

Product Responsibility Best Practices	SUBJECT ISO 10377 Consumer Product Safety Guidelines for Suppliers		LAST UPDATE July 2018
	APPLIES TO • Suppliers	FOCUS ON How ISO 10377 provides practical guidance to suppliers on assessing and managing the safety of consumer products.	
	QUICK LINKS • PPAI Corporate Responsibility: http://www.ppai.org/corporate-responsibility/ • Consumer Product Safety Commission: http://www.cpsc.gov/		Intended for advanced compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

Purpose Of ISO 10377

The *International Organization for Standards (ISO)* is an independent organization that develops voluntary international standards. The purpose of *ISO 10377* is to provide suppliers with practical guidance concerning the safety of the consumer products they manufacture. According to ISO, “ISO 10377:2013 provides practical guidance to suppliers on assessing and managing the safety of consumer products, including effective documentation of risk assessment and risk management to meet applicable requirements.”

As stated in the ISO 10377 documents, the standard provides the necessary direction to:

- Reduce the product safety risk to consumers
- Reduce the risks to suppliers
- Provide consumers with the information they need in order to make informed choices with respect to the safe use and disposal of consumer products
- Assist governments by improving the safety of consumer products

The information provided in the ISO 10377 standard is designed for suppliers of all sizes. Ultimately the standard will assist “in assessing and managing the safety of the consumer products they supply—from the design of the product, to the input of raw materials, to production, to distribution, to retail, and to the final product end-user and disposal.” Small and medium-sized businesses will benefit greatly from these guidelines. Additionally, since distributors are still responsible for product safety, there are examples in the standard that will benefit them as well.

These basic principles are at the core of ISO 10377:

1. Promoting a product safety culture within the organization
 - How a company communicates and demonstrates to staff that safety is important. Ways to accomplish this include incorporating company compliance values into mission statements and policies.
2. Promoting a product safety culture outside the organization
 - How a company communicates its values and compliance expectations to vendors and other

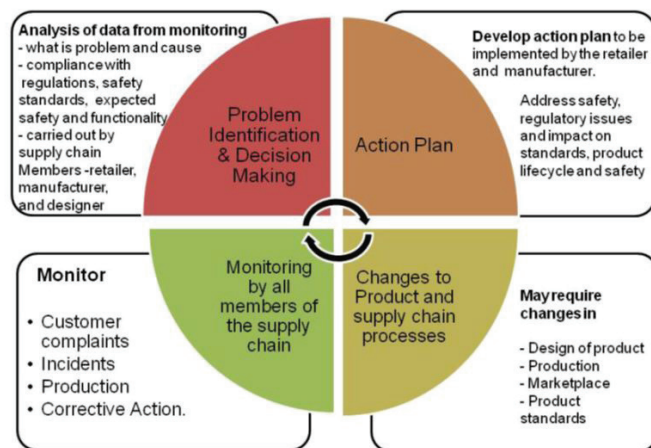
business partners throughout the supply chain. This can be accomplished through contracts, vendor policies, codes of conduct, and audits.

3. Commitment to providing safe products

- A company demonstrates its commitment to compliance through investments in capital and human resources. True commitment involves investment, and this type of commitment must come from the top management in real terms of why this is important to the organization. Leadership is responsible for driving this commitment down through the organization to all levels, through training, resource allocation, and ensuring processes are in place for proper records management and document control.

4. Continual improvement

- Safety is ongoing and ever improving with continuous monitoring of processes and outcomes. Companies must continually monitor themselves and look for improvement opportunities. Tracking issues and defects allows for in-depth analysis of risks and offers data needed to build in or re-engineer safety into products.



Continuous Improvement - d. at Clause 5, General Requirements, Continuous Improvement (§5.3)

5. Precautionary approach

- Requires looking at the risks involved with a product, being able to understand those risks and actions needed when an incident occurs. The precautionary approach allows for reasonable decisions and action, based on risk involved, to be made in lieu of avoiding decisions based on a lack of scientific data or absolute proof. Understanding where products are going and what laws, regulations and standards apply will mitigate risks.

6. Sharing information

- Sharing information and feedback is critical to the success of risk mitigation and the production of safe products. Communication back and forth throughout supply chains is not only necessary but considered a best practice in nearly all industries (Figure 1). Enhanced communication ensures all parties know and understand what is going on, where they impact the process, and allows them to react appropriately based on the given situation.

Communication throughout the supply chain, guided by these principles, enhances the effectiveness of documented policies. Information must flow in both directions—down through the supply chain for direction and back up the chain for process improvement and data analysis. Corrective Action Plans (CAPs) depend on this type of two-way communication.

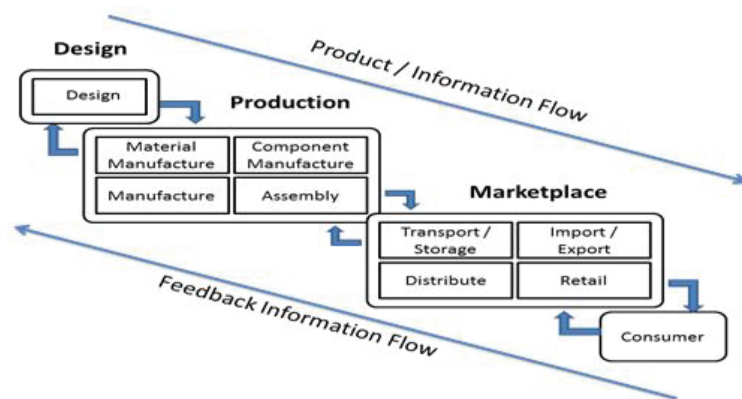


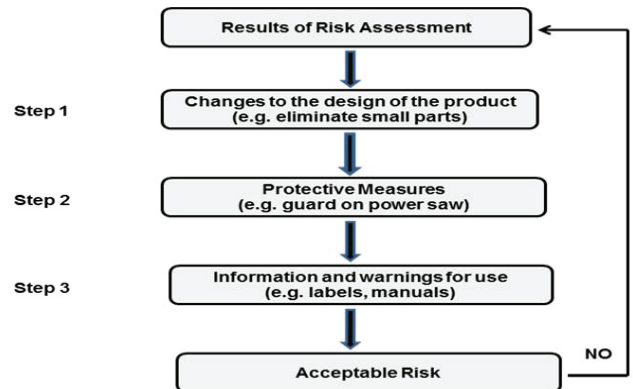
Figure 1: "ISO 10377 - Clause 5, General Requirements, draft Figure 3: The Supply Chain"

Stages Of Production

There are three stages of production as defined within ISO 10377. Each stage has specific requirements that pave the way for the following stage's execution. Communication protocols should be established as effective information sharing provides consistency and is essential to building safety into a product.

- Design Stage:** The design stage is the first stage of the product life cycle and critical in that a good design minimizes safety issues. In this stage specifications are developed and documentation is established to address:

- Risk assessment:** Develop scenarios for how people will use a product and what hazards could occur. The risk assessment identifies the severity of hazards in order to determine whether risk level is high or low – and what is acceptable. It is performed first in the design stage and again over time as factors change.



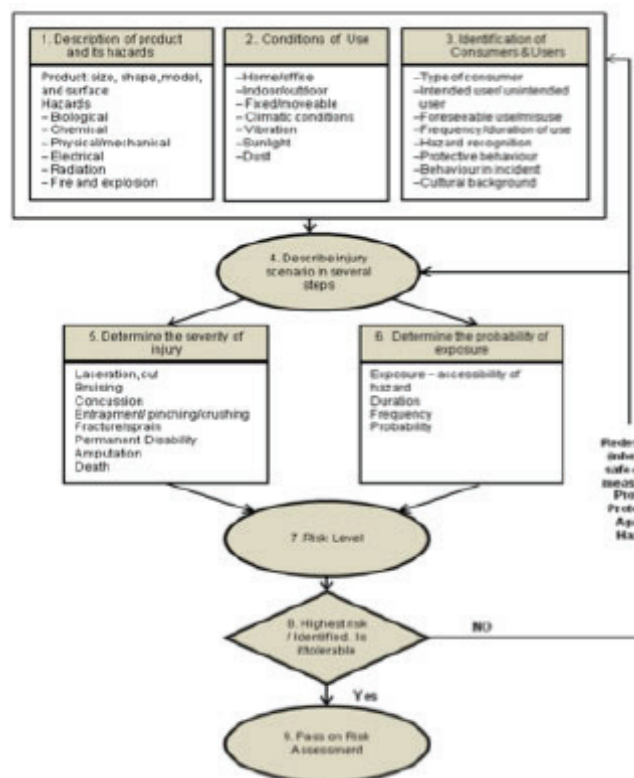
Id. at Clause 6, Risk Reduction, draft Figure 6: Example of Risk Reduction Process of an Organization*

- Hazard identification:** Product safety is a challenging issue in the promotional products industry because the ultimate use and users of the product are not always known at time of manufacture. Promotional products that are intended for use by adults may end up in the hands of children. This does not mean that every promotional product must be designed as safe for children of all ages, but it does mean that a determination about its appeal and foreseeable use by children needs to be considered when manufacturing or distributing a promotional product.
- Use, misuse, and abuse:** When determining foreseeable use, consider the product instructions and how the manufacturer intended the product to be used. This includes warnings, labels, and illustrations. Consider also the product features and how a consumer may use it if they did not read the instructions.
- Testing requirements:** Implement a production testing plan that provides a high degree of assurance in continuing compliance. This includes incorporating process management techniques such as control charts, statistical process control programs, or failure modes and effects analyses specific to each factory and product. When testing children's products, the minimum testing requirement is typically annual. However, if the production testing plan includes product testing by an ISO 17025 accredited test lab, periodic testing may be extended to once every three years.
- Technical file requirements:** A technical file is a comprehensive collection of information and

documents that details nearly everything about your product. Documentation should include details about the design, manufacture, and operation of a product as well as compliance documentation.

In the design stage, a risk assessment will aid in determining the design specifications with consideration given to the foreseeable use and foreseeable misuse of a product. Document requirements are established here based on regulations and voluntary standards.

Understanding consumers and how they may use the product enables safety to be designed into the product up front. This risk assessment chart guides developers through creating scenarios for how people may use a product.



The results of the risk assessment provide essential information that will make a product safer.

2. Production Stage: During the production stage the pre-work established and completed during the design stage is set into motion. Actual steps will be established to incorporate basic principles of product safety throughout the entire manufacturing process. Best practices in this stage include:

- Design validation
- Prototypes
- Materials management (purchasing)
- Machining and tooling
- Testing protocols
- Product inspections and factory audits

Proper training and adequate resource allocation are critical to ensure consistency in manufacturing safe product. Robust records management and document control procedures are essential components of an effective manufacturing and quality control process intended to produce safe products.

With the rise of extended supply chains and reliance on multiple production facilities for all component parts, it is imperative that all production partners are closely monitored. It is important to ensure that all production partners and subcontractors have established processes for assessing and verifying raw materials, components, and subassemblies. In addition, ongoing production quality monitoring and finished product testing processes provide direction for how to deal with material shortages and other manufacturing issues that may arise.

3. Marketplace Stage: This stage directly impacts the distributor and supplier. Both the supplier, or importer of record, and the distributor have an obligation to only introduce safe products to the market. Once in the market, proactive data collection efforts through monitoring of defects, incidents, ongoing assessments of product, warranty issues and other trends will enable the manufacturer to make assessments regarding the actual risk associated with the product and provide for necessary corrective actions including but not limited to recalls.

A pre-purchase agreement with vendors is recommended to define how incidents will be handled and what role each party will assume in the corrective action, reporting to regulators and communicating to customers and/or the public.

When selling abroad, knowledge of international laws and the laws that govern the destination country are also an element of an effective product safety program as this gives an organization control over what standards to apply based on the final destination.

Product identification and traceability, whether selling domestically or internationally, protects you, your company and your customers while enabling you to more easily find your products once in the stream of commerce.

- Identification and traceability best practices will enhance the ability to trace a product back to the original source which improves recall effectiveness. The more unique a product is the easier it is to identify and trace. The more a product resembles other products on the market, or the more generic it is, the more difficult it is to identify and trace. Traceability also protects businesses by helping them know where their products are in the stream of commerce. In addition, to the advantages of traceability best practices, certain laws require specific identification and forms of traceability.

- Unique or specifically mandated markings, labels, and tags can assist with providing identification and traceability for products once in the stream of commerce. Examples include the Consumer Product Safety Improvement Act (CPSIA) which requires that all children's products, articles and toys have permanent tracking labels applied to the product and packaging. Additional examples include: technology markings, state chemical registries and plush registries to name a few.

Question to ask in this area:

- What are the traceability laws or regulations for the countries where the products will be marketed?
- Does the product carry a unique identifier?
- Can the original source of the product be traced back?

Standards And Guides

Full standards are available through ANSI <http://webstore.ansi.org/> and ISO <http://www.iso.org/>. Included are the standards, guides and bibliographies for ISO 10377.

- Annex A – List of ISO Standards and Guides
- Annex B – Guidance for small businesses
- Annex C – Hazard identification and risk evaluation
- Annex D – Product safety management plans
- Bibliography– List of national, regional and international guides and standards on consumer product safety

Summary

Regulators will look at industry best practices and voluntary standards, in addition to laws and regulations, when making decisions and handing down judgments. Regulators consider voluntary standard as a mandatory standard. According to the CPSC, companies are expected to know, understand, and apply all standards that apply to their products whether mandatory or voluntary.

- *“...Courts have permitted the introduction of voluntary safety codes and standards, such as those promulgated by ANSI, as evidence of applicable standards and have regarded the violation of such standards, where relevant to the factual circumstances of the case, as evidence of negligence...” – Kent Village Associates Joint Venture v. Smith, 657 A.2d 330, 337 (Md.App.1995)*
- *“Reliance on professional guidelines or standards is generally appropriate methodology for experts to use when opining on an applicable standard of care.” – Gilden v. US, 923 F.Supp.2d 168, 191 (D.C. 2013)*

Regardless of the relationship, a firm must “trust but verify” its supply chain. Document everything throughout the entire

process, from the design stage through production and once product enters the stream of commerce, in order to effectively monitor and manage incidents involving your products. Require your production partners to provide evidence they have a robust compliance program in place.

- Do you have any certifications, like ISO 9001?
- Do you have a Good Manufacturing Plan (GMP) in place? Is it documented?
- Do you know and practice the various parts of ISO 9001?

When making decisions, be sure to document your thought process, determinations, and results so that you have an accurate record of due diligence to share with regulators should you find yourself involved in a product investigation or recall. Regulators are much more amicable when due diligence can be demonstrated.

Product responsibility is not a one-time thing. It requires a consistent, documented approach and continuous monitoring. Documented policies provide the groundwork for effective guidelines, protocols, and procedures. These policies and procedures allow organizations to self-regulate and offer specific assurances to customers by being in compliance with various federal and state regulations.

Online Resources:

PPAI Environmental Responsibility:

www.ppai.org/corporate-responsibility/environmental-responsibility/

PPAI Product Inspections:

www.ppai.org/media/1812/pr-bp-product-inspection.pdf

International Standards:

www.ppai.org/media/1809/pr-bp-international-standards.pdf

Recalls: www.recalls.gov

CPSC Business Guidance:

<https://www.cpsc.gov/Business--Manufacturing/Business-Education/>

ISO: <http://www.iso.org>

ISO 10377 Consumer Product Safety Guidelines:

<https://www.iso.org/standard/45967.html>

ISO 10393 Product Recall: <https://www.iso.org/standard/45968.html>

Consumer Product Safety Improvement Act (CPSIA):

www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/

PPAI Webinar - Tech Products Part 2: What You Must Know

for Selling Promo Tech Products: <https://onlineeducation.ppai.org/products/technology-what-you-must-know-for-selling-promotional-tech-products>

PPAI Proposition 65: www.ppai.org/media/1814/pr-bp-proposition-65.pdf

PPAI State Regulations:

<https://www.ppai.org/media/1819/pr-bp-state-regulations.pdf>

PPAI Webinars: www.ppai.org/members/education/online-education/

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