7.8% of process manufacturers in IDC's 2010 Vertical Group *IT Survey*. Yet more than 38% of both discrete and process manufacturers identified increasing productivity as a top initiative in the same survey.

We believe the connection between improving compliance processes and productivity is critical and also gets to the reason why we emphasize that IT must be part of the solution.

A 2008 survey sponsored by the Consumer Electronics Association (CEA) of more than 200 OEMs, electronics manufacturing services (EMS) providers, and component manufacturers estimated that the global electronics industry spends about $3 billion to maintain RoHS compliance or 1.1% of industry revenue on top of initial compliance costs. CEA's average cost for RoHS annual compliance works out to just under $500,000 per year for each of its respondents. Beyond costs normally associated with product compliance, the survey highlighted the fact that product compliance potentially increases inventories (and inventory carrying costs), as well as component, module, and manufacturing costs.

CEA's average cost for RoHS annual compliance works out to just under $500,000 per year for each of its respondents.

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If we also examine REACH compliance, we find cost estimates that are all over the map, from 2.8 billion euros for direct costs (such as filing or testing) to as much as 9.5 billion euros over an 11-year period. Examples from *Chemical Week* of the cost implications from well-known manufacturers include:

- BASF estimated annual REACH compliance–related costs of 50 million euros, including compiling registration documents and carrying out additional studies through 2018 for 2,500 substances, potentially resulting in 550 million euros over 11 years.
- Bayer expected the cost of REACH compliance to be in the "double-digit millions of euros" in 2007 alone.
- BP expected to spend at least $60 million based on registering at least 1,000 substances at approximately $60,000 each, taking into account preparation, pre-registration, and registration costs.

The scope of those costs could be debilitating to the manufacturing industry without some means of recouping those costs, namely starting with productivity. We are seeing examples of how companies have been able to use an IT-based compliance system to actually lower the existing costs of compliance.

Product Compliance as a Path to Greater Business Benefits

Productivity improvement over how product compliance is done today is a good starting point, and we are seeing benefits from compliance excellence that extend to other business benefits as well, with real customer examples in Table 1.

Basically, IDC Manufacturing Insights believes that product compliance processes can work positively to contribute to business objectives relating to time to market, new product introduction, customer satisfaction, productivity, process control, product quality, and sustainability. Companies that adhere to well-defined compliance management processes and data can use that information internally and externally to drive new and improved controls and processes and make decisions that make their companies stronger, whether they relate to improving margins, protecting revenue, or increasing revenue. But there are key points to keep in mind — namely, there must be not only a defined process but also a process that is followed consistently and with an audit trail and a level of assurance.

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TABLE 1

Examples of Business Benefits Achieved from Product and REACH Compliance in Manufacturing

Category	Examples
Risk mitigation and controls	• Reduce organizational risk by implementing a well-defined system that ensures compliance processes are adhered to and auditable • Provide a centralized information source and a single point of access to chemical information stored in multiple systems and databases, effectively providing one global system of record for compliance-related information • Simplify processes for compliance and audit preparation and increase confidence in ability to comply with and adapt to new regulations with greater visibility and business intelligence • Meet detailed, constantly changing product and/or process regulations for multiple countries in a consistent manner across the entire business worldwide • Coordinate information gathering for REACH compliance for many substances across many sites and support for improved hazardous material communications • Protect substantial investments in markets impacted by regulations, including the earlier example of protecting $2 billion of annual revenue requiring REACH compliance • Institute single standard worldwide for compliance initiatives, including label management • Track the volumes and status of all substances in REACH compliance and establish an audit trail for registration-related activities
Productivity and cost savings	• Reduced costs, including IT cost reductions, by removing manual steps and increasing the efficiency of the process • Significant cost and time reductions from streamlined labor-intensive processes and automated processes, such as reducing substance volume tracking time from four days to one day and compliance processes that are 90% faster than the manual alternative • Greater cost savings and data accuracy through centralized tasks and a consolidated, integrated solution, with one example resulting in 15% reductions in annual recycling fees by paying for only those products that needed to be recycled • Reduced time to comply with new regulations from years to weeks • Ability to proactively detect supply chain disruptions and keep regulators informed in real time • Reduced number of FTEs required to manage compliance as well as decreased IT costs of compliance • Increased "compliance capacity," such as tracking 3 million transactions for 500,000 products and substances and cutting shipping delays caused by waits for compliant labeling
Opportunity	• Ability to take advantage of opportunities such as new business, new customers, and new product bundles • Ability to respond easily and quickly to customer or partner requests for detailed compliance information and maintain customer relationship • More on-time shipments by ensuring compliance requirements are satisfied up front with integrated workflow between receiving, processing, and delivering an order • Potential for new sales or market expansion through more readily available and accurate business intelligence, with compliance checks performed in real time from a centralized source • Increased competitive advantage from early compliance readiness and a foundation for rapid compliance with regulations that are not yet finalized • Built-in capacity to expand as the business grows, tracking more products, more substances, and more transactions • Comprehensive EHS functionality that supports ongoing growth toward corporate sustainability

Source: IDC Manufacturing Insights, 2010

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A Starting Point for Environmental Sustainability

If we think about product and REACH compliance as one potential starting point for environmental sustainability, we can see how manufacturers can benefit from investments in these areas. Over the past couple of years, we reviewed the financial performance of manufacturers that are in our Global Performance Index and the Dow Jones Sustainability Index. Our research has shown that those manufacturers in both indices achieved higher profits, lower inventories, and higher revenues in 2009. While it's not a guarantee that a strong compliance process will make a company more profitable, we are very comfortable emphasizing that without an auditable and verifiable compliance process, those manufacturers would most likely not be able to confidently and publicly promote their sustainability achievements.

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Data from an IDC Manufacturing Insights study conducted in September 2008 demonstrates the long-term interest manufacturers have in relating product design with sustainability. For example, 67.4% of manufacturers already had or planned to have sustainability initiatives related to product redesign, fairly consistently across all types of manufacturers. Of course, redesign for sustainability also means reviewing the materials and components in a product and its packaging for regulatory compliance and much more. The ability to easily access product and REACH compliance data and share that data with other groups across the organization is important to taking the next step to sustainability.

Highlighting the Contribution to Business Value

To be even more specific regarding the business benefits of an integrated and comprehensive view of product and REACH compliance, we define the following as value levers for compliance excellence:

- **Lower cost and risk of compliance itself.** A more automated IT-based system removes the possibility of fines, lowers risk through the added visibility and audit trail, and allows employee resources to be more productive and responsive to customers without creating compliance gaps.

- **Increased revenue.** This includes opening the door to new markets where regulatory compliance effectively creates a barrier to entry, faster new product introduction because compliance is no longer holding up the process, and a higher level of customer orders delivered complete and on time because of compliance efficiencies.

- **More resilient supply chain.** Fewer supply chain disruptions from noncompliance also carry over into cost savings from the need to stock less inventory (less safety stock) and less frequent write-offs from noncompliant stock as well as lower transportation costs (less expedited freight, for example).

- **More consistent, predictable product quality.** A compliance review can drive process consistency in other disciplines, especially product quality. This can result in a stronger connection between product quality and customer expectations and pricing, not to mention a better synch with a company's reputation and brand.

- **An environmental sustainability starting point.** Sustainability ultimately starts with compliance for manufacturers, though there's no need to stop there. But without accurate data, a manufacturer won't have the information to use sustainability to its advantage.

Given the significance of these levers to the business, we believe improving the product compliance management process can be a big win for the business and a way to make compliance costs become an opportunity for improvements beyond just satisfying a single regulation.

Why Technology Is Critical: Consistency, Confidence, and Assurance

Ideally, IT can best support the compliance process and open the information and intelligence in that process to other stakeholders.

Companies require frequent product compliance data collection, reporting, and audit trails. An IT-based system addresses a range of requirements that are integral to the compliance process, such as verifying the accuracy and source of data, maintaining data quality standards, integrating with multiple information sources as well as business processes, and getting information and analysis into the hands of the right people. Ideally, IT can best support the compliance process and open the information and intelligence in that process to other stakeholders.

One of the mistakes we see too often is a reliance on basic spreadsheets and spreadsheet consolidation. The result could theoretically create one source of information, but the integrity of the data can be easily questioned. Is the data coming from the best source? Is the context correct? Did manual steps introduce any errors? Can the process be audited? One chemical manufacturer spoke about the need to manage EHS compliance across 20,000 products; 5,000 chemical substances; 1,000 hazardous substances; and 800 dangerous goods — with only 15 product stewards. Spreadsheets just aren't going to get the job done in this case or in the example provided earlier of 100 products resulting in thousands of use cases and complex volume tracking requirements.

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A more rigorous IT-supported compliance process should include:

- **A central repository or database for all product compliance information and a global system of record.** This will also simplify sharing this data with groups outside the immediate users of the system.

- **A rules- or workflow-based system to ensure that procedures are followed, with the ability to identify specific events or exceptions.** This will automate previously manual compliance checks and procedures, plus add a control system to provide a level of audit trail and assurance.

- **Integration with other applications or data sources such as ERP or materials or order management.** This ensures that data is kept up to date and allows the manufacturers to make broader use of the data; for example, in bill of materials management, procurement, quality management, and sales order management.

- **Reporting or analytics.** This includes simplifying compliance reporting externally, but our minimum expectations are for reports that verify the process is working and create an accurate compliance picture in such a way that it's useful to the entire organization for areas such as sales, production, distribution, and logistics.

We'd also add core IT requirements, such as the ability to create a single centralized system that can be accessed worldwide and supported globally and that supports multiple languages. This type of integrated compliance system is up and running in many manufacturing organizations, yielding the benefits we referenced in Table 1.

Companies that have this system in place can respond to new regulations with a level of efficiency that other companies can't. They also can respond more rapidly and with less disruption from other types of compliance requests — those coming from stakeholders or customers, including requests related to environmental sustainability. The goal is to put a system in place that can adapt as the business must change and that becomes a foundation for better decision making related to compliance, quality, and safety.

CONCLUSIONS

We suggest that manufacturers keep the following points in mind as they work to drive business benefits and return on investment from their product and REACH compliance processes:

- Make sure that your investment in managing product and REACH compliance across your operations is more than a cost — link your performance in these areas to goals such as product quality, productivity, customer satisfaction, time to market, and brand protection. Your compliance information is a valuable component in these broader business goals.

- More integrated and automated product and REACH compliance processes with audit trails will not only reduce the burden of compliance but also create a much-needed confidence level in your products, your operations, and the supply chain. You'll have the assurance you need to make your business commitments and pursue your business goals and mitigate risk.

- Consider IT an important component of the process, for both enabling and enforcing the new process. This isn't an easy transition for many companies, and IT is essential to making it happen as quickly as possible and providing visibility into the success of the program.

- There's no need to explain why regulatory compliance is important, but we'd also like to emphasize that the long-term survival of the business depends on a company's ability to adapt; therefore, any compliance process must be flexible and able to incorporate compliance changes.

We believe that it's worth recognizing the business case for an integrated and comprehensive view of product and REACH compliance processes for more than just compliance.

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