

GOVERNMENT REGULATIONS IMPACTING YOUR SUPPLY CHAIN

A Look at Some of the Regulations Involving Chemicals,
Prescription Drugs and Food That Are Affecting Supply Chain Businesses



A Guide By  **datex**
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With the increasingly global nature of the supply chain, businesses are now encountering more and more complex governmental regulations across the world. Companies that handle the importing and exporting of products may be required to comply with a variety of international requirements, possibly involving multiple agencies that regulate trade and shipping. Having the ability to track goods, meet and provide documentation of regulatory compliance quickly can mean the difference between smooth sailing and crippling delays in the supply chain. In addition, supply chain businesses may be subject to fines and civil penalties as well as lost business and damaged client relations.

Chemicals of Concern

EU REACH Regulations

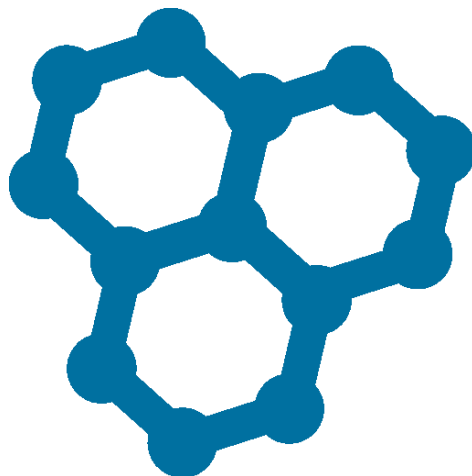
[European Union's Registration, Evaluation, Authorization and Restriction of Chemicals \(REACH\)](#) is in effect.

More chemicals were added to its Substances of Very High Concern (SVHC) list and Restriction of Hazardous Substances Directive (RoHS). REACH was adopted by the European Union in order to improve the protection of the environment and human health from chemicals. The regulation also serves several other purposes. It aids in enhancing the competitiveness of the EU chemicals industry and promotes alternative methods for assessing the hazardous nature of substances. The chemicals included in REACH are not only for industrial purposes but also those used in daily living such as for cleaning, painting and other purposes.

With the burden on companies, businesses must identify and manage the risks associated with dealing the substances that they manufacture and market in the EU. Over 30,000 chemicals are covered by REACH. REACH regulations are based on the substance used in each product rather than on its end use.

Companies that sell into the EU or have a supply chain that touches any of the EU countries must avoid chemicals considered to be toxic by either and in some cases both regulations. In most cases by 2017, all companies that are conducting business in Europe will need to comply.

Who Do the EU REACH Regulations Affect? EU importers, manufacturers, EU-based downstream users, and third party representatives such as 3PLs. As the regulations are fully implemented, 3PLs will need to develop procedures to deal with shipments that are detained in EU countries due to insufficient or incorrect documentation.



How Can Technology Help? If you have a business impacted by this regulation, you will need software that can keep track of the composition of products. It will be beneficial for you to have the ability to have complete product traceability and to be able to create reports customized for your needs and in the format of your choice. Having software that can also house documentation to aid in proof of regulatory compliance is also useful.

Prescription Drug Products

FDA DSCSA, Also Known as Title II of the Drug Quality and Security Act (DQSA)

Established to address downstream risks in the supply chain, [DSCSA](#) helps to facilitate the exchange of information about drug products in the supply chain. The new FDA regulation is designed to help enable drug legitimacy verification and to help facilitate more efficient, effective product recalls.



Key provisions of this FDA regulation include:

Drug Product Identification: Drug re-packagers and manufacturers will be required to place unique product identifiers such as bar codes and serial numbers on certain prescription drug packagers for easy electronic scanning and readability.

Drug Product Traceability: Businesses in the supply chain including manufacturers, wholesale drug distributors, re-packagers and dispensers (usually pharmacies) will be required to provide information about drug products including every time it has been handled and sold in the U.S. market.

Drug Product Verification: Businesses including manufacturers, wholesale drug distributors, re-packagers and dispensers (primarily pharmacies) throughout the supply chain will be required to establish processes and systems that enable the verification of the product identifier on certain prescription drug packages.

Pharmaceutical Drug Suspect Product Detection and Response: Specific types of supply chain businesses must be able to quarantine and quickly investigate

drug products once they are identified as suspect. Suspect drug products are those that may have been counterfeit, unapproved or in some way potentially dangerous.

FDA Drug Product Notification: Specific types of supply chain businesses need to establish procedures for notifying the FDA and other stakeholders if any illegitimate drug products are found.

Wholesaler and Third Party Logistics Provider Licensing: Reports now need to be made to the FDA by wholesale drug distributors regarding their licensing status and contact information for release to a public database. 3PLs that handle, store and transport drug products are now obligated to obtain a state or federal license.

Who Does FDA DSCSA Affect? Manufacturers, re-packagers, wholesale drug distributors, third party logistics providers, drug dispensers (primarily pharmacies)

How Can Technology Help? If you have a business impacted by this regulation, you will need software that can house documentation including certificates, photographs, reports and other documents. Your software needs to be able to handle barcoded and/or serialized products and provide detailed drug product traceability. In addition, your business will benefit from workflow-based software that can automate quality assurance processes such as inspections, holds and quarantines. Using workflow-based software can help your business to reduce manual processes and make operations more accurate and efficient. In addition, having software that can create customizable reports in the format of your choice would be highly useful.

Food Products

FDA Food Safety Modernization Act (FSMA)

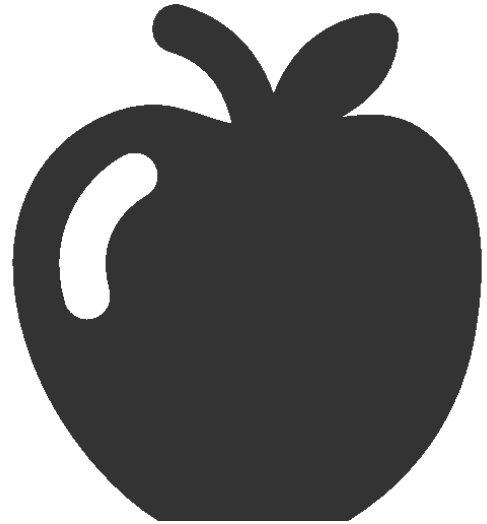
Enacted in 2011, the Food Safety Modernization Act involves a new set of rules for companies that handle food and food packaging materials. Rather than focusing on simply responding to food safety crises, FSMA helps to shift the focus to help prevent food contamination from occurring.

Inherently broad in scope, FSMA impacts food imports from countries outside the U.S. and includes the documentation and verification of foreign suppliers in the Foreign Suppliers Verification Program (FSVP).

The new FSMA regulations are designed to provide more accountability for companies that ship food products in order to enable greater food product traceability and food safety. In accordance with the new food safety regulation, the FDA now has more oversight over food products entering the United States. The FDA must ensure that they have the necessary infrastructure and governance in place to inspect food products in the supply chain.

Who Does FDA FSMA Affect? The new food safety regulations can impact companies across the supply chain either directly or indirectly. Because of the new requirements, it is likely that more time and cost will be incurred to ensure compliance and to avoid potential fines. Companies that are involved in food production, distribution, handling and other operations need to evaluate potential hazards in their operations. In addition, these companies need to take steps to implement measures in order to prevent food product contamination and have plans in place in case food safety procedures are breached, putting food products at risk.

How Can Technology Help? Collaborate with other businesses across the supply chain to obtain proof of both forward and backward Lot traceability. Make sure that you include carriers as food regulations vary from state to state. Make sure that you are using software that can facilitate and house the documentation needed for compliance. Use technology solutions such as automated data



collection methods such as barcoding and RFID along with a state-of-the art warehouse management solution can save your business time, money and frustration. Use a WMS that provides a web portal for easy real time sharing and notification of information critical to your business. It is essential that your business have the technology needed to provide backward and forward traceability and to be able to track and trace food products in a variety of ways including by ingredient, batch, Lot, UPC and more.

Conclusion

In today's global marketplace, supply chain businesses now must comply with a wider range of governmental regulations than ever before. New complex regulations and guidelines can slow down product movement and choke movement through the supply chain without the proper planning, oversight and resources.

Using innovative technological tools available on the market today can help your business maintain its reputation, business standing and help ensure compliance with a complicated array of regulations.

About Datex

Datex provides flexible, reliable supply chain technology solutions to help make businesses more profitable, including supply chain software, mobility solutions, professional services and mobile device management. In business for over 35 years, Datex has a wealth of experience in helping companies across the world meet these critical business challenges.

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