Hazard Identification

Product safety is a challenging issue in the promotional products industry because the end use of the product is not always known at time of manufacture. Promotional products that are intended for use by adults are given out at tradeshows and in workplaces and 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.

Product Design

The majority of products recalled are due to design hazards rather than regulatory non-compliance. Standards and regulations are the minimum requirements. All products entering the U.S. stream of commerce must not simply be compliant—they must not expose consumers to undue risk of injury or even death.

To reduce the risk of injury consider the following:

- Regulatory test requirements – assure the product meets safety regulations and establish a quality assurance program
- Conduct an age analysis to determine the appropriate user
- Evaluate the design, beyond regulatory requirements, prior to production
- Review recall and injury data for similar products
- Establish manufacturing controls – define and document your expectations

The need for costly design changes can be reduced by addressing potential hazards early and throughout the product’s manufacturing process. Hazard checklists provide a list of known hazards that have been identified throughout the industry, typically through product incident reports, recalls, and medical injury analysis.

A decision tree, or fault tree analysis, is a deductive method of analysis, to evaluate the risks and rewards of each option, aimed at enhancing one’s decision process.

A Failure Modes and Effects Analysis is a systematic method for identifying the severity and likelihood of failures. This process helps to identify failure modes, or injuries, based on past experiences with similar products, with the intention of designing-out hazards based on potential consequences. This process aids in determining your company’s acceptable level of risk.

Human Factors

Human factors is an area of psychology that studies the relationship between people, their environment, and the objects in their environment. A human factors review will
typically go beyond the regulatory standards and try to anticipate foreseeable use and unintended use scenarios. This type of evaluation helps identify and correct vulnerabilities early in the design phase to reduce the possibility for injury and product recalls. A human factors evaluation may include:

- An age analysis to determine what is the appropriate age range for the product
- Intended and unintended users
- Foreseeable use and misuse
- Design evaluation and safety assessment
- Materials, assembly and production methods, packaging and labeling
- Injury analysis
- A design evaluation for fit, comfort and size

Children explore their environment and products through their senses; that is by touching, tasting, smelling, looking, shaking, and throwing. For these reasons a human factors analysis should take into consideration certain features of a product and evaluate how these features may promote alternative uses:

- Size, shape, and weight
- Material and texture
- Cause and effect features
- Sensory elements like smell
- Lights and sounds

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 he did not read the instructions.

Alternative uses or unintended users may stem from product similarities. Products that look like toys will be used by children. Additionally, the human factors analysis must incorporate the dynamic stages of child development, specifically the physical, social, and cognitive abilities and limitations of children.

Another factor to consider is how well the product fits the intended user, again that is matching physical characteristics of the product and the user. Children do not develop at the same rate, and factors such as gender, culture, racial differences and health, affect human development.

A human factors analysis can be conducted in house or contracted out to a third party test lab. It is important to ensure that the human factors expert is allowed to operate independently from the marketing, design and sales process.

**EU Toy Safety Directive**

The new European Toy Safety Directive, 2009/48/EC, includes an essential safety requirement that toys, including the chemicals they contain, shall not jeopardize the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behavior of children. This is where the human factors just discussed are so important.

In order to determine compliance of a product with this essential safety requirement, the European Directive mandates that a safety or risk assessment of each product be performed. It is a regulatory requirement that before placing a toy on the market, the manufacturer must carry out an analysis of the potential hazards and assess the potential exposure of these hazards. The hazards to be assessed include chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards. The requirement went into effect in 2011, for products imported into Europe as of that date, with the exception of chemical requirements, which went into effect in 2013.

**CPSIA**

In the US, while a formal risk assessment of a product design is not mandated, it is no longer sufficient to simply test a final product for compliance and be done with it. CPSC’s reasonable testing program, part of the Consumer Product Safety Improvement Act (CPSIA), requires not just a certification test of the final product, but
also a production testing plan to help ensure continued compliance and sufficient manufacturing quality controls. The manufacturer or importer must also know when and where the product is manufactured and have detailed product specifications on the item.

**Hazard Prevention**

Hazard prevention begins with identification. Efforts to protect consumers from preventable injuries begins with eliminating hazards through product design, especially for products that children will use.

For some products, it may not be possible to eliminate the hazards without affecting the products’ intended function and/or performance. In these instances, the strategy for reducing injury is to guard or shield against the hazard to prevent children from coming in contact with the hazard. When hazards cannot be eliminated by use of the first two methods, designing out or guarding against; the last line of defense is to provide a warning. The goal in providing a warning is to draw attention to the hazards so that behaviors can be modified as needed. This is considered the lowest line of defense because behavioral change depends on a number of factors, including whether or not the consumer notices and reads the warning.

When all three preventative measures fail to work, removing products from the market though a public product recall may be the last resort. Due to the steps required for a successful product recall, and the need for consumer awareness, designing hazards out continues to be the best defense.

**Online Resources**

- **Consumer Product Safety Commission**: [www.cpsc.gov](http://www.cpsc.gov)
- **Recalls**: [www.recalls.gov](http://www.recalls.gov)
- **American National Standards Institute (ANSI)**: [www.ansi.org](http://www.ansi.org)
- **ASTM International**: [www.astm.org](http://www.astm.org)
- **Global Classification Codes**: [www.gs1.org/gdsn/gpc](http://www.gs1.org/gdsn/gpc)
- **U.S. Customs and Border Protection**: [www.cpb.gov/](http://www.cpb.gov/)