Understanding Regulatory Compliance

The imperative to understand regulations and compliance is critical. Here’s how Wipro can help.

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Over the past few years, there has been a rapid boost in the new global product-related regulations/standards development activities, with a multitude of new restrictions, reporting, classification and labeling and packaging requirements. As a consequence of which, organizations are trapped in the complex loop of various local, national and worldwide product targeted regulations.

A simple reporting error, lack of proper registration and compliance can result in significant fines and penalties, ban from selling the products/product recall, customer and supplier loss and severe damage to the corporate image.

In 2012, Nestle’s Nesquik; a chocolate powder was voluntarily recalled by Nestle USA due to possible presence of Salmonella. In 2011, The U.S. Consumer Product Safety Commission and Health Canada, in cooperation with IKEA Home Furnishings, of Conshohocken, Pa, voluntary recalled about 94,000 and 34,000 units of FÖRSTÅ Coffee/Tea Makers in the US and Canada respectively due to burn and laceration Hazards. In 2008, six infants in China died and approximately 300,000 people were sickened due to consumption of infant formula and milk, and other food materials and components, adulterated with melamine. After this incident, at least 11 countries banned imports of Chinese dairy products. To avoid occurrence of such incidents, governments are making stricter standards and regulations targeting product safety and stewardship.

In the current scenario, governments, suppliers and consumers are giving more emphasis on the determination of chronic health and environmental hazards associated with the life cycle (production, use, storage, transport and disposal) of materials and products. For example, lead is used in paints to speed up drying and increase durability of the paint. But long-term exposure to deteriorating lead-based paints that is shedding, fragmented, etc. can cause nervous system damage, stunted growth, kidney damage and delayed development in children under age six. Consequently, in countries like The United States, Consumer Product Safety Commission (CPSC) banned lead paints in 1977 (“16 Code of Federal Regulations 1303”), along with toys and furniture containing lead paint, “The Environmental Protection (Controls on Injurious Substances) Regulations 1992”, passed in The European Union controlling lead paint use and several other countries have imposed limits on the lead content of household paints.

Apart from product compliance initiatives, there has been growing drive towards “Extended Producer Responsibility” (EPR). The OECD defines, “EPR as an environmental policy approach in which a producer’s responsibility for a product is extended to the post-consumer stage of a product’s life cycle”. In response to this, many manufacturers now willingly take back or buy back their products from end users at the end of product life cycle for proper recycling and waste management. The European Union Waste Electrical and Electronic Equipment (WEEE) Directive and End of Life Vehicles (ELV) Directive are the classic examples of EPR concept supporting directives. The WEEE directive targets collection, recycling and reclamation of all types of electrical and electronic equipments on the other hand ELV targets automotive products. In fact, many product based companies are currently focusing on the production of safer and biodegradable materials.

The list of product-targeted regulations is long. Some of the important regulations/standards are: Restriction of Hazardous Substances (RoHS), Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH), Waste Electrical and Electronic Equipment (WEEE) directive, Ecodesign directive, GHS/EU-CLP system of classification and labeling, Toxic Substances Control Act (TSCA), End of Life Vehicles directive, California Green Chemistry Initiative, Regulation (EC) No 1980/2000 (Eco-Label) and IATA-DGR.

The important characteristic of these regulations is that they transfer the risk management responsibility over to the producers and importers of the products.
The following are few of the major business challenges faced by an organization in product compliance:

- Inability in obtaining correct and timely data from various sources like suppliers, third party vendors, consultants, etc.
- Lack of knowledge among suppliers regarding regulatory requirements and their role and responsibilities in the supply chain.
- Gaps in recognizing and evaluating risks associated with the non-compliance.
- Lack of reliable, transparent and auditable business processes.
- Lack of resources to facilitate process compliance assurance.
- Time consuming and inappropriate compliance data collection and reporting methods.
- Problem in determining true compliance report of products due to lack of pertinent systems for measuring and enforcing compliance.

Companies can reduce the burden in complying with different product-related regulations by some crucial steps, listed below:

- Understand the relevant product-targeted regulations, their compliance requirements and impact thoroughly.
- Identify and map the organization product lines/processes to specific regulation in a compliance matrix.
- Conduct a methodical gap analysis to identify possible loopholes.
- Since most of the product-targeted regulations are data intensive with burden of proof on industry. So develop an efficient data management system.
- Ensure hazard identification and risk assessment of all your products on to the human health and environment.
- Supply chain collaboration is important for product compliance. For example, REACH registration requires information from up and down the supply chain.
- Confirm safe and compliant handling, storage and transport of regulated materials and products.
- Implement non-biological procedures like (Quantitative) Structure Activity Relationships for Toxicological Risk Assessment (TRA) of chemicals rather than biological Models (rats, mice, guinea pigs, etc.). This step prevents unnecessary animal testing at the same time it is cost-effective as well.
- Adopt “green chemistry” and create new ways to make your products “sustainable”. Such kind of practices is often termed as “Design for the Environment” (DfE).

For instance, “The U.S. EPA’s Design for the Environment program” recognize safer consumer and industrial and institutional products7 and it also defines “best practices in several areas by promoting the use of safer alternative chemical products and cleaner, more efficient practices”8.

- Last but not the least: implement automated systems that can help you in managing regulatory compliance by analyzing regulatory changes, material data, suppliers, or BOM change, and quantity and movement tracking.

The best advice is “be prepared” and “comply fully as soon as possible” because non-compliance may have severe effects on your business and corporate image.

References:

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