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Consumer product safety — Guidelines for suppliers

Sécurité des produits de consommation — Lignes directrices pour les fournisseurs

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is Project Committee ISO/PC 243, *Consumer product safety*.

Introduction

A number of governments have established laws and requirements for suppliers to place only safe products on the market. In this way, they are trying to deal more broadly with dangers associated with consumer products, rather than developing standards or regulations for every single product.

However, many suppliers have limited experience and few available resources or practical reference documents to guide them through this process, which consists of the following:

— identifying the hazards;

— assessing the risks;

— identifying and implementing risk reduction measures;

— identifying and reducing risks in the production process;

— implementing processes to trace and identify products;

— communicating use and warning information to consumers;

— monitoring the product in the marketplace;

— identifying any safety risks and managing them.

This International Standard provides practical guidance for suppliers of all sizes to assist them 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. This International Standard is intended to be particularly valuable to small and medium-sized enterprises, as well as to suppliers that do not design or produce products, but are still responsible for their safety in many jurisdictions. To assist them, useful information and examples are provided in Annex B.

The supply chain for consumer products is made up of a number of suppliers, often in different parts of the world, where products or product components are being designed, produced and sold in other countries. Therefore, it is important that the guidance provided is aligned with international best practice, easy to understand and applied consistently by suppliers. The overall objective of following internationally consistent guidance is to produce safer consumer products, and thereby:

a) reduce the product safety risks to consumers;

b) reduce the risks to suppliers of product recalls;

c) provide consumers with the information they need in order to make informed choices with respect to the safe use and disposal of consumer products;

d) assist governments by improving the safety of consumer products.

This International Standard does not cover issues such as worker safety, protection of the environment, or social and ethical issues, which are covered extensively by other standards. Instead, this International Standard focuses on consumer products and providing guidance on reducing the risk of harm to consumers and users. It has been developed in parallel with ISO 10393, which focuses on product recall. The relationship between this International Standard and ISO 10393 is illustrated in Figure 1.

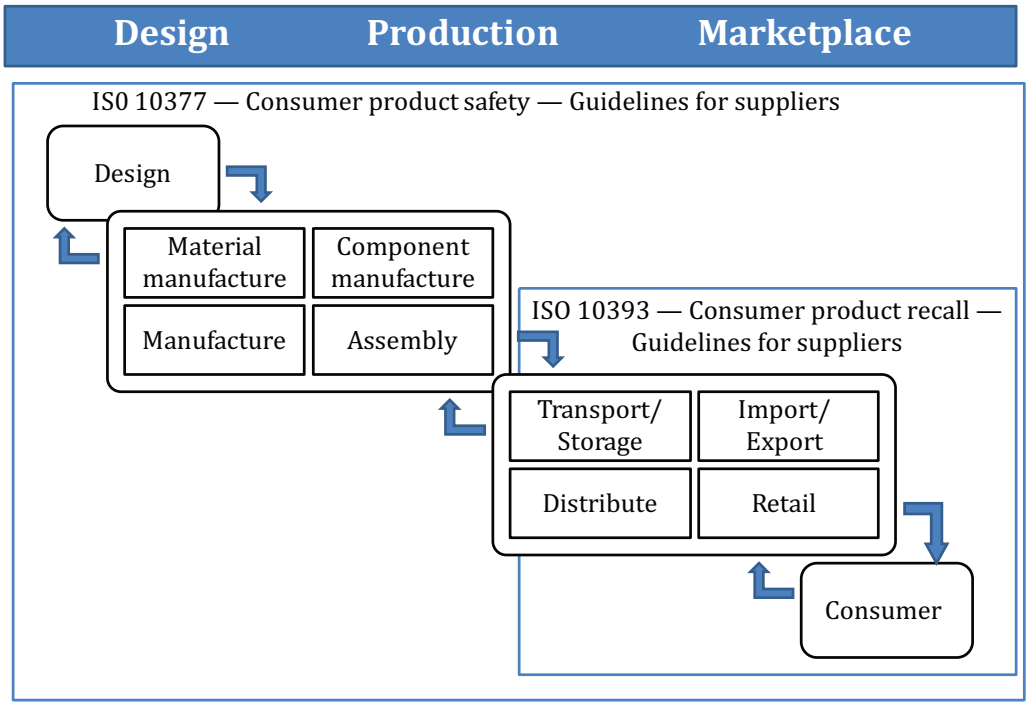

Figure 1 — Relationship between this International Standard and ISO 10393

It is important that suppliers maintain an awareness of and comply with the laws and regulations of the countries where the products are manufactured, imported, distributed or sold.

ISO/IEC Guide 51 and the revisions proposed to it were taken into account in the drafting of this International Standard.

This International Standard is presented in the form of practical guidance. Terms used in this International Standard are defined in Clause 2, although individual countries have established or might establish different specific definitions in law. Clauses 3 and 4 provide principles and general requirements that apply to all members of the supply chain. Clauses 5, 6 and 7 are targeted to specific sectors of the supply chain. Information on relevant International Standards and Guides, useful information for small business, examples related to hazard and risk evaluation, and product safety management plans are provided in Annexes A, B, C and D, respectively.

Consumer product safety — Guidelines for suppliers

1 Scope

This International Standard 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.

This International Standard describes how to:

— identify, assess, reduce or eliminate hazards;

— manage risks by reducing them to tolerable levels;

— provide consumers with hazard warnings or instructions essential to the safe use or disposal of consumer products.

This International Standard is intended to apply to consumer products, but might also be applicable to decisions concerning safety in other product sectors.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
consumer
individual member of the general public purchasing or using property, products or services for private purposes

[SOURCE: ISO 26000:2010, 2.2]

2.2
consumer product
product designed and produced primarily for, but not limited to, personal use, including its components, parts, accessories, instructions and packaging

2.3
competent
suitably trained or qualified by knowledge and practical experience to enable the required task or tasks to be carried out

[SOURCE: ISO 22846-1:2003, 2.6]

2.4
corrective action
action intended to remove potential for harm and to reduce risk

Note 1 to entry: For the purposes of this International Standard, corrective actions are referred to as “recalls” because the public and media more readily recognize and respond to that description.

[SOURCE: ISO 10393:2013, 2.4]

2.5
foreseeable misuse
improper or incorrect use of a product that is capable of being known or anticipated in advance, based on a supplier's best knowledge about the product and human behaviour

EXAMPLE Improper use by children or the elderly.

2.6
foreseeable use
use of a product that is capable of being known or anticipated in advance based on a supplier's best knowledge about the product

2.7
harm
physical injury or damage to the health of people, or damage to property

[SOURCE: ISO/IEC Guide 51:1999, 3.3, modified]

2.8
harmful event
occurrence in which a hazardous situation results in harm

[SOURCE: ISO/IEC Guide 51:1999, 3.4]

2.9
hazard
potential source of harm

Note 1 to entry: The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, biological hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

[SOURCE: ISO/IEC Guide 51:1999, 3.5]

2.10
hazardous situation
circumstance in which people or property are exposed to one or more hazards

[SOURCE: ISO/IEC Guide 51:1999, 3.6, modified]

2.11
intended use
use of a product in accordance with information provided by the supplier

[SOURCE: ISO/IEC Guide 51:1999, 3.13, modified]

2.12
organization
entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives

Note 1 to entry: For the purposes of this International Standard, organization does not include government acting in its sovereign role to create and enforce law, exercise judicial authority, carry out its duty to establish policy in the public interest or honour the international obligations of the state.

[SOURCE: ISO 26000:2010, 2.12, modified]

2.13
product recall
corrective action taken post production to address consumer health and safety issues associated with a product

[SOURCE: ISO 10393, 2.12]

2.14
protective measure
means used to reduce risk

Note 1 to entry: Protective measures include risk reduction by inherently safe design, protective devices, personal protective equipment, information for use and installation, and training.

[SOURCE: ISO/IEC Guide 51:1999, 3.8]

2.15
residual risk
risk remaining after protective measures have been taken

[SOURCE: ISO/IEC Guide 51:1999, 3.9]

2.16
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:1999, 3.2]

2.17
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:1999, 3.10]

2.18
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: ISO/IEC Guide 51:1999, 3.12]

2.19
risk communication
exchange or sharing of information about risk between the decision maker and other stakeholders

[SOURCE: ISO/IEC Guide 73:2002, 3.2.4, modified]

2.20
risk evaluation
procedure based on the risk analysis to determine whether the tolerable risk has been achieved

[SOURCE: ISO/IEC Guide 51:1999, 3.11]

2.21
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO Guide 73:2009, 2.1]

2.22
risk reduction
actions or means to eliminate hazards or reduce risks

2.23
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 51:1999, 3.1]

2.24
supplier
organization or person that provides a product or service

EXAMPLE Designer, producer/manufacturer, importer, distributor, or retailer of a product.

Note 1 to entry: A supplier can be internal or external to the organization.

Note 2 to entry: In a contractual situation, a supplier is sometimes called “contractor”.

[SOURCE: ISO 9000:2005, 3.3.6, modified]

2.25
supply chain
network that designs, manufactures, imports, distributes and sells a product

2.26
tolerable risk
risk which is acceptable for a specific user group based on the current values of society

Note 1 to entry: For the purposes of this International Standard, the terms “acceptable risk” and “tolerable risk” are considered to be synonymous.

[SOURCE: ISO/IEC Guide 51:1999, 3.7, modified]

2.27
traceability
ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component

[SOURCE ISO 9000:2005, 3.5.4, modified]

2.28
unforeseeable misuse
use of a product in a manner that a supplier cannot reasonably know or anticipate

2.29
user
person who interacts with the product or service

2.30
vulnerable consumer
consumer who could be at greater risk of harm from products due to their age, level of literacy, physical condition or limitations, or inability to access product safety information

3 Basic principles for addressing consumer product safety

3.1 General

Adherence to the basic principles in 3.2 to 3.7 will assist members of the supply chain to develop and maintain a shared commitment to consumer product safety. This includes a commitment to the prompt implementation of corrective action when hazards are identified as a result of incorrect design, deficiencies in the production process and problems during distribution or storage.

3.2 Promoting a product safety culture within the organization

Consumer product safety should be a key consideration in the organization’s governance structure. This can be accomplished by putting in place a product safety management plan that is implemented and endorsed by the governing body and/or top management. Examples of two different approaches to product safety management plans are presented in Annex D.

The organization should understand and comply with the laws, regulations and standards that cover the consumer product produced for the marketplace in which the product is manufactured or sold. Responsibility for compliance should be clearly stated and assigned with appropriate resources allocated to develop, maintain, monitor and continually improve the product safety compliance programme.

3.3 Promoting a product safety culture outside the organization

An organization should promote a consumer product safety culture throughout the supply chain. Such promotion may include setting contractual provisions or incentives, promoting good industry-wide practices, forming partnerships with sector organizations and others, sharing of information, and providing consumers with the information they need to assemble, use, maintain and dispose of a consumer product safely (see ISO 26000).

3.4 Committing to providing safe products

Product safety is best addressed at the design stage to reduce the risk from hazards. This will help to avoid the need to expend resources to fund the costs of the recall of unsafe products and the potential of redesign and retooling. Management is accountable for assigning responsibilities for implementing the principles and guidance set out in this International Standard, including providing appropriate resources for training, records management and product traceability.

3.5 Continual improvement

A structured approach for continual improvement that defines objectives for the improvement of consumer products and processes through the analysis of data should be applied to safety in product design, production and the marketplace. Continual improvement activities and their outcomes should be documented and regularly reviewed by management so that continual improvement objectives are being met.

3.6 Precautionary approach

The precautionary approach means that the lack of full scientific certainty should not be used as a reason for postponing risk reduction measures, especially where there are threats of serious or irreversible damage to human health. Due to the increased use of and reference to the precautionary approach, suppliers should consider it when assessing the safety of consumer products.

3.7 Sharing of information

The organization should share information on a continuous basis on the product's performance, compliance, and risks with other members of the supply chain.

4 General requirements

4.1 General

The key issues for all members in the supply chain (designers, manufacturers, importers, distributors and retailers) include the following:

a) designing safety into the consumer product;

b) identifying the potential hazards associated with their products;

c) determining or estimating exposure to the potential hazard;

d) assessing the risks to consumer health and safety;

e) managing these risks by eliminating or reducing them to a tolerable level;

f) providing consumers with hazard warnings and instructions essential to the safe use and disposal of the products;

g) approving any change or substitution of design, materials, or production processes.

The functions carried out by members of the supply chain are outlined below and illustrated in Figure 2:

— design: the development of the requirements and specifications to make a consumer product, taking into consideration the product's intended use and foreseeable use and misuse;

— material manufacture: the production of materials to be used in the manufacturing process;

— component manufacture: the production and supply of component products to be used in the manufacture of another product;

— assembly: the production of a consumer product by assembling components that may be used to manufacture another product, or may be a final product;

— manufacture: the production of a product to be supplied to a purchaser;

— transport: the movement of products from one location to another;

— storage: the temporary storage of products, intended for distribution;

— import/export: the movement of products into and out of a country;

— distribute: the logistics function to store and move products, which may employ transport and import/export functions;

— retail: the marketing and sales of products to consumers, which may employ transport, import/export, distribution and storage functions, in getting the product to its final destination;

— consumer: the purchaser and user of a product, who may also install, service, maintain or repair a product, or cause these to be done.

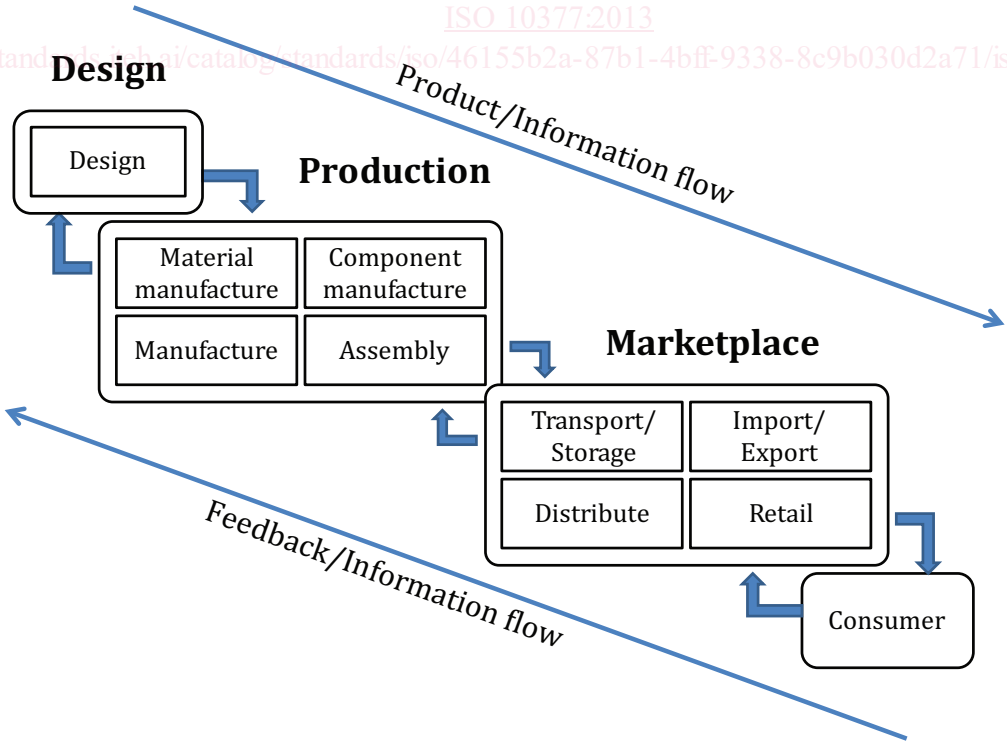

Figure 2 — The supply chain

4.2 Commitment to providing safe consumer products

4.2.1 Competency and training

The organization should ensure that those involved in consumer product safety, whether they are internal or external to the organization, have the necessary education, training, technical knowledge and experience for carrying out their responsibilities.

The organization should establish and maintain (a) procedure(s) for the following:

a) to define the competency requirements for those responsible for consumer product safety;

b) to ensure competency to carry out duties and responsibilities for consumer product safety, including product safety specifications;

c) to inform those involved in the safety of consumer products about the potential consequences of providing unsafe products.

Training activities may be provided either within the organization or by external sources and should include elements that are:

— based on the competency requirements and the duties and responsibilities for ensuring consumer product safety;

— conducted by competent persons;

— updated as required to ensure that information remains current;

— evaluated and modified as necessary to ensure relevance and effectiveness;

— recorded appropriately and kept by the organization.

4.2.2 Adequate resource allocation

An organization should ensure that appropriate technical, financial and human resources are allocated to safety in design, production and/or the marketplace, e.g.

— financial and human resources;

— access to expertise and relevant reference documents on consumer product safety;

— training of staff on consumer product safety issues;

— records management and document control;

— verification and testing to determine if ongoing production continues to meet safety requirements.

4.2.3 Records management and document control

The organization should establish and maintain procedures to record, control, retain and retrieve all principal documents and data that reflect safety in design, production and the marketplace. These items should include the following:

— records arising from the implementation of this International Standard;

— records required to comply with laws and regulations;

— documents created during management of safety in design (see Clause 5), e.g.

  — hazard analysis and hazard reduction plan;

  — significant design choices and safety decisions;

  - drawings, product specifications and bill of materials;
  - product quality tests and approved product samples;
  - validation of the design;
  - warnings and instructions and language(s) in which they are produced;
  - design testing and inspection;
  - cost-benefit analysis of corrective action options;
  - compliance with regulatory requirements and product specific industry standards;
  - third-party testing and conformity assessment, as required;
- documents created during management of safety in production (see Clause 6), e.g.
  - good manufacturing practices;
  - quality assurance records;
  - purchase orders and instructions to the supply chain;
  - testing and inspection at the factory;
  - third party testing of ongoing production, as required;
  - production plan, design validation and creation of the product prototype;
  - change requests and subcontracting;
  - contamination incidents;
  - production readiness, including supply chain management, tooling, commissioning the factory, training and product specifications;
- documents created during management of safety in marketplace (Clause 7), e.g.
  - post delivery inspections, audits and consumer product safety testing;
  - consumer complaints and consumer product safety incidents;
  - records from the sale and distribution of products throughout the supply chain;
  - product literature, including advertising, marketing and packaging;
  - communications with suppliers and consumers, including product registration, post-sale warnings, market surveys and feedback from buyers;
  - reasons for returned products and service records;
  - corrective actions.

Documents created should reflect information and records retained from the original design, production and marketplace, as well as those generated as a response to potential hazards, issues, complaints and reviews about the organization's products. All written responses should be placed in the organization's own product files to record that the organization considered all available information about the product, its hazards and its risks. In addition, records related to the expiry date of a product and its useful life should be recorded.

Documents created during all stages in the supply chain should be retained at a minimum for the reasonable life of the consumer product, or as required by law. The documents should be consulted before the next production cycle of the product as part of the organization's continual improvement process.