The globalization of trade is the primary driver for the increase in imports. Imports and offshoring are no longer just an incidental part of trade in the U.S. They are increasing at an explosive rate in a wide range of industries for retail-ready consumer products as well as consumable foods, bulk raw materials, chemicals, steel and manufacturing components. Companies involved in imports and outsourcing to foreign countries are well advised to have a robust product liability prevention program and strategies in place to manage risks from imported products.

Introduction

In recent years, several large products recalls for potentially unsafe products imported from China and other foreign countries have received much adverse media attention. These products range from toys, pet foods and tires to clothing and electronics. While imported product recalls are nothing new, what is new is the scope and magnitude of these recent recalls. According to the U.S. Consumer Product Safety Commission (CPSC), approximately two-thirds of recent U.S. product recalls are for imported products – of which a large majority is manufactured in China. Yet, while Chinese products are currently drawing the most attention from the public, media and government agencies, the risks and challenges are not limited to imports from China alone.

Companies affected by these recalls are usually manufacturers with some portion of their products or components procured from a foreign source. Others affected may be wholesalers and retailers that import all or most of the products they sell. Some of these companies may also have their products private-labeled for sale.

What these companies need to understand is they are ultimately responsible for the safety of their products, and they cannot rely solely on the assurances given by the foreign manufacturers. If a foreign manufacturer or supplier does not have U.S. assets or insurance protection, any company selling these products is vulnerable to potential liability litigation.
Therefore, failure to manage risk from imported products exposes a business to significant liabilities, expensive recalls and, perhaps most importantly, an adverse impact on its reputation and brand.

Discussion

Globalization as a driver of increased risk

The globalization of trade is the primary driver for the increase in imports. Imports are no longer just an incidental part of trade in the U.S. They are increasing at an explosive rate in a wide range of industries for retail-ready consumer products as well as consumable foods, bulk raw materials, chemicals, steel and manufacturing components. After moving production facilities to Mexico and Canada in the early years of globalization, many U.S. businesses are now using manufacturers in China and other Pacific Rim countries with lower labor costs in pursuit of reducing production costs. Although exports are improving, increasing imports are resulting in a staggering trade deficit.

The reasons for increased imports vary by industry, ranging from diminishing production capability and capacity to constant pressure for lowering costs. The containerization of cargo has also resulted in a significant reduction in ocean cargo shipping and logistics costs that led to a major shift to importation.

The role of government

Importers cannot solely rely on government inspections to ensure the safety and quality of the goods they import. Companies are responsible for ensuring all their imported products comply with applicable U.S. product safety standards and regulations. The U.S. Customs Service is required to inspect incoming shipments at port of entry and clear them for distribution in the U.S., and has the authority to seize products that do not meet mandatory standards – such as the adulterated foods, drugs and medical device standards. However, it does not have the statutory authority to block products that do not comply with voluntary standards. Other federal agencies, such as the U.S. Food and Drug Administration (FDA) and the CPSC, conduct market surveillance inspections, but they have only limited pre-market jurisdiction over imports. Unfortunately, the increased volume of imports, container inspections related to terrorism security and inadequate resources mean these inspections have limited effectiveness.

In September 2007, an interagency taskforce published a general framework in a report to the president “Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety.” Since then, there have been some efforts to increase government oversight, including passage of Consumer Product Safety improvement Act of 2008 and Food Safety Modernization Act. Although mandatory testing and reporting requirements and publicly reported. http://www.saferproducts.gov/ may help improve compliance with U.S. safety standards, it is only a partial solution. Importers still have to step up their own surveillance and inspection efforts. Importers are ultimately responsible and liable for the quality and safety of the products they import, and it will not help to play the “blame game” by pointing the finger at a foreign supplier or lack of adequate government oversight.

Can you sue the foreign supplier?

There are several legal roadblocks to suing a foreign manufacturer in U.S. courts or across national borders for liability arising from injuries or property damage caused by defective and unsafe products. Therefore, U.S. importers, distributors and retailers become prime targets of this litigation without any hope of enjoining their foreign suppliers. Foreign manufacturers are seldom able to provide any evidence (certificates of insurance) of liability risk transfer and insurance coverage in the U.S., at least with adequate limits. Without this or financial
assets in the U.S., the U.S. importer has the ultimate liability and responsibility for ensuring the safety of the products it imports. This liability can come from both product design and development risks as well as manufacturing risks.

Whereas some companies design the product but outsource manufacturing to a foreign manufacturer, increasing trend is for a foreign manufacturer to collaborate with the U.S. business in design and product development. In these cases, the importer is probably in a better position to influence the foreign manufacturer in terms of quality and compliance. If product defects are caused by inadequate design or specifications, however, the U.S. importer is still likely to be held liable in U.S. courts.

In addition to design and product development risks, the U.S. importer also carries the burden of the liability risk for manufacturing defects caused by the foreign manufacturer, including allegations of non-compliance with safety standards and failure to inspect products before they are sold. In liability litigation, U.S. courts do not have jurisdiction over a supplier in a foreign country and the importer is likely to be treated as a manufacturer and held liable for all aspects of design, manufacturing and labeling. In either case, the reputation risk of product recalls and the financial risk of liability litigation can be significant. Effective risk management strategies must be in place to manage this risk.

**Guidance**

**Strategies for an effective product liability risk management for imported products**

Because governmental inspections and customs regulations are proving to be inadequate to ensure safety of imported products, the importer must evaluate its risk according to the inherent dangers of its products. Although there are many ways to approach product liability risk management, the importer’s risk management plan must be robust with redundant, with multiple layers of controls – particularly in the case of safety-critical products and specifications. Plans should address the entire life cycle from product design and specifications to manufacturing, distribution, logistics, post-sales monitoring and ultimate disposal.

**Select qualified suppliers**

The first critical step in this process is to select qualified suppliers that operate with a rigorous vendor management program. While you should already be doing this for selection of a domestic supplier, selecting a foreign supplier presents several unique challenges. In addition to the geographic distance, there are cultural and language barriers. The differences in safety standards and governance infrastructure preclude making any assumptions. Although trading company arrangements are available to help select an outsourcing partner, conducting a face-to-face meeting and plant visit are still the best approaches to ensure long-term success. Certification of quality management systems – like ISO 9001 certification or the independent product certifications by reputable agencies such as the Underwriters Laboratory (UL) or Canadian Standards Association (CSA) – are desirable, but not a substitute for your own due diligence and vigilance. These certifications do not guarantee quality: There have been cases where imported products with UL or other third-party approval were recalled.

If a foreign manufacturer is responsible for the complete product, including design, extra care must be taken to review product specifications for compliance with industry and governmental standards and regulations. This is particularly crucial for regulated products such as children toys, jewelry, textiles, food and pharmaceuticals. For many food ingredients, there are established purity grades (such as food grade, pharmaceutical grade and feed grade) for product specifications. If the importer is providing the product
specifications for procurements from the foreign manufacturer, these specifications should be clear and unambiguous and should be used as a basis for inspection.

Any intellectual property and technology transfer risks to a foreign manufacturer require additional contractual and legal consideration and protection. You should use extra vigilance in addressing this risk, including the risk associated with counterfeit import products. These counterfeit products might even carry counterfeit third-party approval stamps and are difficult to distinguish from the genuine products. This is a serious problem affecting many industries. Counterfeit products present the risk for significant safety hazards, potential legal liability, loss of customer goodwill and brand dilution.

Due diligence efforts in selection of a qualified supplier should also include adequacy of effective risk transfer and contractual arrangements. Always explore the possibility of getting any financial or global liability insurance protection from the supplier that will respond to a potential litigation in North America.

**Establish clear product specifications and quality assurance**

Whether you design the product and outsource production to a foreign supplier, direct import a final product or have the foreign supplier private label a product for you, an importer is ultimately liable for the safety of an imported product in the chain of commerce and it is important to ensure that the product meets all applicable safety requirements including any mandatory safety standards. The next step in your risk management strategy is to document and agree on the following with your foreign manufacturer:

- Product specifications
- Fair price
- Quality inspections
- Delivery schedules and other logistics / supply chain parameters

You should also evaluate the first piece / pilot runs and product samples, and conduct plant audit visits as part of this selection and approval criteria. If you use a sampling inspection approach, the sampling plan and sampling frequency should be consistent with the criticality and desired level of quality and safety assurance and desired confidence level. Safety-critical product characteristics – such as lead content in paints for juvenile products, flammability of fabrics and presence of toxic contaminants in food products – require greater vigilance and the appropriate level of testing for each shipment. A certificate of guarantee can and should be requested for the desired level of assurance, but it should be accepted only with appropriate monitoring, testing and verification. After the actual production runs start, consider conducting:

- Pre-release inspections of shipment lots at the plant either by the importer’s own staff or a reputable and qualified independent third-party service
- Similar inspections at the port of entry or before the products are released for general distribution
- Sample splitting or parallel inspections by two separate laboratories on critical parameters for quality assurance

Effective quality control is crucial to mitigating risks of imported products. Ideally, the best control is to have your own quality team on the ground at the supplier(s) or in the country conducting inspections prior to shipment. If you are relying on an independent third party to monitor quality, you should check their
credentials and references thoroughly before contracting. If you are relying on the supplier to give you samples for inspection, make sure they are random and representative.

**Use product warnings**

An area that is often overlooked with outsourced and imported products is the responsibility for product warnings and instructions. Because importers are ultimately liable for the product safety, they must ensure the warnings are clear, commensurate with the degree of hazard, and comply with all applicable industry and government standards. A warning label is not a substitute for a safer product design, but it should warn against risks that cannot be reduced by a safer design or guarding.

Key elements of an effective warning include:

1. An appropriate signal word (“Danger”, “Warning,” “Caution”) commensurate with degree of risk
2. A statement of hazard
3. Avoidance instructions
4. Consequences and any special information

Additional considerations include color, use of pictograms, location, durability and readability of warning labels. The inspection process should include specifications for labels to ensure durability.

In addition to an effective warning to help a user avoid the unsafe use of a product, it should have proper instructions to reinforce its safe use. The instructions should target the appropriate user profile for readability and ease-of-use. Ensure proper translations for original instructions in a foreign language to avoid any confusion. Translation of warnings labels and instructions from a foreign language can present some unique challenges of their own and it is a risk that is often overlooked.

**Monitor for quality slippage**

Another crucial phase is to continually monitor product quality so no slippage in quality occurs. In addition to initial selection and approval of a supplier, be sure to include tier II subcontractors in the supplier review process. Changes in production processes, materials or subcontractors can alter quality so insist on any change notification and approval.

This ongoing monitoring covers two aspects: supplier issues and how you approach subsequent vendor price negotiations. Although it may be tempting to negotiate cost reductions in face of unrelenting pressures for cost reduction, you must be careful to avoid any pressure that could lead to quality and safety slippage. Even under the best of circumstances, continually pressuring suppliers to cut costs can adversely impact product quality. In response to the pressure, the supplier may cut corners on specifications, material or workmanship that can lead to incrementally poor quality over time. This pressure may also provide an incentive for unscrupulous practices in product testing and inspection to disguise poor quality and slippage. Failure to recognize this hidden cost of adverse impact on quality can lead to serious consequences, liability litigation, expensive product recalls and brand and reputation damage.
Post-sale monitoring
In addition to monitoring for product quality, post-sale vigilance is important for seeking and monitoring customer complaints and other sources of feedback. Obtaining and analyzing trends and root cause analysis can be an excellent source of early warning insight of an impending product safety problem that can help in taking a prompt mitigation action to prevent injuries, product recalls and expensive lawsuits. Also don’t forget the mandatory prompt reporting obligations to report a serious safety hazard to Consumer Product Safety Commission or other governmental agencies or face expensive fines.

Prepare an effective product recall program
Even with “due diligence” in supplier selection and stringent quality monitoring controls, defective products can slip through the screening process and reach customers. If these defects are safety-critical, they can cause injuries that can lead to product liability lawsuits and damage to a company’s reputation. This can result in adverse media publicity and need for a professional crisis communication strategy. Being prepared for such an event is why you should have an effective brand protection and product recall program in place that quickly removes unsafe products from the hands of customers. Product recalls are expensive, but they may be necessary for reducing future injuries and liabilities.

A good recall program should start with the company’s corporate quality policy, and must have an organization in place to oversee the recall with roles and responsibilities clearly defined. The program should identify the resources needed – both internal and external – and establish a clear implementation plan. In addition, you should develop a plan for determining the validity of complaints received and whether a recall is warranted. Once a decision is made to conduct a recall, the action plan and procedures for that particular recall must be developed and implemented promptly.

The components of an effective recall program include tracing products and monitoring post-sales safety issues, such as customer complaints and adverse incidents. Without adequate traceability, all the quality control and recall planning will be wasted. You must be able to track your import shipments by date or lot numbers from factory to dock to wholesaler to retailer to customer. Upstream traceability through supply chain and downstream traceability through sales network and to the customer allow you to isolate defective products effectively by date / lot numbers. Without the ability to track products, you might have to expand the recall beyond what is actually necessary. The Consumer Product Safety Act has a prompt notification requirement for any substantial hazard discovered in a consumer product. Failure to notify the CPSC promptly may result in substantial fines and penalties.

Any product recall brings with it the risk of adverse publicity and media scrutiny. This adverse publicity may result in customer mistrust of the company’s products and brand – with potential backlash against all imported products and future sales.

A major recall and litigation with associated adverse publicity can tarnish the company’s reputation, and can drastically affect the stock price. A company should proactively implement their established crisis communications strategy during and following an event. Design the communications strategy around possible scenarios that could occur. Establish a designated spokesperson and a crisis communications team and make sure everyone in your organization know who these individuals are and when they are to be involved. Emphasize the importance of directing all media contact through the designated spokesperson. The last step is to incorporate the communications strategy into the recall plan.
Be aware of supply chain risks

In addition to the quality and safety related risks, importing OEM and retail-ready products or critical products and raw materials present significant supply chain risks, including business continuity risks. Managing this risk requires balancing competing priorities of maintaining quality, controlling costs and boosting profitability. Additional risks of geopolitical instability, trade restrictions, currency fluctuations and logistics must be carefully considered. Managing your supply chain requires careful balancing of supply-side planning for long lead times and low costs associated with sourcing from a foreign country with agile demand-side response to rapidly changing customer demand. Any unanticipated quality or safety issues and product recalls can lead to further uncertainty, resulting in empty shelves and loss of future sales and customers.

Conclusion

Regardless of why or how you outsource production of products or components, you must be aware of the many risks associated with these decisions. Implementing a strategy to assess and manage these risks is critical and requires ongoing vigilance. The business culture, legal requirements and regulatory infrastructure of the supplier’s country will be significant factors in determining how much you will need to oversee its activities and how vigilantly you must control product quality in order to manage risk. Ignoring or failing to manage this risk effectively can have serious consequences – resulting in liability litigation, expensive recalls and serious damage to your company’s reputation and brand.

References

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- “What are Counterfeiting and Piracy Costing the American Economy" by U.S. Chamber of Commerce
- The U.S. Customs Service: APHIS-CBP Joint Task Force on Improved Agricultural Inspections
• US Census Bureau: Foreign Trade Highlights 2011:
  http://www.census.gov/foreign-trade/statistics/highlights/annual.html

Related documents

• Online resources for product recalls: http://www.recalls.gov/cpsc.html

• Publicly available Consumer Product Safety Information Database:
Appendices

Importer’s checklist

1. Perform "due diligence" analysis of a foreign manufacturer before entering into any outsourcing arrangement, including on-site visit and a review of references.

2. Consult competent legal counsel familiar with laws in the supplier’s country in all contract negotiations – particularly for any patents, copyright and intellectual property issues.

3. Insist on a written contract to document all the terms and conditions of your outsourcing arrangement – including all specifications, compliance requirements, costs, logistics, quality inspections, certificates of guarantees, returns / recalls, and warranties.

4. Explore and negotiate insurance protection from the foreign manufacturer under a U.S. insurance policy with adequate limits and indemnity terms whenever possible

5. Perform an on-site assessment of a supplier’s facility before finalizing outsourcing arrangements

6. Insist on prior notification and approval for any changes in materials, production processes, subcontractors and specifications.

7. Arrange for on-site sampling and periodic audits by your own personnel or by reputable third-party organizations with a U.S. affiliation.

8. Perform additional sampling and inspections of incoming shipments at the port-of-entry and before distribution of products into the chain of commerce.

9. Implement a post-sale monitoring program that includes tracking of customer complaints and trends.

10. Develop and implement a product recall and crisis communications program for brand protection.