

Regulatory and business compliance in the process of handling and using hazardous substances and mixtures

The importance of digitalization and process automation



In an ever-changing regulatory landscape, companies face a multitude of obligations including **national and international regulations, industry standards and specific customer requests**.

Effective management of these requirements, particularly with regard to compliance in the handling and use of toxic or hazardous substances and mixtures, is essential to protect the **health of workers**, protect the **environment** and preserve the **competitiveness** of its products in the marketplace.

Although these requirements can be challenging in their application, they are at the same time an opportunity for companies to distinguish themselves by enhancing their reputation, accessing sustainable supply chains and defending themselves against competition from less regulated countries or markets whose products do not guarantee the same standards of quality, safety and environmental responsibility.

Regulatory regulations: a complex and layered puzzle

In Italy, the use and management of hazardous chemicals are regulated by a complex regulatory framework that integrates European regulations and national provisions. Here are the main rules and regulations in force, regardless of the sector they belong to:

1. European Regulations

- **REACH (EC Regulation No. 1907/2006)**
The REACH Regulation governs the registration, evaluation, authorization and restriction of chemicals. It defines the obligation to communicate and update hazards along the supply chain through Safety Data Sheets (SDS). It aims to ensure a high level of protection of human health and the environment while promoting the safe use of chemicals.
- **CLP (EC Regulation No. 1272/2008)**
The CLP Regulation covers the classification, labeling and packaging of chemicals and mixtures. It introduces harmonized criteria for identifying hazards and communicating information through labels and Safety Data Sheets (SDS).
- **PIC Regulation (EU Regulation No. 649/2012)**
This regulation applies to the export and import of hazardous chemicals, ensuring compliance with international conventions.
- **Seveso III Directive (EU Directive No. 2012/18)**
Applies to major accident hazard establishments where hazardous substances are present in quantities above certain thresholds. Imposes obligations for prevention, risk management and emergency planning.

2. National Regulations

- **National Unified Workplace Health and Safety Standards**
specific obligations for managing the risks associated with the use of hazardous chemical agents in the workplace, including:
 - ✓ management, circulation, and proper use of SDSs
 - ✓ chemical risk assessment
 - ✓ adoption of preventive and protective measures
 - ✓ worker training and information

- **Environmental regulations**

Includes provisions for the management of hazardous chemicals and wastes derived from them, with the aim of protecting the environment and natural resources.

Industry compliance and customer demands: ever-higher standards

In addition to legal obligations, many companies must comply with international, industry or customer-imposed Standards and adapt their processes to rules that are often more stringent than current regulations, for example:

- **ISO standards (e.g. ISO 45001 and ISO 14001)**
Voluntary standards that provide for the integration of hazardous chemical management into corporate management systems to improve health, safety and environmental processes
- **MRSL** (Manufacturing Restricted Substance List) that is, lists of substances prohibited or restricted for use in manufacturing processes, frequently updated and requiring constant monitoring
- **Product/industry certifications** to certify compliance, quality, safety and sustainability
- **Client or third-party audits** to demonstrate compliance with contractual and supply standards

Compliance: an essential factor for business continuity and growth

Managing large amounts of ever-changing data can be extremely challenging for those who deal with it on a daily basis. However, effective compliance management achieves important benefits, including:

- increase the operational efficiency and reliability of the company
- ensure the compliance and competitiveness of its products in the market
- reduce sanction, legal and reputational risks
- access qualified markets, where compliance is a prerequisite

In a global context, **customers and partners favor reliable suppliers** who can demonstrate a tangible commitment to **compliance, safety** and **sustainability**.

Digitalization: the key to efficient and safe management

Digitalization and automation of chemical management processes are crucial to **simplify** compliance management, **reduce the efforts and errors** associated with manual management, and enable accurate and continuous **control** of information.

Thanks to digitalization it is possible:

- ✓ **Indexing and centralizing information**

Ensure that data on hazardous substances and mixtures are reliable, always up-to-date, and easily accessible. Also, ensure that the receipt and storage of documents, such as SDSs, are managed efficiently to avoid duplicate and outdated information.

[Learn how digitalization has facilitated product information management at Holcim: Managing a centralized digital repository of SDSs, updated and accessible to all staff](#)

- ✓ **Automating processes**

Reduce manual errors and improve efficiency in the management of SDSs, regulatory communications, and compliant distribution of SDSs along the supply chain.

[Learn how digitalization has helped Manica in supply chain management: Manica - Responsible sustainability and traceability for the entire supply chain](#)

- ✓ **Monitor and analyze data**

Comply with regulatory and business changes, monitor them automatically, receive alerts on non-compliant substances allowing timely adaptation.

[Learn](#) how digitalization has transformed compliance management for **E.Miroglio**: [Product Compliance, Audits and Certifications: E.Miroglio Overcomes Challenges in Textiles with SDS-FullService](#)

Conclusion

Digital management of SDS and chemical information, combined with **automated monitoring** of compliance with Regulated Substance Lists, significantly simplifies regulatory and business compliance, which is critical for business continuity and growth. Adopting digital solutions to manage compliance in the selection and use of chemicals is a strategic choice for operating responsibly, safely and sustainably, preserving the competitiveness of its products in the global market and strengthening stakeholder trust.

Regulatory compliance: legal and business compliance. [Read our article published at "Il Sole 24 Ore"](#).