
Consumer product recall — Guidelines for suppliers

*Rappel de produits de consommation — Lignes directrices pour les
fournisseurs*



This document is a preview generated by EBS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
3 Purpose and principles	4
4 General requirements	4
4.1 General	4
4.2 Policy	4
4.3 Documentation and record keeping	5
4.4 Regulatory requirement	5
4.5 Expertise required to manage a recall	5
4.6 Authority for key decision	6
4.7 Training and recall simulation	6
5 Assessing the need for a product recall	8
5.1 General	8
5.2 Incident notification	9
5.3 Incident investigation	9
5.4 Assess the risk	10
5.5 Traceability	10
5.6 Product recall decision	11
6 Implementing a product recall	11
6.1 General	11
6.2 Initiate the recall action	12
6.3 Communication	14
6.4 Implement the recall	16
6.5 Monitor and report	17
6.6 Evaluate effectiveness	18
6.7 Review and adjust recall strategy	19
7 Continual improvement of recall programme	20
7.1 General	20
7.2 Reviewing the recall	20
7.3 Corrective actions to prevent reoccurrence	21
Annex A (informative) Hazard and risk evaluation	22
Annex B (informative) Examples of product recall posters and press releases	27
Annex C (informative) Product recall checklist	31
Annex D (informative) Improving recall effectiveness — Examples	32
Bibliography	38

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

The committee responsible for this document is Project Committee ISO/PC 240, *Product recall*.

Introduction

There is a wide variety of products available to consumers in the global marketplace. Products routinely travel across borders in order to meet increasing consumer demand as suppliers seek to lower cost and expand markets. While many products are safe and fit for intended use, statistics show that, each year, millions of people suffer injuries or illness, or die from unsafe products.

While regulations and standards exist in many countries, and industries do all they can to make products safe and fit for intended use, problems related to design flaws, manufacturing defects, inadequate warnings or instructions still result in unsafe products entering the marketplace. In those instances, it is critical that corrective actions, which include recall, are carried out quickly and effectively. Although many countries have regulatory requirements and guidance for suppliers to conduct product recalls, many do not. Even in countries with well-developed requirements, recalls may be ineffective. As a result, there are inconsistencies in the approaches to product recall and other corrective actions, and products that pose health or safety risks to consumers remain in the marketplace.

This International Standard is designed to provide practical guidance in determining whether corrective actions, including recalls, need to be carried out by the supplier of consumer products. It also provides best practices for conducting a product recall if it is necessary. The guidance provides information and tools that suppliers of all sizes can use to develop a documented and validated product recall programme that will help them implement timely and cost-effective recalls, minimize legal and reputation risks, and reduce health or safety risks to consumers.

Although this International Standard is intended for suppliers, it might also help government agencies in developing or improving product recall policies and guidelines.

Broad application of this International Standard will lead to a more consistent approach to removing unsafe products from the global marketplace, to improving coordination between government and consumer products organizations in different countries, and to increasing consumer confidence in the safety of products available in the marketplace.

This International Standard has been developed in parallel with ISO 10377, which focuses on product safety. The relationship between this International Standard and ISO 10377 is illustrated in [Figure 1](#).

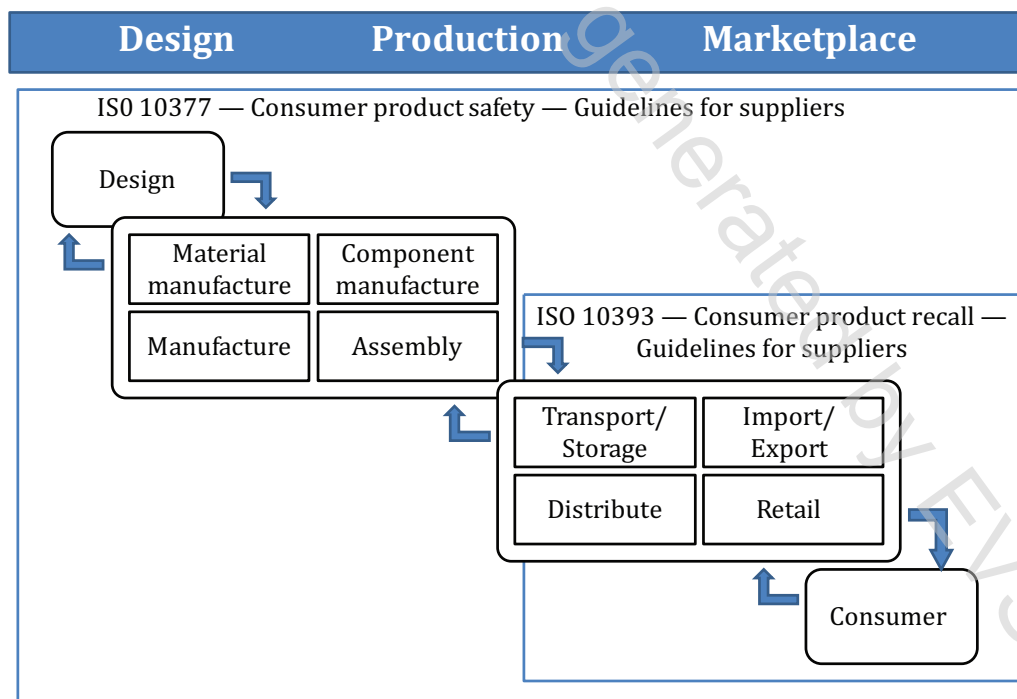


Figure 1 — Relationship between this International Standard and ISO 10377

Consumer product recall — Guidelines for suppliers

1 Scope

This International Standard provides practical guidance to suppliers on consumer product recalls and other corrective actions after the product has left the manufacturing facility. Other corrective actions include, but are not limited to, refunds, retrofit, repair, replacement, disposal and public notification.

This International Standard is intended to apply to consumer products, but might also be applicable to other 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

[SOURCE: ISO 10377:2013, 2.2]

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.

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.

[SOURCE: ISO 10377:2013, 2.5]