

**Baker
McKenzie.**



**GLOBAL
PRODUCT RECALL
Handbook**

FOURTH EDITION

Global Product Recall Handbook

Fourth Edition



Foreword

Baker McKenzie was founded in 1949. For almost seven decades, we have provided nuanced, sophisticated advice and leading-edge legal services to many of the world's most dynamic and successful business organizations.

With more than 7,000 internationally experienced lawyers in 47 countries, including 36 of the world's largest economies, Baker McKenzie provides expertise in all of the substantive disciplines needed to formulate, develop and implement a global product recall. Our fluency in working across borders, issues and practices allows us to simplify legal complexity, foresee regulatory, legal, compliance, reputational, and commercial risks others may overlook and identify commercial opportunities that many miss. Taken together, this combination of deep practical experience and technical and substantive skills makes us advisers of choice to many of the world's leading multinational corporations.

Our clients want a new breed of lawyers with excellent technical skills and industry expertise who can look ahead to help them navigate a constantly changing product regulatory landscape. It means having lawyers who can anticipate what is coming next and provide practical legal resources that are helpful to the business at all levels. The Global Product Recall Handbook is one such resource, collecting, combining and synthesizing the advice of lawyers throughout Baker McKenzie focused on the consumer goods, pharmaceutical and medical devices, food and beverage, and motor vehicle industries. We are pleased also to make this edition of the Handbook available on a dedicated Dynamic Publisher site and accompanying mobile app. Both the site and the app make accessing the content easy and allow our readers to search and compare topics for jurisdictions of interest, at the click of a button.

On behalf of the editors and contributors, we are very proud to publish the fourth edition of our extremely popular Global Product Recall Handbook. We hope you continue to find it a useful tool.

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Editors' Note

Baker McKenzie is pleased to provide you with the updated fourth edition of its popular publication, the Global Product Recall Handbook. With decades of experience advising clients on multi-jurisdictional product recalls, we coordinate and manage the legal and strategic aspects of world-wide product recalls for many of the world's best known manufacturers of consumer and B2B products. This handbook reflects that experience, summarizing and integrating product recall laws and related regulatory standards for general consumer products in 45 countries. The Handbook truly lives up to its global title.

This edition updates the country content to reflect the ever-changing product regulatory environment affecting product recalls. Additionally, and recognizing that many countries have enacted specific regulatory regimes that address product recalls for specialty consumer products, we felt it critical to expand this fourth edition to cover such product-specific regimes. Each country chapter therefore has a section dedicated to addressing any recall regulations that are specific to pharmaceuticals and medical devices, food and drink, and motor vehicles.

This Handbook is the product of the efforts of dozens of lawyers across Baker McKenzie focused on the consumer goods, healthcare, food and automotive industries and experienced in product recalls, many of whom are listed in the following pages. The editors are extremely grateful to these knowledgeable lawyers for their contributions.

The Handbook is one of two product recall-related resources available. We also offer a Product Recall Portal, an online repository that contains everything you need to manage the legal aspects of your recall. In difficult situations, it is crucial to have access to the right information as quickly and as simply as possible, from experts who have seen it all before. The portal is an easy way to keep track of all aspects of a global recall in one place. We would be happy to share

more information on our Product Recall Portal and its capabilities, and how it can help your business.

For further details on any of the information contained in this Handbook, or to obtain additional copies or gain access to the Dynamic Publisher site, please contact one of us or your Baker McKenzie relationship partner. Further details on the firm, our people, and our practice groups may be found at www.bakermckenzie.com.

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Chapter 1

Introduction

The global movement of products is a reality for most companies, large and small. More and more companies are outsourcing their manufacturing or sourcing their component parts or materials from suppliers located in jurisdictions far away – and often far different – from their own. With these realities comes the need to address the possibility that somewhere in the chain of supply or distribution, product safety may be compromised. Government regulators across the globe are exercising their supervisory powers to ensure product safety, and are cooperating with each other more than ever before. Legislative focus on product safety has also increased, resulting at times in disparate regulations and laws throughout the globe that require heightened compliance diligence.

Consumers and regulators both continue to demand more information about where products are manufactured, what materials are contained in products, and how well products are made. If a product presents a health or safety hazard, regardless of how the problem arose or whose ultimate problem it is, there is an immediate focus on the use of a corrective action, such as a product recall, to eliminate the hazard. For ease, we refer throughout this Handbook to product recall, while noting that there are many other corrective actions, short of a full, consumer level product recall, which may be appropriate and legally permissible in any given situation.

Indeed, since the first edition of this book was published in 2006, the number of product recalls has continued to increase, resulting in an almost daily announcement of a large-scale consumer product recall somewhere in the globe. Recalls of products sold in multiple jurisdictions largely require companies to assess the appropriate response on a country-by-country basis. Against this backdrop, the importance of foreseeing and planning for multijurisdictional consumer product recalls cannot be overemphasized. If a product sold globally presents a safety issue, understanding local rules for

responding to and correcting or eliminating the issue in every country where that product is located is critical to ensuring the implementation of a rapid, effective global response. Particularly in the present regulatory environment, manufacturers failing to prepare for and implement product recalls properly and promptly may confront an array of short- and long-term problems in the jurisdictions where affected product is found: a crisis of consumer confidence; an onslaught of adverse media publicity; multiple product liability claims; irreparable reputation and brand damage; plummeting profits and stock price; substantial regulatory fines and business interruption; and criminal penalties. Worst of all, in the most egregious cases, some companies may even face the specter of lives lost or serious injuries sustained when those tragedies might have been prevented.

Baker McKenzie's product safety lawyers regularly advise manufacturers, retailers and other clients confronting the challenges associated with global product recalls. We assist them in managing those challenges by approaching the issue holistically. We assess the recall requirements of affected jurisdictions, coordinate regulatory communications, prepare the corrective action plan, develop appropriate media responses to increase consumer awareness and protect the corporate brand, formulate appropriate litigation strategies, and work closely with senior executives as they make each critical decision in the process.

Product recalls and corporate crisis management, particularly on a global scale, are areas of practice where Baker McKenzie has unique advantages and capabilities that set us apart from other law firms. With 77 established offices in 47 countries, we have the ability to seamlessly implement global product recalls in multiple jurisdictions and to defend our clients against any regulatory investigations or resulting claims, whether in courts, alternative dispute resolution forums, or before other tribunals. Indeed, our lawyers are local lawyers, licensed in over 250 jurisdictions, familiar with local laws, regulations, practices and customs in their respective jurisdictions. For



global recalls and the claims that so often flow from them, this local perspective in major markets around the world provides great benefit to our clients.

This Handbook reflects that need for global preparedness and responsiveness. Drawing on decades of experience from our extensive global team of product liability lawyers, it includes jurisdiction-specific information on planning for the multi-country product recall. In each country, we offer an overview of four topics: (1) Definition of a “consumer product”; (2) Agencies involved in regulating consumer products; (3) Reporting requirements and recall procedures; and (4) Legal consequences of noncompliance. We felt these four topics are the most important and relevant starting points that manufacturers, retailers and other entities in the chain of supply and distribution need to consider in making a preliminary assessment of whether – and how – to conduct a consumer product recall in each jurisdiction.

We also felt it was critical to address the existence of recall-related regulations and regimes in many countries for specialty consumer products. We have therefore added a section in each country chapter addressing such regulations for pharmaceuticals and medical devices, food and drink, and motor vehicles and their parts.

As important as effective recall implementation and the defense of related litigation are, proactive planning can go a long way toward reducing global recall and product liability risks so that the need for any form of corrective action, such as a recall, can be minimized on the front end. We regularly prepare and review product recall protocols and procedures. We emphasize the importance of pre-litigation counseling on product warnings, labeling, and directions for use. Product warnings, for example, cannot be assessed without examining how consumers use a particular product – and that assessment may require a careful review of how local customs and practices affect consumer behavior. Contract provisions in the supply and distribution chains related to product safety, warranty, insurance and indemnification are also critical steps in proactively limiting a

company's exposure to global recall and product liability risks. It is advisable for companies to consider all these issues before problems arise, because doing so makes responding to a global product issue easier to manage.

The reader is advised that the systems and bodies of law in most countries are ever changing, as is reflected by the need to publish this fourth edition within a decade of the initial edition. This Handbook is designed to be a starting point for more in-depth review and analysis. It is not intended to serve as a definitive statement setting forth the laws and regulations applicable to every consumer product recall; nor is it a substitute for legal advice tailored to individual client requirements.



Chapter 2

Managing a Global Product Recall – Best Practice Guidelines

Managing a global product recall or other corrective action campaign, which can include the withdrawal from sale, replacement, retrofitting and/or refurbishment of the product, requires a manufacturer, supplier, distributor or retailer to consider an array of issues. The most important of these is ensuring consumer safety, as protecting consumers from injury is the paramount priority. Closely aligned with this priority is complying with regulatory requirements in all jurisdictions where the product is found. Next is the natural desire of the manufacturer, supplier, distributor or retailer to ensure that any product recall or corrective action campaign helps to avoid or at least mitigate potential product liability. Finally, the company involved in a recall will wish to minimize or, where possible, avoid altogether, collateral damage either to product goodwill or the company's overall reputation. These objectives should not be regarded as conflicting, for if the first two are achieved, accomplishment of the second two frequently follows.

The primary purpose of a product recall is to bring the product risk to the attention of affected consumers and to enable them to adopt the company's recommended corrective measures as quickly as possible. How this is accomplished depends in part on how recalls are to be conducted in jurisdictions where the affected product is found. Regulatory compliance is an important component of every product recall, and many countries or regulatory bodies have mandatory reporting requirements in place. Failure to comply may be met by the application of various enforcement mechanisms, which differ from jurisdiction to jurisdiction. These mechanisms may include mandating a recall, destroying products or placing them in quarantine, closing the borders to any further imports, assessing significant civil or regulatory fines, and even imposing criminal penalties.

For many manufacturers and others in the chain of production and distribution, however, the question of whether even to conduct a product recall is not always clear-cut. In many instances, judgment calls need to be made about whether the product actually presents a safety risk to the consuming public, often with little notice to the company and with an incomplete picture of the key facts at its disposal. In reaching an informed decision, a company's management team should investigate the facts, engage the appropriate technical and operational expertise, whether internal or external, and then assess the potential risk or hazard presented by the product in question. Decisions often need to be made very quickly, with input from experienced, qualified team members. If a product recall and notification to the public are not initiated when they should have been, the specter of serious bodily injury, coupled with the damage to a company's goodwill and business reputation, regulatory fines, criminal penalties or resulting litigation, are potentially catastrophic.

The risks associated with mishandling a product safety issue or product recall highlight the need for pre-planning during calmer times. Prepared proactively in advance rather than reactively in response to a series of major product safety complaints, an effective product safety protocol can go a long way towards guiding the prudent company when confronted with a crisis. A product safety protocol should be tailored to reflect the business of each company. A "one size fits all" approach is almost always less effective than a customized one, particularly for companies that sell products globally.

Some recommended best practices commonly included in many comprehensive product safety protocols are set forth below.

Before a Safety Issue Arises

(a) Identify Decision-Makers

A company's product safety protocol should identify what to do, whom to contact, when to share the information, and where the



relevant information is located in the event it becomes necessary to assess a product safety issue. It is advisable to establish a clear line of reporting for all product safety issues so that the appropriate decision-makers are aware of them in timely fashion. It may be advisable to identify a product safety or risk management director or committee to whom any safety related complaints from customers will be directed and whose members will help assess and implement the planning and execution of any product recalls that become necessary. However, it is expected that senior management and board or governing body oversight of corporate product safety compliance efforts exists.

(b) Know Your Supply Chain and Distribution Channels

A company that knows its products, its supply chain, and its distribution channels well is likely to find a product recall much easier to plan and implement.

Companies first need to fully understand what is in their products and where those components come from (and what, in turn, is in them). Failures in the supply chain are ripe sources of product safety issues. Companies also need to be able to track the distribution of their products. Some companies track only the initial sale of a product, but when a product safety issue arises, they find that they are requested, and in some countries required, to provide details on the entire chain of distribution to the end user. Some consumer product safety laws have attempted to codify the requirement that a product be traceable through a tracking label to assist in implementing a product recall.

If a recall is undertaken, regulators are concerned about its efficacy, which requires companies to demonstrate that they diligently took steps to reach affected consumers and notify them of the product safety issue and any corresponding corrective action. Information about where the affected product is located - whether in inventory, with retailers, or with consumers - should be readily available to the person or team members who will be responsible for managing the recall.

In addition, information about both the supply chain and product distribution channels is typically necessary to comply with regulatory reporting and recall requirements in most jurisdictions. Adequate recordkeeping of such information makes any regulatory reporting easier to complete. Examples of information that will need to be supplied to regulators, and therefore should be adequately maintained and easily accessible, include:

- Details of the company making the notification and contact details of the representative who will be the liaison point with the regulator (address, telephone/fax number, website and email address)
- Full details of the affected product (including a description, brand name, model/serial number/bar code and a digital photograph that the agency can post on its own site if its local laws or policies require that it do so)
- A description of the nature of the defect and possible injuries to persons and property it might cause (or has already caused, if any), and its root cause
- Details (address, telephone/fax number and email address if possible) of the company that manufactured the defective product and, if relevant, the various components relevant to the issue concerned
- The dates when the affected products were manufactured, distributed and sold to customers, and numbers of any products that remain in the supply chain
- Contact details of all of the relevant entities in the supply chain
- Details of any incidents that have already occurred and have been brought to the company's attention
- Measures taken to address the safety hazard, ie, the "fix"



- Details of the notice to consumers and the corrective action plan being offered to eliminate the product safety risk

Once a Safety Issue Arises

(a) Take Action Promptly on a Potential Safety Issue

Speed is one of the keys to a successful recall and to satisfying regulatory authorities. In many jurisdictions, particularly the United States and the member states of the EU, the timetable for notification is triggered once the company becomes aware, or on the basis of the information available should be aware, that a product poses a more than minimal safety risk to consumers. Consequently, if a company delays in the hope that the incident will be a “one-off” episode that goes away quietly, it may be in breach of its duty to notify and not only could face fines but, in some countries, could even expose its personnel to criminal sanctions as severe as imprisonment.

The duty to act promptly in a jurisdiction may also be triggered by incidents that occur outside of that jurisdiction.

(b) Understand the Risk and Be Prepared to Defend Your Decision

A proper and timely risk assessment by the appropriate decision-makers at the company must be carried out to assess whether a genuine safety issue is presented or whether the problem is truly an isolated one that does not present a hazard to a larger group of consumers. Understanding how the product is going to be used, even if it is being used in a way not originally intended by the manufacturer, is an important consideration in any assessment of product safety risk. If necessary, it may be advisable to utilize external expert consultants with specialized expertise and credentials, who can lend independent support for the company’s decision either to conduct or not to conduct a recall.

Some countries provide guidance on how to undertake such a risk assessment. Some countries use the risk assessment to classify the

recall, which in turn dictates how the recall will be performed. Other countries identify the factors that may be used to inform the risk assessment. Regardless of approach, the following are typical factors that a company should consider in assessing any potential product safety risk typically include:

- The nature of the claimed defect
- The likelihood that the product defect would actually cause injury to consumers/damage to property
- The health and safety implications to the public of the hazard caused by the defect
- The seriousness of any potential hazard
- Whether any regulations are violated by the presence of the alleged defect, regardless of whether the defect is substantial or is likely to cause injury
- The percentage of the total product affected
- Whether the product could be retrofitted and the issue remedied, or in the alternative, if the product must be recalled and replaced, how to safely dispose of the product so it does not reach the hands of the consumer again

In many situations, there is a justifiable question as to whether notification to the authorities and a product recall are required. Among the examples of such situations are where there is only a very remote risk that an identified hazard will materialize; where a consumer has misused the product, especially in ways that are not reasonably foreseeable; or where only a very small number of products are affected with no broader pattern of risk. When the decision is not immediately self-evident, companies should weigh issues that include not only the risk of injury to consumers, but also the potential damage to the product/company's reputation if no recall is initiated, and the



likelihood of government enforcement action if relevant authorities believe notification was required. The disruption and reputational damage of having to announce a product recall is usually short-term, as consumers are becoming more and more familiar with product recalls and often consider companies who carry them out to be responsible corporate citizens who do not take unnecessary risks.

In our experience, in most cases, it is better to be safe than sorry. This approach is also consistent with the regulatory requirement related to reporting found in some jurisdictions.

It may also be appropriate for a company to consider contacting the relevant authorities in affected jurisdictions for guidance. Before taking this step, a company's management must be prepared for an outcome that affords little choice but to recall, although an endorsement by regulators that no recall is necessary can go a long way to avoiding any subsequent second-guessing about the company's decision. Whatever decision is ultimately reached, a thorough risk and liability assessment (preferably utilizing outside counsel familiar with product recall and product liability issues) is advisable.

Before initiating a product recall, or as soon as practicable thereafter, companies should also address such important issues as early notification to the company's insurer and adherence to the cooperation clause of a product recall or product liability insurance policy.

(c) Select the Most Appropriate Communication Method

One of the key features of any recall campaign is the method by which the company will communicate the product risk and proposed corrective action to its distribution channels and direct to consumers. In most jurisdictions, the method(s) and content of this communication are reviewed and approved by relevant regulators. How to effectively communicate the recall will depend, in part, on the type and volume of products involved and their likely location, as well as how the company sells the product to end customers.

For example, if the recall involves high-value or technical products that customers will have registered through company warranty programs, or that companies sell directly to their customers with backup documentation, e.g., through frequent-purchaser rewards programs, the best method is likely to be direct mail or email to registered customers, as well as point-of-sale notices and website notices. However, at the other extreme, where the product is sold through retailers to hundreds of thousands of customers, it may be necessary to issue newspaper advertisements, in addition to point-of-sale notices and website notification. The key consideration is whether the selected method will effectively and clearly communicate the product safety issue to the affected consumers.

Some jurisdictions take the communication decision-making out of the company's hands, mandating how notification of a recall is to be communicated to consumers. Regardless of how consumers of the product may be reached, some local laws require publication in local newspapers or other forms of media likely intended to reach the affected consumers. For some companies, complying with local regulations may result in the implementation of a global recall plan looking noticeably different from one country to the next, depending on the jurisdiction and the regulators involved.

A new consideration which has arisen in recent years is the use of social media, such as Facebook, Twitter or Instagram, as a method of publicizing the recall. While unlikely to be suitable as the primary method of communication, depending on the product's consumer population, it may be a suitable and helpful secondary method of publicity. Indeed, some regulators, for example in Australia, have recognized this and issued guidance to this effect. Additionally, some regulators, such as the US Consumer Product Safety Commission, use social media to publish their own official notifications about a product recall and expect a recalling company to have a social media notification plan in place with respect to the recall.



(d) Make the Recall as Easy as Possible for Customers and Consumers

In addition to selecting the most appropriate method of communicating with customers, the company must also decide upon the method for actually recalling and replacing the products. In many cases, the best option will be to set up a dedicated section of the company's website into which customers can enter their contact and purchase details to order a replacement product, and to arrange for them to return the product in packaging sent with the replacement. For some products, however, this may not be practical, so an alternative will have to be found, such as asking customers to contact their local dealer or retailer to arrange a repair or replacement, or to contact the company itself. As with the method of communication, the method of recalling the product is typically approved by relevant regulators.

(e) Keep Open Lines of Communication With Regulators

Most regulators require preapproval of any communication to consumers and the proposed corrective action. It is therefore highly recommended to consider using outside counsel to communicate with the regulators, particularly in a global recall where multiple notifications are required. The relevant regulators are much more likely to view a product recall campaign, including the notification to consumers, favorably if it is complete and is accompanied by relevant, practical information for consumers. If a company is certain that it needs to make a notification about a product safety issue, but is missing some of the important information, it is likely still advisable to make a preliminary notification to relevant regulators to start a dialogue, and to preempt any suggestion that the notification was not made quickly enough. A courtesy contact to the regulators also helps prevent a scenario in which a regulator feels ambushed as a result of receiving little or no advance notice before the recall is announced - and inevitably receives consumer and media inquiries.

(f) Coordination Across the World

If a recall is global, coordination of notification efforts and commencement of the recall campaign across all affected jurisdictions are highly advisable. A coordinated effort is more cost efficient and easier for the company to implement than one that is done piecemeal. However, there are some instances in which companies have a recall campaign that is jurisdiction-specific (e.g., notification via publication is mandated in some countries but not others). Ultimately, regulators are often in contact with each other, so what a company does or fails to do in one jurisdiction often becomes known in another, especially with enhanced communication among product safety agencies in major markets and the widespread publication by regulators of recall information on the Internet.

Some companies also face the obligation to recall products because of a technical violation of a jurisdiction-specific regulation or law. In addition, the laws of some jurisdictions require companies to conduct a recall (or at least notify the appropriate regulators) in that jurisdiction if the company is required to conduct a recall in any other jurisdiction, even if the recall is not necessarily safety-related (e.g., a product labeling violation that requires a recall, but does not present a product safety hazard). The bottom line is that when dealing with multiple jurisdictions, it is important to assess compliance requirements in each affected jurisdiction. Failure to do so could result in significant penalties.

(g) Monitor Progress

Although getting the product recall campaign underway and making the required notifications are crucial, it is also important to monitor the progress of the recall to enable the company, in cooperation with the relevant regulatory authorities, to assess whether further action is needed to increase the recall's effectiveness, often measured by its consumer response rate. Most regulators are involved in monitoring



progress, or at least require progress reports, so proper documentation of all recall efforts is critical.

As these best practices suggest, planning and consistent handling of potential product safety claims are important to implementing and coordinating an effective product safety campaign. In short, a company is well served to:

- Establish a product recall team that includes members with appropriate technical expertise to make the decision whether to conduct a recall;
- Adopt a product safety protocol that enables the company to trace and account for products as they move through the global distribution chain;
- Identify who is opening lines of communication with affected regulators;
- Outline the steps to be taken to appropriately notify consumers of a product safety issue, which may require notification to dealers, distributors and retailers in affected jurisdictions, and obtain approval from regulators, where necessary;
- Utilize, where appropriate, technical consulting experts to assist the company in assessing the potential product safety issue and in formulating an appropriate, effective response; and
- Consider the role of outside counsel, not only in formulating and implementing the recall procedure itself, but also in communicating with regulatory agencies in affected jurisdictions.



Argentina

There are no laws that specifically regulate consumer product recalls in Argentina, and few recalls have occurred in Argentina.

1. Definition of a “consumer product”

The purpose of Consumer Protection Law No. 24,240 (the “Law”) is to protect consumers or users of products and services. It defines “consumer” as any individual or legal entity that acquires for its final consumption, or that of family or acquaintances, goods, services or new real estate for housing purposes. However, the Law does not define “consumer product.”

Judicial interpretations of the Law have found that it applies to the purchase of goods and services by businesses when those goods and services are not directly related to the commercial activity of the particular business (eg, a computer bought by a medical clinic to use in support of its activities), thus broadening the scope of protection originally granted by the Law.

2. Agencies involved in regulating consumer products

The Commerce Secretariat is the agency that is primarily engaged in overseeing the application of the Law at the national level. However, provincial authorities and the government of the city of Buenos Aires have jurisdiction if an infringement of the Law takes place in their respective territories and affects consumers domiciled there.

In the case of recalls of products sold nationwide, it may be argued that the Commerce Secretariat is also the exclusive competent authority because such a recall affects interstate commerce, which is subject to the exclusive jurisdiction of the federal government.

3. Reporting requirements and recall procedures

There are no specific rules regulating recalls. In fact, very few recalls have ever taken place in Argentina. The obligation to perform a recall

may be inferred from Articles 4, 5 and 6 of the Law, and from Article 4 of National Decree No. 1798/94, whereby the manufacturer, distributor or seller of a dangerous product must inform the consumer that the product is dangerous and take any action necessary to protect the health and safety of the consumer.

In those recalls that have been performed, companies have usually first voluntarily approached the Commerce Secretariat, informing it about the problem and arranging with it the most effective way to perform the recall, which is usually by means of an advertisement placed in a major national newspaper.

Since no specific regulations exist, however, a recall may be publicized by any other means, provided that the information reaches the targeted audience. In this respect, an analysis must be performed on a case-by-case basis.

4. Product-specific regimes

Pharmaceutical products and medical devices have a specific regime for recall of products set forth in section 7.1.1.8 of the Mercosur Technical Regulation of Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products, which was approved by Resolution No. 3266/2016 of the National Administration of Medicines, Food and Medical Technology (ANMAT). According to this regulation, each manufacturer has the obligation to determine the recall of products when necessary and to perform other field actions in cases where products are already distributed. ANMAT is the regulatory agency for recall of pharmaceuticals and medical devices.

There is a specific regulation for the recall of food products and beverages in the Argentine Food Code (Law No. 18.284 regulated by National Decree No. 2126/71). Chapter 21 of this Code sets forth a procedure manual for recall of products, which can be performed by the company or by the local or national health authority. ANMAT is the regulatory agency for recall of food products, and jointly with the



local health authority, must audit the recall when it is performed by the company.

Recall of vehicles and their parts does not have a special regime.

5. Legal consequences of noncompliance

As there are no laws that regulate recalls in Argentina, there are also no regulations that apply to the non-performance of a recall.

It is not clear under Argentine law whether the execution of a recall may effectively protect the company performing it against civil and criminal claims from the affected consumers. In fact, it may well be the case that the actual performance of a recall might be used by the consumer as evidence that the company introduced a dangerous product into the market, and thus must be liable for any damage caused by that dangerous product.

New sources of information

Resolution No. 3266/2016 of ANMAT.

Australia

Product recalls in Australia are governed by Part 3-3 of the Australian Consumer Law (ACL), which is Schedule 2 to the Competition and Consumer Act 2010 (Cth). The ACL is Australia's federal consumer protection legislation. It is mirrored in corresponding state and territory legislation.

The ACL provides for both compulsory and voluntary recalls. However, compulsory recalls are rare in Australia; most product recalls are conducted voluntarily.

1. Definition of a “consumer product”

The recall provisions in the ACL apply to “consumer goods,” which is defined as goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption. This includes any goods that have become fixtures since the time they were supplied.

2. Agencies involved in regulating consumer products

At the Commonwealth level, the Minister for Small Business, in conjunction with the Australian Competition and Consumer Commission (ACCC), which is the Commonwealth consumer protection regulator, regulates recalls of consumer goods. Each state and territory also has its own regulatory authority, as do certain industries, such as food and therapeutic goods, among others.

3. Reporting requirements and recall procedures

Compulsory recalls

Under the ACL, the Commonwealth minister (currently the Minister for Small Business) or a responsible state or territory minister may order a compulsory recall of consumer goods of a particular kind if:

- a person in trade or commerce supplies consumer goods of that kind



- either:
 - it appears to the minister that the goods will or may cause injury to a person
 - it appears to the minister that a reasonably foreseeable use (including a misuse) of such goods will or may cause injury to any person
 - the goods do not comply with an applicable mandatory safety standard
 - an interim or permanent ban on the goods is in force
- it appears to the minister that one or more suppliers of such goods have not taken satisfactory action to prevent the goods from causing injury to any person

In exercising these powers, it is not necessary for the minister to know the identities of any of the suppliers of the consumer goods that are the subject of the recall. Where the supplier's identity is not known, the ACCC or an equivalent state regulator will conduct the recall.

Unless the goods pose “an imminent risk of death, serious illness or serious injury,” the minister must provide the supplier with an opportunity to request a conference to discuss the matter with the ACCC prior to the issue of the recall notice. Generally, the minister will only order a compulsory recall if he or she considers that the voluntary recall action taken, or proposed to be taken, by the supplier is inadequate.

A recall notice may require one or more suppliers of the goods or, if the identity of the supplier is not known, the ACCC or equivalent state regulator to take one or more of the following actions:

- recall the goods

- disclose to the public or a class of persons specified in the notice one or more of the following:
 - the nature of a defect in or dangerous characteristic of the goods
 - the circumstances in which a reasonably foreseeable use or misuse of the goods is dangerous
 - procedures for disposing of the goods
- if the identity of the supplier or any of the suppliers is known, inform the public or the class of persons specified in the notice that the supplier undertakes to do whichever of the following the supplier thinks is appropriate:
 - unless the notice identifies a dangerous characteristic of the goods, repair the goods
 - replace the goods
 - refund the price of the goods to the person to whom the goods were supplied (whether by the supplier or another person)

The recall notice may specify the manner in which the action required to be taken by the notice must be taken.

If the recall notice requires the ACCC or state regulator to take action to recall the consumer goods, the responsible minister may specify in the notice that the regulator must retain, destroy or otherwise dispose of the goods.

A recall notice for consumer goods may be issued, even if the goods have become fixtures since they were supplied.



Voluntary recalls

The majority of product recalls conducted in Australia are voluntary recalls (including those undertaken by negotiation between suppliers and the ACCC). Although voluntary recalls are the responsibility of the supplier, the legislation requires suppliers to provide early notice of the recall to the ACCC, which then monitors the recall. For certain kinds of goods, such as food, therapeutic goods and electrical products, specific industry regulators also need to be consulted at the beginning of the recall and these regulators will monitor the recall.

Product recall information for Australia is available on the Product Recalls Australia website, www.productsafety.gov.au. This site contains information regarding product recalls carried out in Australia and a copy of the Consumer Product Safety Recall Guidelines issued by the ACCC (the “Recall Guidelines”), found at <https://www.productsafety.gov.au/publication/consumer-product-safety-recall-guidelines>.

Conducting a voluntary recall is the responsibility of the supplier. However, it is advisable to conduct product recalls in a way that is acceptable to the ACCC, so as to reduce the risk of the ACCC referring the matter to the minister for the issue of a compulsory recall notice.

The ACCC’s Recall Guidelines include recommendations for:

- what information should be included in recall notifications
- persons to whom notifications should be sent and the time frame for responding
- required regulatory notifications

Specific industry codes, as well as additional notification procedures (see below), must also be complied with for relevant classes of goods.

The ACL requires the supplier, within two days after taking recall action in Australia, to give the minister notice in writing of the recall. The notice must specify the goods that are the subject of the recall and must state that the goods are subject to recall. The notice must also:

- set out the nature of any defect or dangerous characteristics of the goods
- set out the circumstances of any reasonably foreseeable use or misuse of the consumer goods which is dangerous
- set out the nature of any noncompliance or likely noncompliance with a safety standard applicable to the goods
- if there is an interim or permanent ban on the goods in force, state that fact

It is particularly important to take this strict two-day time frame for notification in Australia into account when a global or international product recall is being launched, especially from Europe or the Americas, because of the large time difference with Australia.

The ACCC takes a wide approach to what supplier conduct comprises “recall action.” In summary, any action taken by a supplier to notify retailers or consumers of a product recall (including, for example, by publishing details of a recall on a website) will be deemed to be recall action triggering the two-day reporting deadline.

Notification of the recall can be made via an online form, which can be accessed on the product recalls website at <https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall>, or by a letter. The ACCC’s preferred method of notification is via the online form.



If goods that are the subject of the recall have been exported from Australia, a supplier must also notify the overseas purchaser as soon as reasonably practicable regarding the recall and:

- the nature of any defect or dangerous characteristics of the goods
- the circumstances of any reasonably foreseeable use or misuse of the consumer goods which is dangerous
- the nature of any noncompliance or likely noncompliance with a safety standard applicable to the goods
- whether there is an interim or permanent ban on the goods in force

A copy of this notice to the overseas purchaser must be sent to the Commonwealth minister within 10 days of giving notice to the purchaser.

Depending on the nature of the product being recalled, it may also be necessary to notify a specialist Commonwealth, state or territory regulatory authority of the recall.

Publicity

Recalls are traditionally advertised in locally circulated newspapers and at locations where the goods were sold. However, the Recall Guidelines specify that suppliers should tailor their communications strategy to the consumer groups affected by the recall. For example, social media is increasingly being employed to notify consumers. In addition, if there is an urgent risk of danger to consumers, more immediate alternative forms of advertising may be required. A media release is also usually issued.

Print advertisements should comply with the form and size requirements specified in the Recall Guidelines.

Suppliers should also place information relating to a product recall prominently on their website.

Where the products sold can be traced to the purchasers and contact details are available so that the purchasers can be contacted directly, advertisement of the recall in the media may not be necessary. Similarly, if the products are still in the supply chain and none have yet been sold to consumers, advertising to the public will not be required. The minister must still be notified of the recall within two days.

If a product safety advertisement is required, all such advertisements should at least contain:

- the words “Product Safety Recall” at the top of the advertisement and “See productsafety.gov.au for Australian Product Recall Information” at the base of the advertisement
- a drawing or photograph of the product if available
- a clear description of the product, including the name, make, model, distinguishing features, batch or serial number
- clear identification of the supplier, including logo and contact details
- a clear description of the defect in simple terms that the average consumer can understand
- a statement of the hazard and the associated risk
- dates when the product was available for sale
- what immediate action consumers should take (eg, cease use, store safely)
- whom consumers should contact to receive a refund or have the product repaired or replaced



- details of how consumers can obtain further information about the recall, including business and after-hours telephone numbers for further information, preferably toll-free, and a website address, if possible
- advice that the recall is at the expense of the supplier

The notice must not include the words “voluntary recall.”

Recordkeeping

The ACCC and/or state regulator will monitor the progress of recalls, usually following up with the supplier within two months of the start of the recall. The ACCC usually requests that suppliers submit a progress report online including details of any variations in the number of affected and remedied products, details of any variations to the recall strategy and whether any complaints were received about the recall. The ACCC also carries out random supplier site visits to assess the effectiveness of product recall campaigns. During these visits, the ACCC will ask to review recall documentation and records. The supplier is no longer required to submit a final report to the ACCC to “close” the recall; instead, the ACCC will keep requesting progress reports until it is satisfied the recall has been complete.

Accordingly, once the advertising and other recall communications have been issued, it is important for the supplier to retain copies of them and to keep a record of how and to whom they were broadcast or sent. Records should also be kept to demonstrate how the recall is progressing (ie, communications made, number of returned products received, replacement or modified products sent to customers and any information received about injuries or damage suffered).

Recordkeeping of this nature will also assist the supplier in monitoring and evaluating the success of the recall, and therefore, in deciding whether additional or alternative publicity is needed to achieve a satisfactory success rate. It also provides crucial documentation for insurance claims or future litigation.

4. Product-specific regimes

Certain types of goods are also subject to industry codes of practice. If a product recall concerns these types of goods, the supplier must:

- contact the applicable industry authority prior to commencing recall action, as most authorities will assist with the conduct of the campaign
- comply with the recall guide issued by the relevant industry authority

Depending on the industry, it may be necessary to notify the relevant industry authority (at the federal and/or state and territory level) in addition to notifying the minister via the ACCC.

The classes of goods and relevant authorities for which this is applicable are:

- motor vehicles and associated products - Department of Infrastructure and Regional Development
- electrical products - state and territory electrical regulators
- food products - Food Standards Australia New Zealand
- gas appliances - state and territory gas regulators
- therapeutic goods (drugs and medical devices) - Therapeutic Goods Administration
- agricultural and veterinary products - Australian Pesticides and Veterinary Medicines Authority

Pharmaceuticals / Medical devices

The applicable regulator for pharmaceuticals and medical devices is the Therapeutic Goods Administration (TGA).



The *Therapeutic Goods Act 1989* (Cth) (the “TGA Act”) empowers the Secretary of the Commonwealth Department of Health to order mandatory recall action of medical devices (Chapter 4), medicines and other therapeutic goods and biologicals (Chapter 3) in certain circumstances, including where a product does not comply with applicable standards or relevant manufacturing principles.

Recalls of pharmaceuticals and medical devices should be conducted in accordance with the Uniform Recall Procedure for Therapeutic Goods (found at <https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf>).

The TGA has information on the recall process at <http://www.tga.gov.au/safety/recalls.htm>, and has issued a recall guide at <http://www.tga.gov.au/industry/recalls-urptg.htm>.

In conducting a recall of therapeutic goods (ie, medicines, medical devices, blood and tissue), strict procedures must be satisfied. The TGA’s web page contains up-to-date details of the Australian and national recall coordinators who should be contacted immediately.

Food and drink

In each Australian State and Territory, the relevant Food Acts empower the relevant food authority to order that a food or type of food be recalled - and specify the manner in which the recall is to be conducted - if that order is necessary to reduce or mitigate the consequences of a serious danger to public health.

Nationally, the applicable regulator for food and drink is Food Standards Australia New Zealand (FSANZ).

Standard 3.2.2 of the Australia New Zealand Food Standards Code, administered by FSANZ, requires a manufacturer, wholesaler or importer of food to:

- have a system in place to ensure the recall of unsafe food

- set out this system in a written document and make this document available to an authorized officer upon request
- comply with this system when recalling unsafe food

FSANZ recommends that food and drink recalls be conducted in accordance with the FSANZ Food Recall Protocol (found at <http://www.foodstandards.gov.au/publications/Documents/FSANZFoodRecallProtocol2014.pdf>). FSANZ publishes information on recalls at <http://www.foodstandards.gov.au/industry/foodrecalls/Pages/default.aspx> and has issued a recall guide at <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodindustryrecallpr1819.cfm>.

A supplier is required to contact the relevant state or territory health department, then to contact the FSANZ Recall Coordinator by telephone, who will then liaise with all applicable state and territory agencies:

Food Standards Australia and New Zealand

Food Recall Coordinator

Tel: +61 (02) 6271 2610 (9 am - 5 pm Monday to Friday)

0412 166 965 (after hours)

If the company supplies to major retailers, they must also complete the Australian Food and Groceries Council product recall form.

Motor vehicles and parts

The *Motor Vehicle Standards Act 1989* (Cth) (the “MVS Act”) does not contain product safety recall requirements. However, the MVS Act does include safety standards for vehicles in Australia which, if not complied with, may subject the supplier of the vehicles to a mandatory recall notice under the ACL. The MVS Act can be accessed at: <https://www.legislation.gov.au/Details/C2016C00857>.



The applicable national regulator for motor vehicles and associated products is the Department of Infrastructure and Regional Development.

Various industry bodies have issued voluntary codes of practice for recalls of motor vehicles, including:

- The Federal Chamber of Automotive Industries Code of Practice for the Conduct of an Automotive Product Safety Related Recall Campaign (the “FCAI Code”) (found at <https://www.fc.ai.com.au/library/publication/FCAI%20Recall%20Code%20January%202014.pdf>)
- The Procedures for the Recall of Vehicles and Associated Products with Safety Related Defects by Registered Automotive Workshops (the “RAWS Recall Code”) (found at https://infrastructure.gov.au/roads/vehicle_regulation/vehicle/recalls/code_practice_raws/index.aspx)

5. Legal consequences of noncompliance

Failure to comply with a compulsory recall notice under the ACL is a criminal offense punishable by a maximum fine for a corporation of AUD 1,100,000.

Failure to notify the Commonwealth minister of a voluntary recall under the ACL (within the two-day period or at all) is a criminal offense and can result in fines of AUD 16,650 for a corporation. Further, any person who suffers loss or damage as a result of such noncompliance may recover damages or seek compensation.

Some of the various product-specific statutes referred to above also impose penalties for non-compliance with recall provisions.

Pharmaceuticals/Medical devices

Failure to comply with a mandatory recall ordered by the TGA is a criminal offense punishable by five years imprisonment or 4,000

penalty units (currently AUD 840,000), or both. It is also a civil contravention punishable by 50,000 penalty units (AUD 10,500,000).

Food and drink

The relevant consequence of noncompliance will vary according to the Australian State or Territory. In New South Wales, for example, failure to comply with a mandatory recall ordered by NSW Food Authority is a criminal offense punishable by a maximum penalty of 2,500 penalty units (AUD 525,000).

Sources of information

Product Recalls Australia

<https://www.productsafety.gov.au/recalls>

Minister for Small Business

c/o Australian Competition and Consumer Commission

G.P.O. Box 3131

Canberra ACT 2601

Tel: +61 1 300 302 502

Fax: +61 (0)2 6243 1073

Email: recalls@accc.gov.au

Other specific products

Food and drink

Food Recall Coordinator

Food Standards Australia and New Zealand

PO Box 5423

Kingston ACT 2604

Tel: +61 (02) 6271 2610 (9 am - 5 pm Monday to Friday)

0412 166 965 (after hours)

Webpage:

<http://www.foodstandards.gov.au/industry/foodrecalls/Pages/default.aspx>



Pharmaceuticals/Medical devices

Recalls

Manufacturing Quality Branch, TGA,

PO Box 100,

Woden ACT 2606

Tel: 1800 020 653 (free call within Australia)

+61 2 6232 8935

Fax: +61 2 6203 1451

Web page: <https://www.tga.gov.au/recalls>

Motor vehicles and motor vehicle equipment

Department of Infrastructure and Regional Development

GPO Box 594

Canberra ACT 2601

Tel: 1800 075 001 (within Australia) or +61 2 6274 7111

Web page: <https://infrastructure.gov.au/vehicles/recalls/index.aspx>

Electrical products

Electrical Regulatory Authorities Council (ERAC)

<http://www.erac.gov.au/rl.htm>

Recall guide: www.erac.gov.au/downloads/RecallGuidelines.pdf

State and territory electricity regulatory authorities will also need to be notified. Please contact Baker McKenzie in order to obtain current contact details.

Agricultural and veterinary products

Australian Pesticides and Veterinary Medicines Authority (APVMA)

<https://apvma.gov.au/node/1081>

Recall guide:

https://apvma.gov.au/sites/default/files/images/1081-apvma-recall-guidelines-feb-2009_0.pdf

Australia

It is sufficient for a supplier to contact the national APVMA Recall Coordinator, who will then liaise with all applicable state agencies:

APVMA Recall Coordinator
Regulatory Strategy and Compliance
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Telephone: +61 2 6210 4793 or +61 2 6210 4800
Fax: +61 2 6210 4813
Email: recalls@apvma.gov.au

Gas products

Gas Technical Regulators Committee (GTRC)
www.gtrc.gov.au

There is no current recall guide produced by the GTRC. It is recommended that each state gas regulatory authority be notified. Please contact Baker McKenzie to obtain current contact details.



Austria

The legal framework for product recalls is set forth in the Austrian Product Safety Act (*Produktsicherheitsgesetz 2004* or PSG), which implements the General Product Safety Directive 2001/95/EC (GPSD).

1. Definition of a “consumer product”

The Austrian product safety rules apply to all products as defined in the PSG. Specifically, the PSG defines the term “product” as follows:

“any movable property, including energy, also where it is part of another movable property or joined to an immovable property, which property is intended — also within the framework of the rendering of a service — for consumers or might be used by consumers under reasonably foreseeable conditions even where it is not designed for consumers. The product must be supplied or made available within the scope of a commercial activity, where it shall be irrelevant whether it is supplied for free or for a consideration and whether or not the product is new, used or re-processed. Products within the meaning of the PSG shall not include antiques or any products which require to be repaired or reprocessed prior to their use, provided that the party marketing them notifies the party thus supplied accordingly and can furnish evidence of having done so.”

The term “consumer product” is not defined under Austrian law. The Austrian definition of “product” encompasses all movable property, provided that the item in question is intended for consumers or may be used by consumers. A product does not necessarily have to be actually used by consumers, but such private use has to be possible.

For example, an item qualifies as a “product” if it was originally designed for commercial customers but is subsequently only used privately (eg, certain do-it-yourself equipment), even without the manufacturer’s intention.

Pursuant to the Austrian Civil Code, a product is “movable” if it can be transferred from one place to another without suffering damage.

The PSG only applies where the product in question is provided within the framework of a business activity. The PSG does not apply to private sales of products.

2. Agencies involved in regulating consumer products

The Federal Minister for Labour, Social Affairs and Consumer Protection (*Bundesministerium für Arbeit, Soziales und Konsumentenschutz* or BMASK) is the competent authority for supervising or ordering the recall of general consumer products in Austria. At the local, federal state level, it is the provincial governors of the relevant Austrian federal state. Furthermore, under the PSG, the provincial governors are responsible for market supervision.

Whenever safety properties of products are regulated in other federal administrative regulations or in directly applicable EU law, enforcement falls under the jurisdiction of the federal minister whose area of responsibility includes such administrative regulations or EU law (see section 4 below).

3. Recording requirements and recall procedures

Notification obligation

The PSG obliges marketers to promptly notify the competent authority if a product is incompatible with the general safety requirement and poses a danger to consumers. Pursuant to the PSG, the term “marketers” refers to manufacturers, importers and vendors. The notification can be made via RAPEX, using the EU’s online Business Application (<https://webgate.ec.europa.eu/gpsd-ba/index.do>); in the case of food and feed, the notification can be made via RASFF.

The notification must contain the following information:

- Which countries are affected



- Information or data about the notifying enterprise (including details of a responsible contact person)
- Data about the manufacturer
- Data about other possibly affected enterprises or companies (eg, suppliers, distributors, customers or consumers)
- Complete information about the affected product, including description, denomination, trade name, model, serial number, batch references, bar code, CN code (combined nomenclature code as issued by the European Commission), a digital photograph and the country of origin
- Description of damage and potential risk or endangerment, and possible injuries and damage that might occur, together with a risk estimation
- The date or period of manufacture and period of placement on the market
- Data about any potential damage that may have already occurred
- Description of the corrective measures taken or planned to be taken by the company
- A warning to the relevant consumers regarding the affected product and information about available remedies

Recall requirements

If a recall is to occur, the recall must take place promptly and efficiently. Moreover, it is of particular importance to inform all affected consumers or customers. Therefore, the marketer has to decide on an adequate measure to achieve this. The marketer is recommended to discuss these measures with the competent federal ministry. Such measures may consist of press announcements, publishing relevant information on the company's website, or if

possible, calling the consumers directly. The notification must detail the following:

- The defect
- The potential risk
- The envisaged recall measures/remedies, including reimbursement
- Any suggested actions or warnings

Within the scope of their business, marketers have to cooperate with the authorities and provide them with information (eg, about distribution channels). They are obliged to present product documentation, test certificates and other suitable documentation that allows the relevant products to be assessed for their risks.

Furthermore, the notifying party must provide the authority with products for testing, and proposals on how to avert danger.

Where the competent authority has become aware of products being unsafe, the authority may determine appropriate measures to be undertaken, such as ordering publication of recall campaigns through the media or recalling products. Equally, the sale of such products may be prohibited. If necessary, these measures may be combined. In cases of imminent danger, local administrative authorities may take preliminary measures.

4. Product-specific regimes

Special recall regimes apply to certain types of products, such as medicinal products (drugs), medical devices, food and drink, and vehicles and their parts. Depending on the relevant type of product, different authorities will be competent, such as the healthcare regulator for medical devices (see table below for further information), and must be notified immediately in case of potential safety risks to consumers. Unless the specific recall regimes for



product types provide for more specific rules on corrective actions, the general provisions of the PSG will apply.

	Applicable legislation	Applicable regulator
Medicinal Products*	Medicinal Products Site Regulation Medicinal Products Act	Austrian Federal Office for Safety in Health Care (BASG)
Medical Devices	Medical Devices Act	
Food and Drink	Food and Consumer Safety Act Wine Act	Provincial Governor Federal Wine Control Board (for wine products)
Vehicles and their parts**	Motor Vehicle Act	Federal Minister for Transport, Innovation and Technology

* For medicinal products, every authorized drug manufacturing and/or drug distribution site (factory) in Austria must have a system for recording and checking complaints, and take effective systematic precautions to ensure that medicinal products can be recalled rapidly at any time. The site must record and check every complaint relating to a defect, and recall plans must be drafted. The site shall immediately report to the BASG any defect that may lead to recall or unusual restriction of sale, and include the recipient countries if possible. The site must immediately inform the BASG, and where applicable, the marketing authorization holder (MAH) of any medicinal product or active substance identified as falsified or suspect to be falsified. Materials and medicinal products, investigational medicinal products and printed packaging material (including labels)

that are to be stored in quarantine or that have been withdrawn from market must be stored separately.

** In practice, the vehicle manufacturer or a representative may, upon application, notify the Austrian Insurance Federation (VVO) by providing the relevant vehicle identification number. The VVO will subsequently inform consumers (vehicle keepers) about the recall, the costs of which must be borne by the manufacturer.

5. Legal consequences of noncompliance

The authorities may impose administrative fines of up to EUR 25,000 in the following cases:

- Marketing of products that pose a serious danger to the life or health of consumers, provided that the marketer knows or should have known about the hazard potential (“serious danger” is defined in Section 3, item 2 of the PSG as any severe danger that requires rapid action on the part of the authorities, even when it has no direct effect)
- Noncompliance with the measures required by an ordinance or decree based on the PSG
- Contravention of those measures

Depending on the type of product, Austrian laws may provide for different legal consequences/penalties. For instance, for infringing food and drink laws, fines of up to EUR 50,000 may be imposed; under medicinal products and medical devices regimes, fines ranging between EUR 25,000 and 50,000 can be imposed.

In the event of noncompliance with measures required by a decree or ordinance based on the PSG, products may also be declared forfeited under the PSG or under the VStG 1991 — Act Regulating Administrative Penalties.



Marketers who violate their duties to inform or to cooperate, or do not take temporary action to avert danger, commit an administrative offense and may be penalized with an administrative fine of up to EUR 3,000 under the PSG.

An administrative offense is not committed when an act, as set forth in Sections 25 through 27 of the PSG, constitutes a criminal offense that falls under the jurisdiction of the courts.

Sources of information

Federal Ministry for Labour, Social Affairs and Consumer Protection
(*Bundesministerium für Arbeit, Soziales und Konsumentenschutz*),
ABT III/2 – Stubenring 1, 1010 Wien

Tel: +43 1 71100 – 2501, 2502; Fax: +43 1 7100 - 2549;
produktsicherheit@bmask.gv.at
www.produktsicherheit.gv.at

Consumer Council at the Austrian Standards Institute
(*Verbraucherrat beim Austrian Standards Institute*)
Heinestraße 38, 1020 Wien
Telefon: +43 1 21300 - 711; Fax: +43 1 21300 - 328;
f.fiala@austrian-standards.at
www.verbraucherrat.at

The Consumer Council represents the interests of consumers in national, European and international standards bodies.

TÜV AUSTRIA (Technical Control Board)
Deutschstraße 10, 1230 Wien
Tel: +43 504 54; Fax: +43 504 54 - 6555;
office@tuv.at
www.tuv.at

Information sheet Product Safety 2006

<https://osha.europa.eu/en/legislation/directives/regulation-ec-no-1907-2006-of-the-european-parliament-and-of-the-council>

Austria

Blue Guide on the Implementation of EU Product Rules

<http://ec.europa.eu/docsroom/documents/18027/attachments/1/translations/en/renditions/native>



Belgium

The General Product Safety Directive 2001/95/EC (GPSD) has been implemented into Belgian law by the Act of 18 December 2002 amending the Belgian General Product Safety Act of 9 February 1994, now incorporated into Book IX of the Belgian Economic Law Code (the “General Product Safety Act”).

1. Definition of a “consumer product”

The General Product Safety Act’s definition of “consumer product” is the same as the definition of “product” given in the GPSD.

2. Agencies involved in regulating consumer products

A product recall may be carried out voluntarily or may be ordered by the competent minister, or by its representatives, with the authority to protect consumer safety. Producers and distributors must notify the Central Reporting Station (*Centraal Meldpunt voor Producten/Guichet Central pour les Produits*) when they know or should know that a product they have placed on the market is incompatible with the general safety requirement and poses risks to consumers.

3. Reporting requirements and recall procedures

Notification of a dangerous product to the competent authority should provide the following at the very least:

- Information identifying, in a precise manner, the product or lot of products at issue
- A complete description of the risks connected to the relevant products
- All information available on the basis of which the product can be traced
- A description of the steps taken to prevent risks to users

Notification can be made by filling out the template form available on the website of the Belgian competent authority (http://economie.fgov.be/nl/ondernemingen/securite_produits_et_services/terugroep_in_van_een_product_andere_corrigerende_maatregelen/) and sending it to the Central Reporting Station.

Alternatively, notification can be made through the online form available at <https://webgate.ec.europa.eu/gpsd-ba/index.do>.

The General Product Safety Act states that producers and distributors must inform the competent authority immediately when they know or should know that a product they placed on the market is incompatible with the general safety requirement and poses risks to consumers.

The primary responsibility for determining whether a product is safe rests with producers and distributors. The guidelines adopted by the EU Commission to ensure efficient and consistent application of the notification procedure on dangerous consumer products, as introduced in the GPSD (the “Guidelines”), explain when a particularly hazardous situation warrants notification to the authorities. The Guidelines also state that producers and distributors should be encouraged to contact the authorities if they have evidence of a potential problem in order to discuss whether a notification is appropriate. The authorities will be responsible for assisting and helping them to correctly fulfill their notification obligation.

Other than the aforementioned notification guidelines, the General Product Safety Act does not provide a specific period in which to notify the competent authority. However, the Guidelines do provide some guidance, as they indicate that when there is a serious risk, the company concerned should inform the authorities within three days after receiving the information that warrants the notification. If the risk is not serious, notification within 10 days would be sufficient. “Serious risk” is defined in the GPSD and in the General Product Safety Act as “any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities.”



No specific Belgian guidance rules have been issued regarding product recalls. The competent Belgian authority follows the guidelines issued at the EU level.

The nonbinding Corrective Action Guide published on the website of the Federal Public Service (FPS) Economy, SMEs, Self-employed and Energy (<http://economie.fgov.be/en/>) contains general observations regarding recall action. An English version is available at http://economie.fgov.be/nl/binaries/01-Prosafe_Corrective_Action_Guide_v112011_tcm325-29772.pdf.

4. Product-specific regimes

Pharmaceuticals

The rules relating to pharmacovigilance are contained in the Belgian Medicines Act of 25 March 1964 and the Royal Decree of 14 December 2006.

The marketing authorization holder for a medicinal product must report any serious adverse incidents within 15 days from having gained knowledge thereof in the Eudravigilance databank. If the marketing authorization holder intends to make a public statement regarding pharmacovigilance, it must inform the Federal Agency for Medicines and Health Products (FAMHP), the European Medicines Agency and the European Commission prior to, or at the time of, releasing such communication.

Medical devices

The rules relating to materiovigilance are contained in the Belgian Royal Decrees of 18 March 1999 and 15 July 1997.

Producers of medical devices must immediately inform the FAMHP of: (i) any bad performance or any impairment of the characteristics or performance of a device, as well as any inadequacy in the labeling or the instructions for use that have caused or could cause the death or serious deterioration in the condition of a patient or user; and (ii) any

technical or medical reason relating to the characteristics or performance of a device which, due to the circumstances mentioned in (i), has resulted in the systematic withdrawal from the market of devices of the same type.

The notification must be made as soon as possible and by the quickest means, using the forms that are available online (https://www.fagg-afmps.be/en/human_use/health_products/medical_devices_accessories/materiovigilance/how_notify).

The completed forms should be sent to the following address:

Federal Agency for Medicines and Health Products

“Vigilance” division

Eurostation II

Place Victor Horta 40, Box 40

B-1060 Brussels

Tel.: +32 (0) 2 524 80 00

Fax: +32 (0) 2 524 81 20

Email: meddev@afmps.be

Food and drinks

Pursuant to the Belgian Royal Decree of 14 November 2003, each food business operator must immediately inform the Federal Agency for the Safety of the Food Chain (FASFS) if it considers or has reason to consider that a food product that it has imported, produced, processed or distributed can be harmful to the health of humans, animals or plants.

If a food business operator considers or has reason to consider that a food product that it has imported, produced, processed or distributed does not comply with the food safety rules, it must immediately set up a procedure to withdraw the product from the market when it has left the control of the first food business operator and must inform the FASFS thereof.



Notification must be made to the Provincial Control Unit of the FASFS (<http://www.afsca.be/lce/>) via a form available online (<http://www.afsca.be/meldingsplicht/opstellenmededeling/>).

Motor vehicles and parts

Belgian law does not provide for sector-specific legislation for notification of safety incidents or product recalls for vehicles and vehicle parts. The general regime set out in section 3 above applies.

5. Legal consequences of noncompliance

Violations of the aforementioned provisions of Belgian law are generally punishable by criminal fines, currently up to EUR 120,000 and which may be doubled for repeat offenders.

Moreover, additional measures may be ordered, such as the following:

- Confiscation of the profit made as a result of the infringement
- Publication of the judgment and/or a summary thereof in newspapers or in any other manner the court deems fit, at the cost of the offender

Sources of information

Central Reporting Station
North Gate III
Koning Albert II-laan 16
1000 Brussels
Tel.: 02 277 92 78 Fax: 02/277.54.38
Email: info.consumentenproducten@economie.fgov.be

FPS Economy, SMEs, Self-employed and Energy
General Direction Quality and Safety
Safety Department Section Product Safety Koning Albert II-laan 16
1000 Brussels
Tel.: 02/277.83.11 or 02/277 76.99

Belgium

Fax: 02/277.54.39

Email: safety.prod@economie.fgov.be

Useful Websites:

FPS Economy, SMEs, Self-employed and Energy:

www.mineco.fgov.be

Includes:

- The General Direction Control and Mediation Service — responsible for global market control
- The General Direction Quality and Safety — responsible for the coordination of controls and technical control of products
- The General Direction of Energy — with regard to the electrical aspects of products



Brazil

The Brazilian Consumer Defense Code (CDC), Federal Law No. 8,078, dated 11 September 1990, establishes the legal principles, obligations and rights that regulate consumer relations. Its rules address, among other subjects: (a) product recall requirements; (b) consumer rights; (c) a liability regime covering liability for failing to ensure the quality and safety of products and services (legal warranties); (d) offer, presentation and advertising requirements; (e) protection of consumers' personal data; and (f) abusive practices and clauses. The CDC also includes rules on civil procedure for individual and collective claims, including class actions, as well as administrative and criminal sanctions.

1. Definition of a “consumer product”

According to Article 2 of the CDC, a “consumer” is a natural person or legal entity that acquires or uses a product or service as an end user. In addition, legal entities may be characterized as vulnerable (ie, technically or economically vulnerable) when they are considered as consumers being subject to the protection of the CDC. In certain circumstances, under the CDC, persons or legal entities other than end users are deemed “consumer-equivalent” and are afforded the same rights and status as consumers. Article 2 of the CDC states that a group of persons, even if indeterminable, who have participated in a consumer-type relationship will be considered consumer equivalents.

In addition, Article 17 of the CDC provides that any “bystander,” or any individual or legal entity harmed by a product or service, is afforded the rights and status of a consumer. Article 29 grants consumer status to an individual or legal entity that is harmed by either a commercial practice or a contractual provision that is considered abusive under the CDC.

The CDC defines a “supplier” as any private or public, Brazilian or non-Brazilian, individual or legal entity that manufactures, assembles,

creates, builds, transforms, imports, distributes or markets products, or renders services to consumers.

A supplier must provide relevant and necessary information to consumers about its products and/or services. Thus, the offer and presentation of products or services should contain correct, clear and accurate information in Portuguese about the characteristics, qualities, quantity, composition, price, guarantee, validity terms and origin of the products and/or services, among other data, and about the hazards those products and/or services may pose to consumers' health and safety. All documents, manuals, labels and advertisements of products and/or services must comply with these criteria.

According to the CDC, a "product" is any movable or immovable material or immaterial asset. A "service" is any activity offered in the consumer market that is subject to remuneration, including a service related to banking, finance, credit or insurance, except where it results from a labor relationship.

In 2012, the Federal Decree No. 7,738 created the National Chamber of the Consumer (Senacon), an entity that integrates and works with the other members of the National Consumer Defense System (SNDC), coordinating the policy of this system.

2. Agencies involved in regulating consumer products

National consumer defense system

Senacon and the Federal Consumer Protection Department (DPDC) are the federal administrative bodies related to the Ministry of Justice and Public Safety, and oversee compliance with the CDC in the federal sphere. Consumer protection policies are enforced by several public entities at the federal, state and local levels that supervise and control the production, distribution and advertising of goods and services with the assistance of private consumer associations. All these organizations are members of the SNDC.



Two main organizations within the National Consumer Defense System are in charge of consumer protection in the administrative sphere. The DPDC is in charge at the federal level, while the Consumer Protection Executive (PROCON) and similar organizations function at the state and local levels. These entities provide guidance to consumers and analyze their inquiries, complaints and suggestions.

PROCON is in charge of enforcing the State Consumer Protection Policies and is granted responsibilities similar to those of the DPDC (eg, (i) to check compliance with consumer protection legislation and impose appropriate penalties; and (ii) to inspect products and services by its own or ad hoc experts, making the results publicly available).

The Brazilian Institute for Metrology, Standardization and Quality (INMETRO) is in charge of enforcing standardization, certification and legal, scientific and industrial metrology policies. At the state level, INMETRO delegates responsibilities to the Weight and Measurement Institutes to perform its activities.

Federal and state district attorneys' offices

The federal and state district attorneys' offices are entitled to initiate civil inquiries and file civil class actions and/or criminal lawsuits to protect "diffuse rights" in Brazil, such as consumer defense matters. "Diffuse rights" are transindividual rights, such as the right to a safe environment and to consumer protection, related to a population and not to specific inhabitants. These rights are protected through collective suits in detriment of individual claims, whereas district attorneys usually claim for damage to the collectiveness of consumers affected. Prior to filing a collective lawsuit, the district attorney's office may initiate a civil inquiry, which consists of an administrative proceeding to investigate a violation of Brazilian legislation, including governing consumer protection. In addition to the DAs, federal, state and local governments, governmental agencies and NGOs also have legal standing for a civil class action pursuant to the Consumer Defense Code.

Civil inquiries may be initiated either in view of an individual claim with collective consequences (ie, a consumer files a complaint at the federal or state district attorney's office) or *ex officio* by the district attorney (when the district attorney is aware of a potential consumer violation without any personal charge being brought).

The civil inquiry pursues all evidence-finding procedures concerning the alleged violation under investigation, in order to determine whether the violation truly occurred and identify the alleged violators.

After collecting evidence, the district attorney in charge of the investigation may: (i) close the proceeding; (ii) execute a Consent Agreement with the identified responsible parties for the violation; or (iii) file a civil class action (similar to class actions in the United States), as regulated by Federal Law No. 7,347/85 and the CDC.

A consent agreement is provided for under the Brazilian legal regime in Federal Law No. 7.347/85, which establishes that "legitimate public bodies may execute a consent agreement with the involved parties for their conduct to comply with the legal requirements, which will have the characteristics of an extrajudicial executive instrument." Non-governmental organizations are not entitled to enter into a consent agreement.

Although there is some debate as to the legal nature of a consent agreement, from an administrative standpoint, it is considered a mutual agreement between enforcement bodies and legal entities or individuals establishing specific conditions for compliance with consumer legislation.

The enforcement bodies that are entitled to execute consent agreements are those public entities that have legal standing to file consumer class actions. These bodies include the district attorneys' offices, federal union, states, municipalities, federal district and governmental agencies under the CDC, Article 82 and Federal Law No. 7,347/85, Article 5.



The effectiveness of the consent agreement instrument in avoiding complex and time-consuming lawsuits is related mainly to the fact that the consent agreement is an extrajudicial execution instrument. This means that if the company does not comply with the consent agreement, the relevant authority may demand that the obligations foreseen in the consent agreement be enforced by the courts. The courts may also enforce the fines foreseen in the consent agreement in case of noncompliance.

Finally, the judicial defense of the rights and interests of consumers and victims may be exercised either individually or collectively. In addition to federal and state district attorneys, Brazilian non-governmental organizations (NGOs) registered with Brazilian public record offices and associations have standing-to-sue suppliers in a public civil action. Very active consumer protection organizations in Brazil commonly file public civil actions and/or act as “watchdogs” on consumer-related issues.

Some district attorneys’ offices are used to getting involved in an autonomous investigation of recall proceedings in spite of the authority of the pertinent administrative bodies (DPDC and PROCONs). The district attorneys’ offices also have legal standing to order the police to investigate crimes against consumers and subsequently file criminal suits on the same matter. For those reasons, it is advisable for a supplier implementing a recall to consider (on a case-by-case basis) notifying the Consumer Protection District Attorney’s Office of the most-affected state.

3. Reporting requirements and recall procedures

According to the CDC and Ordinance No. 487/2012, published by the Ministry of Justice on 16 March 2012, a manufacturer that, after the introduction of a product to the market, discovers unforeseen risks associated with the use of the product or service must immediately inform the competent authorities (through notification) and consumers (through advertising notices and a publicity campaign) about the risks posed by the product or service. Along with such communication,

suppliers must recall the defective product in order to repair the problem.

Intent to implement a recall proceeding in Brazil must be communicated to the DPDC and all 26 state PROCONs, as well as to the responsible regulator and the normative agencies (ie, the National Department on Traffic or DENATRAN, and the National Agency of Health Surveillance or ANVISA, among others). Communication to the DPDC is made by filing a petition or submitting the same petition at a meeting with DPDC representatives. The communication to each PROCON may be made via email or letter. At the DPDC level, the recall communication can be registered by electronic means, in a procedure still to be established by the department. The recall rules do not vary according to the defective product or the magnitude of the risk posed by the product on the market. As detailed more fully in section 4, there may be additional requirements for specific products, such as health and agriculture products, according to which other governmental agencies must be informed.

Depending on the specificities of the recall campaign, suppliers could schedule meetings with the DPDC and the PROCON of the Brazilian state that is most affected by the defective products in order to explain the defect and the proposed recall procedure. These meetings will reinforce the company's concern for the safety of its consumers in Brazil. As mentioned above, it may also be advisable for manufacturers to submit a recall petition to the Consumer Protection District Attorney's Office of the most affected state.

The Brazilian consumer defense and protection legislation establishes precise rules on recall proceedings; these rules do not allow a recall without the required publicity. Accordingly, recall procedures must include the following:

- Information to the relevant authorities
- Public notices through television, radio and newspapers (procedures such as letters directed to each consumer, website



information and other communication methods are allowed as additional measures, but may not replace advertisements through television, radio and newspaper)

- A model risk warning to the consumer
- A customer support plan

Requirements established by law for conducting a recall are found in Article 10 of the CDC, which establishes that suppliers must not place any product or service on the consumer market that they “know or ought to know is highly harmful or hazardous to health and safety.” This provision further states:

“Any product or services supplier who, after introduction thereof on the consumer market, becomes aware that [the product or services] are hazardous, shall communicate the fact immediately to the competent authorities and to consumers, by publicity notices.”

The publicity notices referred to in the preceding paragraph must be circulated in the press and on radio and television, at the expense of the supplier of the product or service. According to the ordinance, the publicity notices can be published on the internet as well.

Unlike in some countries, Brazilian law requires a recall in cases where a product on the market poses a risk to consumers, provided that such risks were unforeseen before the supplier’s introduction of the product on the market. There are no “voluntary” recalls under Brazilian law. In addition, the law does not define what level of risk or injury would mandate a recall. Article 10, paragraph 1, which establishes the recall obligation, only mentions that a product that is hazardous to consumers must be recalled. Therefore, if a product is in any way hazardous to the consumer, it must be recalled.

Brazilian courts have confirmed that a Brazilian company may be considered as a “supplier” even where it has not introduced a product or service to the Brazilian market. If a product or service was introduced onto the market by other companies, distributors or by

consumers that acquired the product or service abroad, a Brazilian company may be considered as a “supplier” if it belongs to the same economic group, including for the purposes of CDC Article 10, paragraph 1, and Ordinance MJ No. 487/2012. In this case, the consumer protection authorities may consider the Brazilian company to be responsible for performing the recall of the product/service.

Ordinance MJ No. 487/2012 sets forth precise procedures for companies to follow when implementing a recall so as to provide consumers with the relevant information. These include the following:

- (i) The recall communication must indicate the names of the company’s administrators.
- (ii) The recall communication must include an image of the product.
- (iii) In the recall communication, the supplier must specify to which countries the product was exported or where the services were provided.
- (iv) The supplier must provide consumers with a recall attendance certificate, which indicates the place, date, time and duration of contact with consumers, as well as the measures adopted by the supplier.

The first step in implementing a recall in Brazil is to notify all pertinent authorities (ie, the DPDC, PROCONs and regulators). Pursuant to Article 2 of Ordinance MJ No. 487/2012, this communication must:

- Identify the supplier and the names of the company’s administrators
- Describe the accidents related to the defect in the product or service



- Present the customer support plan, with a description of the channels available to contact consumers in order to correct the defect or substitute the defective product or service
- Explain the defects in detail, providing technical clarification
- Explain the risks posed by the defective product to consumers and address any possible consequences of use
- Indicate the quantity of products affected by the defect and the number of consumers affected by the recall
- Indicate the percentage allocation of the products in each Brazilian state
- Specify the date on, and the manner through, which the supplier became aware of the risk
- Identify the measures taken to solve the defect and remove the risk
- Detail the media coverage plan, as provided in Article 3 of the Ordinance, including: (i) the period of the plan; (ii) the means, frequency and text of the announcements; and (iii) the facilities available to repair or replace the defective product; and report any accident acknowledged to have caused injury to any person or property due to the defect, providing the place and date of such accidents, information about the victims, a report of the injuries and damage, a report of any existing judicial claims, and measures taken to address such injuries and damage

The DPDC may request further information at any time.

Article 3 of Ordinance MJ No. 487/2012 notes the specific requirements of the media coverage plan. This provision requires the supplier to immediately inform consumers of the hazard or danger posed by the product or services introduced on the consumer market, by making notices publicly available anywhere consumers of such

product or services exist. Article 3 also requires that publicity notices be presented in the press, radio and television, at the supplier's expense, and that such notices must be sufficient to inform all consumers of the product or service. The provision further requires that the notices specify the product or service defect, the risk and consequences posed, the preventive and corrective measures consumers must take to prevent injury, and additional information to ensure consumer safety. Finally, Article 3 provides that the supplier may use supplemental means to communicate with consumers, if necessary, including letters, internet publicity and telephone calls.

If a product is being recalled in more than one country, the authorities will usually request information from suppliers on the procedures adopted in the other jurisdictions in order to avoid performing a less restrictive recall in Brazil. Therefore, suppliers must avoid any "double standard" in conducting recalls. Journalists may access websites of consumer protection agencies of other countries to check the information provided to consumers and, if they realize that the recall measures in Brazil are less restrictive, may publish this fact in Brazilian newspapers, which may prompt the authorities to request information on this issue.

All information provided to the authorities is public. Therefore, unlike in some countries, a company conducting a recall in Brazil will not provide detailed information to the authorities and more general information to the public.

Article 7 of Ordinance MJ No. 487/2012 requires suppliers implementing a recall to submit a monitoring report of the media coverage plan every 60 days, providing at least the number of consumers reached and the quantity of products repaired or replaced in each state. The DPDC may request the supplier to submit this report on a more regular basis, eg, every month.

If the campaign does not reach all the consumers of the products or services subject to recall, the supplier must present, in the final recall report, the reasons and measures to be adopted related to the



percentage of products and services not recovered or repaired, as well as the means by which the consumers learnt about the risk warning.

The DPDC will analyze the final report and decide whether the media coverage plan must be extended. If the DPDC finds the results of the recall satisfactory, the proceeding will be closed. However, the DPDC is of the view that a product recall must never be closed unless it reaches every consumer that purchased the product. In practice, our experience is that the DPDC does not close proceedings.

It is recommended that suppliers inform the DPDC even when a product recall is performed abroad and does not affect products marketed in Brazil. However, this recommendation has not been formally published by the DPDC. Brazilian authorities do tend to monitor recalls performed abroad via official databases, such as SIAR — Inter-American Rapid Alerts System of the Consumer Safety and Health Network of the Organization of American States.

4. Product-specific regimes

Pharmaceuticals

The Board of Directors of ANVISA issued Resolution RDC No. 55/2005 (the “Collegiate Board Decision Resolution”) which regulates the recall of medicine, and its requirements are applied with the general rules set forth by the CDC and Ordinance No. 487/2012. According to the RDC, any medicine that appears to have quality deviations and/or represents risks or serious consequences to human health must be recalled by the company responsible for the medicine registration (manufacturers or importers) before ANVISA.

The interested company must inform the health and surveillance agencies, providing the name of the product, the registration and batch numbers, the manufacture and expiration dates and a description of the deviation detected. Consumers must also be warned by an alert message to be transmitted by media. Please also note that the interested company is accountable for the final destination of the medicine collected during the recall campaign.

Food and beverage

Resolution RDC No. 24/2015 regulates the recall of food and beverage and its requirements are applied with the general rules set forth by the CDC and Ordinance No. 487/2012. According to the RDC, the interested company must establish a recall plan, which must be available to the team involved as well as to health and surveillance agencies.

The plan must be documented as a Standard Operational Procedure (POP) and must specify traceability obligations and several procedures in order to recall the product from the market. The RDC imposes specific information to be disclosed on the risk warning.

Motor vehicles

The automotive industry has to comply with specific obligations set forth by Ordinance No. 69/2010 (edited by the National Traffic Department DENATRAN and the Ministry of Justice), which imposes the following obligations on the supply chain of such industry during the implementation of a recall campaign: (i) immediately inform DENATRAN electronically about the campaign in order to register at the national registry of vehicles; (ii) provide DENATRAN with an attendance report within 60 days after the start of the campaign, providing additional reports every 15 days.

Bills of Law Nos. 6624/2009 and 1634/2015 propose changes to the CDC and the National Traffic Code to impose several new obligations during the recall campaign of vehicles, such as disclosure of the identification number of the affected vehicles on the internet and informing consumers about the recall campaign by sending a letter to their residence, among other tools.

5. Legal consequences of noncompliance

Noncompliance with the requirements of the specific obligations set forth by the Brazilian legislation may subject the infracting party to administrative and criminal penalties provided by CDC, Federal



Decree No. 2.181/1977 and Federal Law No. 6,437/1977. For instance, Article 64 of the CDC provides that a party that fails to inform the competent authorities and consumers about harmful and hazardous characteristics of products of which it becomes aware after the product's introduction to the market may be imprisoned for a period from six months to two years and incur a fine.

Furthermore, the CDC establishes that the authorities may impose a fine, among other things, which may range from approximately BRL 600 (USD 200) to BRL 9 million (USD 3 million). Please note that this amount is updated on a quarterly basis.

A person who fails to withdraw a harmful or hazardous product from the market immediately upon requirement by the competent authorities may incur the same penalties. If a supplier complies with its requirements, it will not be subject to administrative and criminal liability. However, any damage caused to consumers must still be indemnified; civil liability remains.

Further, it is important to mention that consumer defense agencies have been extremely severe in inspecting and punishing suppliers that do not observe the legal requirements while promoting a recall.

Brazilian consumer protection agencies do not have a formal consultation service for companies that are unsure of whether a certain product poses a risk to consumers. Thus, the burden of deciding whether to implement a recall falls completely on the supplier. In the event of doubt, it is often advisable to implement the recall. A supplier may be well advised to retain an expert with a view toward seeking an expert report indicating that the product does not present any risk to consumers. However, the competent authorities may challenge such expert reports and may still impose penalties on an allegedly violating supplier.

Canada

Introduction

The Canada Consumer Product Safety Act (the “Act”) imposes record keeping and mandatory reporting obligations relating to consumer products on members of the supply chain. The Act’s stated purpose is the protection of the public by addressing or preventing dangers to human health or safety posed by consumer products in Canada, including those that are circulated within Canada and those that are imported. A consumer product constitutes a “danger to human health and safety” when it poses an unreasonable hazard, existing or potential, during or as a result of its normal or foreseeable use, which hazard may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual’s health, including an injury. The death or adverse effect need not occur immediately after the exposure to the hazard.

1. Definition of a “consumer product”

The Act defines “consumer products” broadly to include any “product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for noncommercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.”

The Act applies to all consumer products, save for those specific products dealt with by other legislation and listed in Schedule 1, including food, drugs, cosmetics, medical devices and natural health products which are regulated under the Food and Drug Act, vehicles as defined under the Motor Vehicles Safety Act and any part that is integral to a vehicle.

The Act includes prohibitions against the following:

- Manufacturing, importing, advertising or selling consumer products that are a danger to human health or safety or are the subject of a voluntary or mandatory recall



- Advertising, packaging or labeling a consumer product in a manner that may reasonably be expected to create an erroneous impression regarding its potential danger to human health or safety or in a false, misleading or deceptive manner regarding its safety certification or compliance with a safety standard
- Manufacturing, importing, advertising or selling certain specifically listed consumer products under the Act, such as polycarbonate baby bottles that contain bisphenol A

2. Agencies involved in regulating consumer products

Under the Act, the Minister, through Health Canada, is charged with administering and enforcing the consumer product safety regime in Canada, including, as will be set out below, protocols established for record keeping, mandatory testing, incident reporting, inspections, product recalls and corrective measures.

The Governor in Council is charged with making regulations to achieve the purposes of the Act, including, for example, regulations regarding the following:

- The exemption of certain consumer products or classes of consumer products from the application of the Act
- The preparation and maintenance of documents and records
- The form and method of communicating health and safety warnings
- The inspection and mandatory testing process
- The levying and amount of administrative monetary penalties

3. Reporting requirements and recall procedures incident reporting

The Act institutes a regime for the mandatory reporting of “incidents” involving consumer products. An “incident” is defined as follows:

- An occurrence in Canada or elsewhere that resulted, or may reasonably have been expected to result, in an individual’s death or in serious adverse effects on their health, including serious injury
- A defect or characteristic that may reasonably be expected to result in an individual’s death or in serious adverse effects on their health, including a serious injury
- Incorrect or insufficient information on a label or in instructions, or the lack of a label or instructions, that may reasonably be expected to result in an individual’s death or in serious adverse health effects on their health, including a serious injury
- A recall or measure that is initiated for health or human safety reasons either within or outside of Canada

Section 14(2) of the Act requires each participant in the supply chain to provide the Minister, as well as the person from whom they received the consumer product, with all information in their control within two days of becoming aware of any incident. According to the “Frequently Asked Questions for the Canada Consumer Product Safety Act” published by Health Canada, the following questions should be asked by a supplier to assist in determining whether a particular event constitutes a reportable incident:

- Does the event relate to a consumer product that I sell, manufacture or import in Canada for commercial purposes (including its components, parts or accessories or packaging)?
- Does it meet the criteria of an incident in any of paragraphs 14(1) (a) through (d) of the Act?



- Does it indicate an unreasonable hazard posed by the normal or foreseeable use of the product or the foreseeable misuse of the product?

Once the supplier completes this analysis and determines that an event is a reportable incident under the Act, they then become “aware” of the incident and are subject to the reporting deadlines set out in Section 14.

The Act imposes additional reporting obligations on the manufacturer (or importer if the consumer product is imported into Canada) of a consumer product that is the subject of a reportable incident. Within 10 days of becoming aware of the incident, the manufacturer or importer, as the case may be, must provide the Minister with a detailed written report regarding the incident, including information about the product involved in the incident, information about any other products that they manufacture or import that, to their knowledge, could be involved in a similar incident, and any measures proposed to be taken with respect to the product.

This regime serves to increase the detail of the information regarding the incident as it passes up the supply chain and to the Minister. This becomes especially important where incidents occur in different locations and are reported by unrelated parties in the supply chain.

Inspections

The Act grants significant investigatory authority and responsibility to inspectors appointed by the Minister for the purpose of verifying compliance or preventing noncompliance, including entering into a place where it is believed that a consumer product is being manufactured, imported, packaged, stored, advertised, sold, labeled, tested or transported, or where a document relating to the administration of the Act is located.

In conducting the inspection, the inspectors are authorized to, among other things, examine or test anything and take samples; open

receptacles or packages; examine, make copies or take extracts of documents; seize or detain articles; and use or cause to be used any computers.

Inspectors are even authorized under the Act to enter a person's home, under authority of a warrant, for the purposes of carrying out their inspection.

Product recall orders and corrective measures

The Act provides the government the ability to take decisive actions to deal with potentially dangerous consumer products, including through the imposition of mandatory product recalls and the requirement that suppliers take certain corrective measures.

Where the Minister believes, on reasonable grounds, that a consumer product poses a danger to human health or safety, he or she may order a manufacturer, importer or seller to recall the product. Such an order must provide, in writing, the reasons for the recall as well as the time and manner in which the recall should be carried out.

A list of consumer products subject to recalls (including those recalls instituted voluntarily by a manufacturer or importer) is updated daily and provided on the Health Canada website.

In addition to facilitating the mandatory recall of consumer products, the Act also authorizes the Minister to order a manufacturer, importer or seller to take a variety of other corrective measures under the following circumstances:

- The person does not comply with an order regarding the testing, study and compilation of information regarding a consumer product
- The person does not comply with a product recall order



- The Minister believes, on reasonable grounds, that the product is the subject of a measure or recall taken voluntarily by the manufacturer or importer
- The Minister believes, on reasonable grounds, that there has been a contravention of the Act or the regulations in relation to the product

The broad measures available to the Minister include the following:

- Stopping the manufacturing, importation, packaging, storing, advertising, selling, labeling, testing or transportation of the consumer product, or causing any of those activities to be stopped
- Any measure that the Minister considers necessary to remedy any noncompliance with the Act or the regulations, including any measure that relates to the product that the Minister considers necessary in order for the product to meet the requirements of the regulations, or to address or prevent a danger to human health or safety that the product poses

If a person does not comply with a product recall order or corrective measure imposed by the Minister, the Minister may carry out the recall or corrective measure at the person's expense.

Record keeping and mandatory testing, studying and compilation of information

Among the many obligations imposed under the Act are the stringent record retention requirements imposed on various supply chain members.

Manufacturers, importers, advertisers and sellers are, among other obligations, required to prepare and keep records of the names and addresses of parties from whom they receive any consumer products as well as those to whom they supply or sell consumer products. These records must be kept for six years after the end of the year to

which they relate. The Minister may, in writing, demand the production of these records for inspection.

The Minister may require a manufacturer or importer of a consumer product into Canada to undergo the following:

- Conduct tests or studies on the product in order to obtain the information that the Minister considers necessary to verify compliance or prevent noncompliance with the Act or the regulations
- Compile information that the Minister considers necessary to verify compliance or prevent noncompliance with the Act or the regulations
- Provide the Minister with the documents that contain the compiled information and the results of the tests or studies in the time and manner that the Minister specifies

Disclosure of business information

The Act grants the Minister broad powers with respect to the disclosure of confidential business and personal information.

Though limited by the Privacy Act, the Minister is allowed to disclose personal information to a person or government, without the consent of the individual to whom the information relates, if the disclosure is necessary to identify or address a serious danger to human health or safety.

Similarly, the Minister is allowed to disclose confidential business information, in relation to a consumer product, to a person or government, without the consent of the person to whose business or affairs the information relates and without notifying that person, if the party to which the information may be disclosed agrees in writing to maintain the confidentiality of the information and to use it only for the purpose of carrying out the function of protecting human health or safety or the environment.



The Minister is also permitted to disclose, without the consent of the person to whose business or affairs the information relates and without notifying that person beforehand, confidential business information about a consumer product that is a serious and imminent danger to human health or safety or the environment, if the disclosure of the information is essential to address the danger.

4. Product-specific regimes

As noted, the Act applies to all consumer products, save for those specific products dealt with by other legislation and listed in Schedule 1, which include food and drink, drugs, medical devices and motor vehicles.

Food and drink

The safety of food and food products, including drink, is primarily regulated by the Food and Drugs Act (FDA), Food and Drug Regulations (FDR) and Canadian Food Inspection Agency Act (CFIA Act). The Canadian Food Inspection Agency (CFIA) is the federal agency responsible for overseeing and enforcing the federal food safety laws.

In addition to the FDA, the Safe Food for Canadians Act (SFCA), which was passed in November 2012, aims to strengthen Canada's food safety system by implementing, among other things, stronger food safety rules and improvements to the CFIA's food safety inspection model. The SFCA will come into force once the Safe Food for Canadians Regulations (SFCR) are enacted. In January 2017, the proposed SFCR were pre-published for public consultation. Currently, final publication of the SFCR is anticipated in spring 2018.

Under the current framework, there are no statutory obligations on a food manufacturer, importer or distributor to report a food safety incident or safety issue. However, under the FDA it is an offense for any person in Canada to sell an article of food that: (i) has in or on it any poisonous or harmful substance; (ii) is unfit for human consumption; (iii) consists in whole or in part of any filthy, putrid,

disgusting, rotten, decomposed or diseased animal or vegetable substance; (iv) is adulterated; or (v) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions. As a result, in order to avoid being found in contravention of the law, companies will typically look to act proactively and voluntarily recall and remove unsafe food and food products from the marketplace when a food safety issue arises. It should be noted, however, that under the CFIA Act, the Minister of Agriculture and Agri-Food has the authority to order a food recall where he or she has reasonable grounds to believe that the food product “poses a risk to public, animal or plant health.”

To assist the food industry, the CFIA has published Recall Plan Guides on its website for each stakeholder in the supply chain (ie, manufacturers, importers, distributors and retailers). These Guides are intended to help stakeholders develop a recall plan, identify food safety issues when they arise, and conduct recalls in a timely and organized manner.

In accordance with CFIA guidance, companies are required to notify CFIA immediately when they suspect that they have sold, distributed, or imported a product that poses a risk to consumers. In order for the CFIA to develop an accurate risk assessment and risk management strategy, companies should strive to provide the following information at the time of initial notification:

- Detailed description of the nature of the problem
- Name, brand, size, lot code(s) affected
- Details of complaints received and any reported illnesses
- Distribution of the product — local or national
- When the product was distributed (specific dates)
- Label(s) of the product(s) which may be recalled



- Total quantity of product imported and distributed
- Name of the company's contact with the CFIA
- Name and telephone number(s) of the company's after-hours contact

With respect to recalls, the proposed SFCR would require companies to have written procedures to handle complaints and recalls, including an obligation to conduct a recall simulation based on the recall procedure at least once a year. Companies would also be required to keep clear and readable records that permit the tracing of food forward to the immediate customer and backwards to the immediate supplier. In addition, traceability information would need to be provided, upon request from the Minister of Agriculture and Agri-Food, within 24 hours, or a specified shorter period, if the information is considered necessary to identify or respond to a risk of injury to human health, or a specified longer period if the information is not considered necessary for a recall that is or may be ordered. Traceability information would need to be accessible in Canada, and would need to be provided in French or in English and, if provided electronically, in a single file and in plain text that can be imported into and manipulated by standard commercial software.

Drugs, medical devices and natural health products

Drugs, medical devices and natural health products (NHPs) are regulated in Canada under the FDA and the following regulations made thereunder: the FDR, the Medical Devices Regulations (MDR) and the Natural Health Products Regulations (referred to collectively herein as the Regulations). Health Canada is the federal regulator with primary responsibility for administering the FDA and the Regulations as they relate to drugs, medical devices and NHPs.

Generally speaking, recalls of drugs, medical devices and NHPs can be initiated: (i) in response to a formal request or order to recall by Health Canada, or (ii) at the initiative of the responsible parties.

“Responsible parties” for the purposes of the Regulations include the following: for drugs and natural health products, manufacturers, distributors, importers, legal agents and wholesalers; for medical devices, manufacturers, importers, distributors and sponsors of clinical trials.

Responsible parties are required to comply with recall orders and orders relating to other corrective measures, and to notify Health Canada within certain timeframes following various events including the identification of a risk to health and when a recall or investigation is initiated. The Regulations generally also require responsible parties to maintain records of sales, complaints and investigations, and to report to Health Canada any incidents relating to medical devices, adverse reactions and serious adverse reactions to drugs and NHPs.

The specific actions mandated by the Regulations in the context of a product recall will differ by class of product.

For example, a manufacturer or importer of a drug is required to notify Health Canada “forthwith” upon commencing a recall. Health Canada interprets this to mean notification must be made, verbally or in writing, within 24 hours of having made the decision to recall. A written report containing sufficient information to enable Health Canada to assess the risk to health should follow the initial notification within 72 hours.

A manufacturer or importer of a medical device is required to notify Health Canada “on or before undertaking a recall.” Health Canada interprets this to mean notification must be made, verbally or in writing, within 24 hours of having made the decision to recall. A written report must follow within three business days and a report on the results of the recall and actions taken to prevent a recurrence must be submitted as soon as possible after the recall is completed.

NHPs are not subject to Health Canada’s power to order recalls; however, a supplier is free to voluntarily initiate a recall. In that case, every manufacturer, importer, distributor and product license holder



who undertakes a recall of NHPs is required to provide a report to Health Canada within three days after the day on which the recall is commenced.

While the term “recall” is not defined under the FDA or the Regulations, Health Canada, according to its published “Recall Policy,” views a “recall” for drugs and NHPs to be “a responsible party’s removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates the Act or the Regulations.” A “recall” in relation to a medical device is “... any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: a) may be hazardous to health; b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or c) may not meet the requirements of the Act or the Medical Devices Regulations.”

It is important to note that a “recall” in relation to drugs, NHPs and medical devices is not limited only to product defects or to health and safety risks, but more broadly includes any failure to comply with the requirements of the FDA or the Regulations, which would include failure to obtain any required product licenses or approvals, as well as noncompliance with product packaging and labelling requirements imposed by the FDA and the Regulations.

Motor vehicles

Motor vehicles are regulated in Canada primarily under the Motor Vehicle Safety Act (MVSA) and the Motor Vehicle Safety Regulations (MVSR). Transport Canada is the federal regulator with primary responsibility for administering the MVSA and its regulations.

The MVSA and MVSR prescribe standards for various classes of vehicles and related equipment, including vehicles such as passenger

vehicles, trucks, busses, motorcycles and all-terrain vehicles, as well as vehicle parts and equipment such as tires, vehicle restraint systems and child booster seats.

Pursuant to the MVSA, a company that manufactures, sells or imports any “vehicle” or “equipment” of a class for which standards are prescribed shall, on becoming aware of a defect in the design, construction or functioning of the vehicle or equipment that affects or is likely to affect the safety of any person, cause notice of the defect to be given in the prescribed manner to (i) the federal Minister of Transport, (ii) each person who has obtained such vehicle or equipment from the company, and (iii) each current owner of such vehicle or equipment.

“Vehicle” is defined in section 2 of the MVSA as “any vehicle that is capable of being driven or drawn on roads by any means other than muscular power exclusively, but does not include any vehicle designed to run exclusively on rails.” “Equipment” is defined as “any equipment set out in Schedule I that is designed for use in or on a vehicle.” Schedule I of the MVSA prescribes “tires” and “equipment for use in the restraint of children and disabled persons” as “equipment” for purposes of the MVSA.

5. Legal consequences of noncompliance

Health Canada

Compliance with the Act is enforced through a number of stringent penalties and measures up to and including lengthy imprisonment. Contravention is an offense punishable by a potential fine of USD 5 million and/or imprisonment for two years.

The contravention of certain provisions of the Act (including those relating to the sale and advertisement of dangerous products and the misleading or obstructing of the Minister or an inspector) and/or the knowing or reckless contravention of any other provisions of the Act may result in potentially unlimited fines and/or imprisonment for up to five years.



A company's directors, officers or agents who direct, authorize, assent to, acquiesce in or participate in the commission of an offense under the Act may be subject to the same punishment provided for the company under the Act, even if the company is not prosecuted for the offense. Furthermore, every day an offense continues constitutes a separate offense for the purposes of the Act.

The Act also imposes administrative monetary penalties of up to USD 25,000 for each violation of a recall or corrective measure order. The Administrative Monetary Penalties Regulations fix a range of penalties for violations depending on whether they are minor, serious or very serious.

The Administrative Monetary Penalties (Consumer Product) Regulations impose penalties which range from USD 1,000 to USD 25,000 per violation, depending on the nature of the violation and the violator's history with the administrative monetary penalty system. AMPs are accompanied by AMP Reports which inform Canadians as to the nature of the product and company at issue, as well as the nature of the noncompliance with the Act and contravention of the Minister's Order.

CFIA

Similarly, there are significant potential consequences for violating food and drink safety laws. A person who contravenes the FDA as it relates to food and drink is guilty of an offense and is liable on summary conviction or indictment to a fine of up to USD 250,000 and/or imprisonment for a term not exceeding three years. The proposed SFCA contemplates even greater penalties for violations, including fines of up to USD 5 million and/or imprisonment for a term of not more than five years.

Any person who contravenes the FDA, FDR, MDR or certain Orders of the Minister of Health in connection with a drug or medical device is guilty of an offense and is liable on summary conviction or indictment to a fine not exceeding USD 5 million and/or

imprisonment for a term not exceeding five years. Where the contravention involves a person who knowingly or recklessly causes a serious risk of injury to human health, these fines and prison terms are increased.

With respect to NHPs, any person who contravenes the FDA or the Regulations is guilty of an offense and is liable on summary conviction or indictment to a fine not exceeding USD 5,000 and/or imprisonment for a term not exceeding three years.

Transport Canada

There are significant potential consequences for violating these motor vehicle related safety laws. An individual who contravenes the MVSA, MVSR or an Order of the Minister of Transport is guilty of an offense on summary conviction or indictment and is liable to a fine of up to USD 20,000 and/or imprisonment for a term of not more than two years. A corporation that contravenes the MVSA, MVSR or an Order of the Minister of Transport is guilty of an offense punishable on summary conviction or indictment and is liable to a fine of up to USD 2 million.

Sources of information

Health Canada

<http://cpsr-rspc.hc-sc.gc.ca/PR-RP/home-accueil-eng.jsp>

Guidance on Mandatory Incident Reporting

http://www.hc-sc.gc.ca/cps-spc/pubs/indust/2011ccpsa_incident-lcspc/index-eng.php



Chile

The general regulation regarding recalls of consumer products is contained in Chilean Consumer Protection Law (CCPL). There are other special rules applicable to products that are approved under a certain standard (eg, motor vehicles, fuels and gas products, electric products, health products).

1. Definition of a “consumer product”

The CCPL does not define what constitutes a consumer product. However, the CCPL does define “consumer” as a person or legal entity that, by means of any agreement for monetary consideration, acquires, uses or enjoys, as a final user, goods or services. Thus, “consumer product” is by implication defined as any product that is acquired, used or enjoyed by a consumer in that sense.

2. Agencies involved in regulating consumer products

The governmental agency that has jurisdiction over recalls of consumer products and automobiles is the *Servicio Nacional del Consumidor* (SERNAC), which is the Chilean consumer protection agency. Additionally, there are other agencies involved in different aspects of consumer products. The National Normalization Institute is the agency in charge of issuing and approving quality standards and testing protocols. The Ministry of Health is involved in cases of products that may affect public health (eg, prohibited substances and paint). In addition, the Fuels and Electricity Superintendency (SEC) is in charge of the regulation and authorization of all electrical products, including household electrical products such as refrigerators, microwave ovens, electric bulbs, music equipment and televisions.

3. Reporting requirements and recall procedures

The CCPL imposes a duty on producers, importers and distributors to report, to the general public and competent authorities, any concerns regarding products that may be hazardous or dangerous, so that appropriate measures can be adopted to prevent or suppress the risk.

SERNAC's view is that the duty to recall has no time limitation with respect to the time of import or introduction to the market. Moreover, once the recall is launched, it is not limited in time.

Thus, disclosure must be made to both (i) the general public and (ii) the relevant authorities. In addition to SERNAC, depending on the type of products and type of danger, the recall may need to be communicated to other relevant authorities, such as the Ministry of Health for products that present a risk to public health; the Ministry of Transportation for automobiles; and the SEC in the case of regulated electrical products. All recalls are published by SERNAC on an internet site at www.seguridaddeproductos.cl.

Although the CCPL does not provide any formal procedure for disclosing information regarding hazardous or dangerous products, SERNAC takes the position that the obligation is fulfilled by publishing an advertisement in a local newspaper along with a short letter to affected consumers, if these can be traced, describing the potential danger and, if applicable, information pertaining to any recall process that is being implemented. The letter is often sent by electronic means, such as email or cellphone, if these contact details are available. Additionally, as a precautionary measure, it is recommended to send the draft advertisement and letter to SERNAC to obtain its approval prior to publication. Although this may not be strictly necessary, the authorities prefer this procedure.

In 2008, SERNAC issued basic guidelines for the safety-related recall of products (the "Guidelines"). The Guidelines are not legally binding rules, but serve as a basis for understanding the public agency's policy on recalls. The main obligations indicated in the Guidelines are as follows:

- The company must offer a solution to consumers, ie, providing a new product, returning the price paid, or otherwise compensating consumers
- The recall process must be entirely free of cost to consumers



- The solution cannot contain conditions less favorable to consumers than those they had when they purchased the product. For example, in a recall, consumers will have the right to exchange the product in the same location where they purchased it
- The right of the consumer to a solution cannot be denied either on the basis of the status of the product to be recalled (eg, whether it is damaged or otherwise) or because the consumer cannot produce an invoice or receipt as proof of purchase
- The recall cannot be limited to products purchased at a specific time, unless that time is relevant to the group of products that need to be recalled
- All information provided on the recall must be conveyed in Spanish
- The information provided to consumers must include at least the following: (i) an explanation of the risks associated with the product; (ii) an option to exchange the products, to obtain a refund or to obtain compensation in another way; (iii) a toll-free telephone number; and (iv) a time frame for the recall
- The relevant information must be provided in an advertisement published in a newspaper with widespread and large-scale circulation

If a court or the authorities find that a certain product is dangerous, the recall of this deficient product will be mandatory. In such a case, the provider must either replace the product or return the purchase price.

SERNAC has become more proactive in requesting periodic information on the results of the recall process, after some time has passed from the initial notification. The information requested usually includes the number of affected units, number of recovered units and procedures employed to mitigate risk.

4. Product-specific regimes

Pharmaceutical / Medical devices

Article 71 No. 3 of Supreme Decree No. 3/2010 on the National System of Human Use Pharmaceutical Products contains the specific recall obligation for pharmaceuticals and medical devices. In addition, the National Public Institute (ISP) has issued special instructions on recalls. In the case of a recall of a human use pharmaceutical product, as well as certain medical devices, ISP and the Ministry of Health are the authorities that will take the lead in the recall process. Consumer Protection Authorities may take a secondary role.

Food and drink

There are no special legal rules regarding recalls for food and drink. However, the Good Practices Manual of the Food Industry can be found at

http://www.inofood.cl/neo_2011/pdf/Manual%20Recall%20FINAL%20V3.pdf. This document contains the food industry's self-regulation on how to conduct a recall. In a case such as this, the Ministry of Health would take the lead in the recall process and Consumer Protection Authorities would take a secondary role.

Motor vehicles and parts

Motor vehicles do not have special recall rules. As mentioned in Section 2 above, SERNAC has jurisdiction over motor vehicle recalls. Accordingly, most vehicle recalls relating to product defects are processed through SERNAC's website - www.seguridaddeproductos.cl. However, there are other quality controls performed by 3CV (the governmental vehicle's homologation agency), which may result in the suspension of vehicle sales. Article 6 of Supreme Decree 54/97 of the Ministry of Transport indicates that if, in the process of verifying conformity of vehicle emissions (which can be done years after the vehicle has been homologated to ensure appropriate aging), it is established that vehicles approved in a previous homologation procedure do not conform with information



provided in the technical description of the vehicle or do not match the measurements made at the time of the initial homologation, then the Ministry will suspend the effects of the Homologation Certificate, so long as the anomalies are not corrected. This does not mean a recall has to be launched but the sales are suspended.

5. Legal consequences of noncompliance

There are no specific provisions providing for sanctions for nonperformance of a recall procedure. However, according to the CCPL, a breach of any of the duties outlined above will render the responsible party liable in damages for any harm caused. Producers, importers and first distributors will be jointly liable for any harm caused to consumers by dangerous or hazardous products. In some cases, this could qualify for a class action, although this has not been the case in practice. In addition, failure to comply with an information request from SERNAC may result in a fine of up to 200 monthly tax units (UTM) per event, equivalent to CLP 40,005. If the acts of the responsible party constitute a felony, eg, reckless distribution of poisonous or potentially dangerous products, the party will be subject to criminal punishment, including imprisonment.

Also, for products that require homologation of the certification certificate (eg, motor vehicles, pharmaceuticals, electric and gas products, cellphones), noncompliance may result in the cancellation of the homologation certificate and, hence, a temporary impediment to sell such products. In cases where there is a risk to the health of the general public, the Ministry of Health may require the preventive seizure and/or destruction of the products (eg, contaminated food, pharmaceuticals with production defect).

China

The Law Concerning the Protection of the Rights and Interests of Consumers (the “Consumer Rights Law”), effective from 15 March 2014, imposes a general recall obligation on business operators when they discover material product defects that may cause personal injury or property damage to a consumer.

The Administrative Measures for Recall of Defective Consumer Products (the “Consumer Products Recall Measures”), which came into effect on 1 January 2016, generally regulate the recall of consumer products. However, the Consumer Products Recall Measures apply to the recall of only consumer products listed under special catalogs promulgated by the AQSIQ (as defined below). These special catalogs list consumer products based on the degree of potential risks of harm and safety hazards that they may pose. Currently, the only special catalog issued by the AQSIQ lists certain electronic and electric appliances and child articles. That said, the recall of other consumer products not listed in the special catalogs should be carried out with reference to the Consumer Products Recall Measures.

The Consumer Products Recall Measures do not apply to tobacco and tobacco products, motor vehicles, civil aircrafts, civil vessels, food, pharmaceuticals, cosmetics, medical devices, and pesticides. The recall of these products is governed specifically by other laws and regulations.

1. Definition of a “consumer product”

The Consumer Products Recall Measures defines “consumer products” as products purchased or used by consumers necessary for daily consumption.

“Products,” according to the Product Quality Law, refers to “products made for sale after processing and/or manufacturing,” but excluding real estate.



2. Agencies involved in regulating consumer products

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

The AQSIQ is a ministerial-level administrative agency that reports directly to China's State Council. The AQSIQ is in charge of supervision and enforcement of product quality in China. The AQSIQ has a presence in every province of the country through the Bureau of Quality and Technical Supervision (QTS) and the Entry-Exit Inspection and Quarantine Bureau (CIQ). The QTS's responsibilities include the supervision of product quality (including food products) manufactured and sold in China. The CIQ is mainly in charge of inspecting and administering the import/export of goods, including products.

The technical institution of the AQSIQ (ie, the Defective Product Administrative Center) and its local counterparts take charge of information collection and analysis, investigation and technical support for the recall of defective consumer products in accordance with the regulations formulated by the AQSIQ.

State Administration for Industry and Commerce (SAIC)

The SAIC is in charge of consumer protection and product circulation. It has promulgated several national standards to regulate product quality and labeling, mainly from the perspective of protecting consumer rights. The SAIC and its local counterparts are responsible for dealing with complaints filed by consumers and have the authority to impose administrative penalties on the relevant business operators who are found to be in breach of product quality or labeling requirements.

China Food and Drug Administration (CFDA)

The CFDA is the ministry-level administrative body in charge of administration of pharmaceuticals, medical devices, food and cosmetics in the People's Republic of China (PRC). As part of its

powers and responsibilities, the CFDA also takes charge of the recall of medical devices and pharmaceuticals distributed within the territory of the PRC. Under the guidance, coordination and supervision of the CFDA, its counterparts at the provincial level (ie, the Food and Drug Administration (FDA)) implement and monitor recalls of medical devices and pharmaceuticals within their respective provinces.

Other agencies

In addition to agencies such as the CFDA that are responsible for the administration of product-specific recalls, the National Development and Reform Commission (NDRC), the Ministry of Commerce (MOFCOM), the General Administration of Customs and other agencies have retained some authority over the recall process within their respective scopes of function.

3. Reporting requirements and recall procedures

The Consumer Rights Law establishes a general requirement for a business operator to report to the relevant authorities (ie, the SAIC and the AQSIQ) any material product defect that may cause personal injury or property damage to a consumer. The business operator is also required to inform the public of such defect and to undertake preventative measures, such as ceasing sales, giving warnings, recalling, making harmless disposals of or destroying the relevant products and stopping production.

According to the Consumer Products Recall Measures, manufacturers are the primary entities responsible for recalling defective consumer products. “Manufacturers,” for this purpose, refer to enterprises that are established legally within the territory of the PRC and produce consumer products with the product qualification certificate issued in their own names. Enterprises importing consumer products from overseas and selling them in the PRC or authorized institutions of overseas enterprises located within the PRC are also deemed as manufacturers for the purpose of a consumer product recall.



The recall of consumer products distributed within the territory of the PRC can be initiated either by the manufacturer as a “voluntary recall” or by the AQSIQ or the competent QTS as a “directive recall.”

Manufacturers are required set up a system to collect, analyze and process information on product defects and the safety of consumer products. In the event that a manufacturer becomes aware of a possible defect, it shall conduct an investigation and analysis immediately. If such defect is confirmed, a manufacturer shall report the findings to the local AQSIQ, take measures in a prompt manner to stop the production, sales and the import of such defective product and implement a voluntary recall.

Where the AQSIQ or its local counterparts find that a consumer product may potentially have a defect, these agencies may also order the manufacturer to take the initiative to launch an investigation, or they may directly launch investigations themselves. If the investigation reveals a product defect, the AQSIQ or its local counterparts may order the manufacturer to undertake a recall.

For a mandatory or voluntary recall, the manufacturer is required to file a recall plan with the AQSIQ or its local counterparts within five working days after confirming that a product is defective or within five working days after being ordered to recall the product.

Within five working days after filing the recall plan, a manufacturer shall inform the public of the consumer product’s defect, the emergency methods to prevent damage, and the measures taken by the manufacturer to eliminate the defect. This notification is to be made through newspapers and periodicals, websites, radio, television and/or other ways that are easily accessible to the public.

Manufacturers are also required to submit progress reports and a summary report for the recall to the competent QTS.

Sellers, lessors, repairers, component suppliers, entrusted manufacturers and other business operators who are aware of possible

defects of consumer products shall notify manufacturers of the issue and report to the QTS at the same time. In such cases, the business operators shall stop selling, leasing and using the defective products and assist manufacturers to carry out recalls.

Manufacturers shall also report recalls conducted outside of the PRC of defective products that are also sold in the PRC to the local QTS, as well as to the AQSIQ.

4. Product-specific regimes

The PRC authorities took an ad hoc approach in promulgating separate recall regulations for certain high-risk products. These products include pharmaceuticals and medical devices, automobiles and food products.

Pharmaceuticals / Medical devices

The CFDA issued the Administrative Measures for Recall of Pharmaceuticals in 2007 (the “Drug Recall Measures”) and the Administrative Measures for Recall of Medical Devices (the “Medical Device Recall Measures”) in 2017. As addressed in section 2, the CFDA and its local counterparts monitor and supervise recall of pharmaceuticals and medical devices.

The Drug Recall Measures require that, with the assistance of drug operating entities (such as dealers and retailers) and entities using pharmaceuticals (such as hospitals), drug manufacturers (including foreign drug manufacturers) shall conduct the recall of pharmaceuticals that have been put in the market but are found to have “potential safety threats” in accordance with the relevant procedures. “Potential safety threats” is defined to mean the unreasonable danger posed by pharmaceuticals to personal health or safety resulting from research and development or production of pharmaceuticals. Drug manufacturers are required to establish sound and complete data recording and retention systems in respect of quality assurance and adverse drug reaction and report the same to the local FDAs in a timely manner.



Similarly, according to the Medical Device Recall Measures, manufacturers of medical devices shall conduct recalls of “defective” medical devices in accordance with the relevant procedures. Operating entities of medical devices and entities using medical devices are also required to provide necessary assistance in the recall of medical devices conducted by manufacturers. A medical device is deemed defective if (i) using it under normal conditions may pose unreasonable risks impairing personal health and life safety; (ii) it does not meet mandatory standards or the registered or filed technical requirements; or (iii) it does not meet the relevant provisions on quality management for manufacturing and supply of medical devices and may lead to unreasonable risks.

For both medical devices and pharmaceuticals, recalls are categorized into three classes according to the severity of the defects involved:

1. Class I Recall: when the use of the pharmaceuticals or medical devices might cause (or has already caused) severe health damage
2. Class II Recall: when the use of the pharmaceuticals or medical devices might cause (or has already caused) temporary or recoverable health damage
3. Class III Recall: when recall is still necessary even if the possibility of causing damages by the use of the pharmaceuticals or medical devices is remote

The manufacturer shall prepare and implement a recall plan according to the applicable recall classification of the products involved, and reflective of the distribution and use of the medical devices and pharmaceuticals subject to the recall. The detailed recall procedures, such as the time limit for notification of the recall, may slightly vary with each classification.

Similar to the recall of general consumer products, the recall of medical devices and pharmaceuticals distributed within the territory of

the PRC can be initiated either by the manufacturer as a “voluntary recall” or by the competent FDA as a “directive recall.” The manufacturer is required to initiate a voluntary recall once any defect in a medical device or potential safety threat posed by a pharmaceutical is discovered. Based on the information reported and collected from manufacturers and other entities involved in the distribution and use of pharmaceuticals or medical devices, the competent FDA may also initiate a directive recall if the relevant manufacturer fails to recall the defective products voluntarily.

As for foreign manufacturers whose products are distributed in China, recalls conducted of products outside China that are also sold in China must be reported to the CFDA by their designated agents or importers based in China. The resulting recall conducted in China shall be performed by the foreign manufacturer’s designated agents or importers based in China.

Notification to distributors and users of a pharmaceuticals or medical device recall must be made within the following time limits:

- Pharmaceuticals - 24 hours (Class I Recall), 48 hours (Class II Recall) or 72 hours (Class III Recall), as applicable
- Medical devices - one day (Class I Recall), three days (Class II Recall) or seven days (Class III Recall), as applicable

Once a voluntary recall is initiated, the manufacturer is required to make continuous filings and reporting to the competent FDA.

For directive recalls, the competent FDA may order the manufacturers, distributors, and users of the pharmaceuticals or medical devices to stop selling and using the relevant products when necessary. Once a directive recall is initiated, the manufacturer of the relevant product is subject to the reporting requirements required for voluntary recalls.



Food and drink

The Food Safety Law of the PRC effective from 1 October 2015 (the “Food Safety Law”), the Provisions on the Administration of Food Recall promulgated by the AQSIQ effective from 27 August 2007 (the “Food Recall Provisions”) and the Administrative Measures for Food Recall promulgated by the CFDA effective from 1 September 2015 (the “Food Recall Measures”) are the main rules regulating recall of food products (the latter two of which provides a detailed legal framework in this aspect). The CFDA and AQSIQ and their local counterparts supervise and administer food product recalls.

Food recalls are classified into three levels based on the severity of the hazard:

1. Class I Recall: when unsafe food has caused or may lead to food pollution, foodborne diseases which cause serious harm to physical health or even death, or the unsafe food has wide circulation and significant social impact
2. Class II Recall: when unsafe food has caused or may lead to food pollution and foodborne diseases which cause harm to physical health at an ordinary level or with a relatively small circulation and social impact
3. Class III Recall: when unsafe food has caused or may lead to food pollution and foodborne diseases that cause harm to physical health to a mild degree or the food has false labels or deficiency in its labels and instructions

A manufacturer is required to immediately report any food safety hazard to the competent local counterpart of the AQSIQ (ie, QTS). If a manufacturer determines that its food products are unsafe, it must stop the production and sale of the affected food products immediately, and inform the distributors and the general public to stop the sale and purchase of the unsafe food products. This notice must be made within a specific time period, according to the classification of

the recall. The manufacturer shall file recall plan reports for the recall with the CFDA and AQSIQ (or their local counterparts). Food manufacturers shall submit recall progress reports according to required interval periods and summary reports within 15 days upon the expiry of the food recall time limits to the AQSIQ or the QTS.

If the manufacturer fails to undertake a voluntary recall, the CFDA and the AQSIQ may issue a notice of directive recall to the manufacturer.

In case of imported food products, the PRC law mainly imposes the recall obligations on importers. Specifically, where imported food products have safety issues that have or may endanger human health or life safety, importers are required to carry out a voluntary recall and make reports to the local FDA and CIQ. The importers shall also publish relevant information to the public, notify the sellers to cease the sale and notify the consumers to cease use.

Motor vehicles and parts

The Administrative Regulations on Recall of Defective Auto Products promulgated by the State Council on 22 October 2012 and its implementing rules (the “Auto Products Recall Regulations”) set out the regulatory framework of recall requirements for defective auto products. The Auto Products Recall Regulations applies to automobiles and trailers (the “Auto Products”) manufactured and/or sold in China. The main authority in charge of auto recall is also the AQSIQ (together with its technical institutions).

In general, the manufacturer shall be responsible for investigating defects and reporting the findings to the AQSIQ, for the submission of the recall plan to the AQSIQ, and for implementing a recall. The “manufacturer” is the enterprise that is lawfully established within the territory of the PRC, produces the Auto Product, and issues the relevant product quality certificate in its name. Companies that import Auto Products into China for sale will be deemed as manufacturers for this recall purpose.



The manufacturer is required to organize and arrange investigations in a timely manner after it becomes aware that the Auto Products may have defects, and must report the investigation and analysis results to the AQSIQ. Where the manufacturer confirms that there is a defect, it shall make a recall plan, file the recall plan with the AQSIQ within five working days from confirming that the Auto Products have defects, notify relevant business operators at the same time it submits its recall plan to AQSIQ and then implement the recall according to the plan.

Manufacturers shall publish information concerning the defective Auto Products and implementation of recalls in the media, including newspapers, periodicals, websites, radio and television, within five working days from the date of filing the recall plan. Manufacturers shall also notify the owners of the defective Auto Products of the defect, the emergency measures taken to avoid adverse consequences, and the remedial measures adopted by manufacturers. This notification must be made by registered letter or other effective means within 30 working days from the date of filing the recall plan. Manufacturers are also required to provide hotlines, network platforms and other means for sharing information about the recall to the public. The AQSIQ will publish recall information, including the identity of the defective products, the recall plan, and other relevant information.

If the AQSIQ determines that certain Auto Products have a defect based on relevant investigation reports, it will notify the manufacturer in writing to recall the Auto Products. A manufacturer may object to such recall notification and submit relevant evidence to refute the AQSIQ's findings. Where it is further confirmed that a defect does exist after technical testing and verification, the AQSIQ may order the manufacturer to implement a recall.

Manufacturers shall submit recall phase status reports to the AQSIQ every three months from the date of implementing the recall plan. Where the AQSIQ has imposed additional special requirements,

manufacturers shall submit recall reports as required. Manufacturers shall submit a final recall summary report to the AQSIQ within 15 working days after completing a recall plan.

Where there are still defective Auto Products in the market after a recall plan has been concluded, manufacturers shall continue to recall the affected Auto Products from the market.

Business operators that are engaged in the sale, lease or maintenance of Auto Products, and manufacturers of accessories to Auto Products, shall also report potential defects in Auto Products to the AQSIQ and notify the same to the manufacturer of the Auto Products.

Business operators shall also assist the manufacturer with implementing the recall.

5. Legal consequences of noncompliance

A business operator that fails to file a written report with the authorities, in circumstances in which it was required to do so, may be subject to an administrative order requesting it to rectify such noncompliance, and a negative remark would then be recorded against the business operator in the credit supervision system.

Further, according to the Consumer Rights Law, if a business operator refuses to implement or delays implementing any order to recall or to take other measures on defective products, it may be subject to (i) an order to rectify the noncompliance, (ii) a warning, (iii) confiscation of illegal gains, and/or (iv) a fine of up to 10 times the amount of the illegal gains (or in case of no illegal gains, a fine of up to RMB 500,000). In serious cases, a noncompliant business operator may be ordered to suspend business for rectification or its business licenses may be revoked. Negative credit records will also be kept by the authority and published.

If a manufacturer knowingly engages in selling hazardous products, it may be exposed to sanctions under the Product Quality Law, which



allows the authorities to impose both administrative and criminal penalties against the manufacturer.

There are separate penalties under specific regulations for failing to recall other products, such as medical devices, pharmaceuticals, food and vehicles.

Pharmaceuticals / Medical devices

If the manufacturer of medical devices refuses to conduct a recall pursuant to the FDA's order, it may be subject to (i) confiscation of the relevant defective medical devices; (ii) fines of up to 10 times the value of the medical devices concerned; and/or in serious cases (iii) an administrative order to stop production and operation and (iv) revocation of medical device registration certificates and the medical device production license.

If the pharmaceutical manufacturer fails to recall the pharmaceuticals upon discovery of safety threats contained in the pharmaceuticals, the competent FDAs may, in addition to an order for a directive recall, impose monetary fines amounting to three times the price for the pharmaceuticals to be recalled. Where the manufacturer fails to recall pharmaceuticals that had severe consequences, the manufacturer may lose the approval certificates for the relevant pharmaceuticals or even the manufacturing permits.

If the manufacturer of pharmaceuticals and medical devices fails to perform timely notification to the authorities of the recall, or fails to satisfy its other filing and reporting obligations during the recall process, the FDAs may issue a warning, require rectification within a limited time period and/or impose monetary fines of up to RMB 30,000.

The FDAs may also impose monetary fines on the distributor and entities using the relevant devices and pharmaceuticals if they fail to discharge their obligations and responsibilities during the course of

the recall, and even revoke their operating permits in severe circumstances.

If the manufacturer has successfully eliminated or mitigated the damages caused by the defective medical devices or pharmaceuticals through a voluntary recall, their administrative liabilities may be reduced accordingly.

Food and drink

Failure to recall unsafe food products or comply with relevant notification and reporting obligations may expose the manufacturer to risks of administrative penalties, such as warnings, orders to rectify and fines of up to RMB 30,000.

Food manufacturers will not be exempted from other legal liabilities that they ought to bear arising from manufacturing and sale of unsafe food products, even if they implement the food recall. However, where food manufacturers voluntarily implement the recall, their administrative liabilities may be reduced.

For imported food products, where the importer fails to implement a voluntary recall, the CIQ may order it to recall the products. The AQSIQ may further publish risk warning notices and take preventive measures, such as (i) restricting importation (including closer monitoring and stricter inspection); (ii) banning importation, destruction of products or return of shipping; and/or (iii) initiating implementation of its food safety emergency treatment plan.

Motor vehicles

Manufacturers may be subject to an order to rectify noncompliance issued by the AQSIQ, as well as monetary penalties in case of noncompliance with recall regulations.

For example, the AQSIQ may impose fines in the range of RMB 50,000 to RMB 200,000 if manufacturers fail to file recall plans and reports; RMB 500,000 to RMB 1 million and confiscation of



illegal proceeds if a manufacturer fails to implement the recall according to the recall plan filed with the AQSIQ or notify the sellers of the recall plan; and in the range of 1% to 10% of the amount of defective Auto Products and confiscation of illegal proceeds if the manufacturer or importer fails to cease the production, sales or import of defective Auto Products, conceals the defects, or refuses to implement a recall after receiving a recall order.

In serious cases, relevant permits and licenses may be revoked.

Sources of information

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

www.aqsiq.gov.cn

State Administration for Industry and Commerce (SAIC)

www.saic.gov.cn

China Food and Drug Administration (CFDA)

www.sda.gov.cn

AQSIQ Defective Product Administrative Center (DPAC)

www.dpac.gov.cn

Colombia

Law 1480 of 2011, effective as of 12 April 2012, introduced a comprehensive modification to the Colombian Consumer Protection Statute (CPS). Such amendment includes mandatory recall procedures if certain conditions are met.

1. Definition of a “consumer product”

The CPS does not include an express definition of a “consumer product.” The law does define a “consumer” as any person (individual or entity) that as an end user acquires, enjoys or uses a given product, regardless of its characteristics, to satisfy one or more of its personal or private needs or those of its family or commercial activity.

With respect to commercial activity, qualification of an entity as a “consumer” requires that the product acquired is not intrinsically related to its corporate activity or purpose. Under this definition, a person or entity that acquires a product to resell it or to incorporate it into another product (eg, raw material) would not qualify as a consumer.

2. Agencies involved in regulating consumer products

Generally, consumer protection and enforcement of Colombian consumer protection rules fall within the responsibilities of the faculties of the Superintendence of Industry and Commerce (SIC). A special division of this agency, the aptly named Consumer Protection Division, is in charge of consumer protection. Governors and city mayors have special faculties at a local level within the cities in which they exercise their authority.

3. Reporting requirements and recall procedures

Recall procedures were not fully described in the former consumer protection rules in effect until 11 April 2012, and it was not clear if these were mandatory. Nonetheless, manufacturers that failed to implement recall procedures upon becoming aware of potential



hazards or safety issues related to their products assumed the risks of harming consumers and were potentially liable for their lack of action.

The new CPS introduces a very strict provision which imposes an obligation on manufacturers, importers, distributors and retailers that become aware of a defect in their products to take all measures necessary to recall the products already sold to the public in Colombia and stop sales of those not yet sold.

These parties must inform the SIC about any sale in Colombia of defective products within three calendar days of the date on which they learned about the defect. There is no specific form for doing so.

A product will be considered defective for the above purposes when its defect causes, has caused or may cause an adverse effect on human beings. Although the provisions do not clarify this point, it is reasonable to assume that the defect triggering a recall is one that may cause harm that was neither disclosed nor intended. Products that may cause harm to humans must indicate so in the warnings and information provided to the consumer.

Decree 679 of 2016 regulates the procedure to be followed by any member of the chain of production, distribution and marketing who is aware of the existence of a defective product and who, because of this condition, has produced or can produce an adverse event against the health, life or safety of consumers. The aforementioned decree also establishes the corrective measures that they must take.

4. Product-specific regimes

Motor vehicles and parts

There is a special recall regime contained in the Consumer Protection Guidelines included in the General Regulatory Framework issued by the Superintendence of Industry and Commerce (ie, the *Circular Unica*). The government agency responsible for overseeing the implementation of such a recall is the SIC.

The General Framework of the SIC (*Circular Unica*) also dictates that notice should be given to the SIC when 4% or more of the consumers of a given product in Colombia have submitted claims to the dealer, distributor, importer or manufacturer which are related to a failure in a vehicle or part of the same line and series.

All the members in the supply and distributor chain are jointly responsible for providing notice to the authorities on the failure of the products and on the future implementation of a recall when (i) 4% or more of the consumers of a given product in Colombia have submitted claims related to a failure in a vehicle or part of the same line and series or (ii) the parties in the supply or distribution chain become aware of a failure in the product that may cause a material threat against the health, integrity, security or life of the consumers.

The information that must be included in the notification of a recall procedure is called a vehicle safety campaign and must include the following:

- Schedule forms number 3ID-V, ó 3ID-VCRC, 3DIV-C and 3CRO-C issued by the SIC, duly filled out, together with the following activities:
 - Draft of the technical bulletin for workshops
 - Verification of the availability of spare parts
 - Verification of the availability of specialized tools
 - Reception and distribution of spare parts to workshops
 - Reception and distribution of specialized tools
 - Official announcement campaign to workshops and distributors
 - Training to administrative staff
 - Draft of the communication to the costumers



- Development of communication media
- Call center training campaign
- Communication campaign to customers by telephone
- Communication campaign to customers by mail
- Broadcast media campaign
- Follow-up procedures to be implemented by the responsible parties

The SIC forms are available at: <http://www.sic.gov.co/anexos-circular-unica>.

Moreover, importers, distributors or dealers of a product must inform the SIC of the defect detected, the line and the model of the vehicle involved, the number of units in circulation and the implementation schedule for each one of the abovementioned activities.

Pharmaceuticals / Medical devices

(a) Medical devices

Manufacturers and importers of medical devices must notify the National Institute of Food and Drug Surveillance (Invima) of the total or partial withdrawal of products from the market when they pose a risk to the health of the patients in which they are to be used in accordance with Article 19 of Resolution 4816 of 2008.

For the notification, manufacturers and importers of medical devices must provide at least the following information:

- Name, references, lot numbers or series of the medical device, object of withdrawal and expiration date when applicable
- Causes that led to the withdrawal of products with documents that support this decision

- Addressees of the medical device in Colombia
- Actions that have been undertaken to carry out the withdrawal of the product from the market, including estimated withdrawal time and final disposal

There is no specific form for doing so. The product's withdrawal report to Invima is not a condition for the manufacturer or importer to carry out the withdrawal of the product from the market.

Manufacturers or importers of medical devices shall notify Invima of the communiqués they provide to their users when they are disclosing aspects that directly or indirectly influence the safety or performance of the medical devices they sell.

(b) Pharmaceuticals

Manufacturers, holders of medical records and distributors must have responsible and written procedures to immediately withdraw from the market drugs and medical devices that do not meet the technical specifications of quality or when requested by Invima in accordance with Resolution 1403 of 2007. The distributor registration system must allow the immediate identification of the destination of all marketed products. The withdrawal of drugs and medical devices from the market will proceed as follows:

1. The manufacturer and/or owner of the health record, on its own initiative or at the express request of the competent authority, shall report on the withdrawal of a product from the market or on the distributor at its disposal, as appropriate.
2. Manufacturers, holders of medical records and/or the competent authority shall inform all customers who have available products and/or the community in general of the decision to withdraw from the market, especially those who have received such products from the lot to be removed.



3. The distributor, or whoever has the products at their disposal, as the case may be, will immediately separate them from the inventory and/or the storage site and place them in a safe area until their final destination is decided.
4. The withdrawal process will be recorded at the time it takes place. The report shall include the number of products delivered by the distributor to whom they are available, the quantity of products withdrawn from the market and the difference between the first quantity and the second quantity. The documentation shall be immediately available to the competent authority.

Manufacturers, holders of health records and distributors, in all cases, will inform Invima within 24 hours following the withdrawal of medications that, during the manufacturing and/or distribution process, do not meet the technical specifications of quality.

Food and drink

The Colombian Consumer Protection Regulation does not provide a specific procedure for food and drinks recall; these recalls should follow the procedure established in Decree 679 of 2016.

5. Legal consequences of noncompliance

For any of the types of products covered in this chapter, failure to implement adequate or “reasonable” recall procedures or failure to inform the SIC within the legal time frame of the need to start such procedures could be viewed as a violation of Colombian consumer protection laws. In such event, the SIC could carry out any of the following:

- Impose fines on the parties responsible of up to 2,000 times the minimum monthly legal salary (For the fiscal year 2017, this value would be equivalent to COP 475 million.)
- Depending on the materiality of the violation, order the suspension of the commercial activities or the definitive

foreclosure of the commercial establishment of the parties responsible for the violation

- Order the destruction of the products that are defective and potentially hazardous to consumers (Failure to follow and comply with the orders of the SIC may trigger fines of up to 1,000 times the minimum monthly legal salary. For the fiscal year 2017, this value would be equivalent to COP 737.7 million.)
- Impose fines against the managers, directors, legal representatives and any other individuals authorizing, executing or tolerating the violation (These fines may be up to 300 times the minimum monthly legal salary, effective on the date the sanction is imposed. For the fiscal year 2017, this value would be equivalent to COP 221 million. The SIC may also order a debarment from commercial activities for a period of up to five years.)

Sources of information

The Superintendence of Industry and Commerce has a web page on which the agency publishes some of its most important decisions. The site is located at www.sic.gov.co.



Czech Republic

General product safety, including rules for product recall and withdrawal, is regulated in the Czech Republic by Act No. 102/2001 Coll., on General Product Safety (the “GPS Act”), which came into effect on 1 July 2001. The GPS Act effectively incorporated into Czech legislation the substance of regulations contained in General Product Safety Directive 2001/95/EC.

1. Definition of a “consumer product”

According to the GPS Act, a “consumer product” means any item that was manufactured, mined or otherwise procured irrespective of the level of its treatment, and that is intended for consumer use, or the use of which by consumers (as defined in the Czech Civil Code) is reasonably foreseeable. According to the Civil Code, a “consumer” is a natural person who, in using the product, does not act within the framework of his or her trade or other business activity or within the framework of independently performing his/her occupation.

2. Agencies involved in regulating consumer products

The primary authority supervising compliance with the GPS Act is the Czech Trade Inspection, which has countrywide jurisdiction. It is divided into the Central Inspectorate and seven subordinated regional inspectorates, which carry out surveillance activities in each region of the Czech Republic.

The Czech Trade Inspection is a state administrative body, subordinated to the Ministry of Industry and Trade. According to Act No. 64/1986 Coll. on Czech Trade Inspection, the Czech Trade Inspection supervises legal entities and natural persons: (a) selling or supplying products and goods to the internal market; (b) providing services; (c) pursuing other analogous activities on the internal market; or (d) operating marketplaces, unless supervision has been entrusted to another administrative authority by a specific law.

3. Reporting requirements and recall procedures

General product safety is assessed according to the processes stipulated in Section 3 of the GPS Act.

In the event that an unsafe product was marketed, the manufacturer or the distributor must inform the competent authority (usually the Czech Trade Inspection) immediately after the defect or risk is discovered and must cooperate with the competent authority on measures to be taken to eliminate or reduce any risks to the consumer inherent in the unsafe product. Such information may be provided using the EU's Business Application form.

In the event of a serious risk to consumer safety arising from placement of an unsafe product on the market that consequently requires rapid action (regardless of whether effects are imminent or not), the information must at least include the following:

- Detailed identification of the relevant product or product line
- Complete description of any risks inherent in the product
- Any available information important for tracking the product
- Description of measures taken to prevent risk to the consumer

If the notification about a defective product is made in another EU Member State, the Czech Trade Inspection usually requires the translation of the notification to the Czech language and country-specific information about the corrective measures.

Czech law does not stipulate a detailed procedure regarding communication of information to consumers (ie, whether the recall should be announced by press release or in another form). However, common practice is to announce a product recall in at least two countrywide daily newspapers. In addition, a manufacturer or distributor can also use other means of communication and media including television, radio or the internet.



The manufacturer or distributor is obligated to physically recall the unsafe product from the distribution chain, including from any retail outlets.

4. Product-specific regimes

Pharmaceuticals and medical devices

Pharmaceuticals safety is regulated by Act No. 378/2007, on Pharmaceuticals, as amended (the “Pharmaceuticals Act”), and medical devices safety is subject to Act No. 268/2014 Coll., on Medical Devices, as amended (the “Medical Devices Act”). In both cases the supervisory authority is the State Institute for Drug Control (the “Institute”), which is a state public body subordinated to the Ministry of Health.

Under the Pharmaceuticals Act, in the event of a risk to the health of treated persons, the marketing authorization holder (MAH, as defined in the Pharmaceuticals Act) is obliged to take all measures necessary to limit the adverse affects of the pharmaceutical at issue. Such measures must be notified to the Institute using the standardized form at: <http://www.sukl.cz/nahlasit-nezadouci-ucinek>, which will publish it on its website. If the MAH detects a defect in the quality of a pharmaceutical (or if the defect is detected by the Institute and reported to the MAH), the MAH must ensure that patients may replace such pharmaceutical at any pharmacy or, if the replacement is not possible, ensure withdrawal from the market and removal of the defective product, unless another measure has been imposed by the Institute.

With respect to the medical devices, the Medical Devices Act provides for a vigilance system of reporting and evaluation of adverse incidents and safety corrective actions. If an adverse incident (as defined in the Medical Devices Act) occurs, the manufacturer of medical devices is obliged to assess the risks with a view to the safety and health of users, patients and other individuals and, if necessary, determine a safety corrective action. The Institute is to be notified of:

(i) determination of a safety corrective action, including distribution of a safety alert (ie, a communication intended for distributors, importers, users or patients concerning the adopted safety corrective action) in the Czech and English languages; and (ii) completion of the safety corrective action (within 10 days after the plan has been completed). The manufacturer is also obliged to inform the concerned authorities of other Member States where the medical device has been supplied to the market. The reporting obligation is to be conducted through a dedicated form available on the Institute's website at: <http://www.sukl.cz/zdravotnicke-prostredky/hlaseni-nezadouci-prihody-zdravotnickeho-prostredku-1>.

The Institute may also decide on withdrawal of a medical device from the market for technical or medical reasons.

Food and drink

Food and drink safety is regulated by Act No. 110/1997 Coll., on Food and Tobacco Products, as amended, and, with respect to animal products, by Act No. 166/1999 Coll., on Veterinary Care, as amended. The supervisory authorities are the Czech Agriculture and Food Inspection Authority and the State Veterinary Administration, both of which are subordinated to the Ministry of Agriculture. In addition, the Ministry of Agriculture has established a Food Authority, which coordinates activities of the abovementioned supervisory authorities and is the main point of contact in relation to the European Food Safety Authority.

Generally, direct or indirect risk to human health from food is reported through the Rapid Alert System for Food and Feed (RASFF) established by the EU Regulation No. 178/2002, which sets out the general principles and requirements of food law. Through this system EU Member States share important information regarding food safety and consumers are informed about the adopted measures. The national point of contact with respect to RASFF is the Czech Agriculture and Food Inspection Authority. If a manufacturer finds out that unsafe food has been placed on the market, it must notify the respective



authorities (as discussed above) and coordinate with them further steps aimed at withdrawing the product from the market and informing consumers.

Vehicles and their parts

Vehicle safety is subject to Act No. 56/2001 Coll., on Operation of Vehicles on Public Roads, as amended, and the supervising authority is the Ministry of Transport.

Under the Act on Operation of Vehicles on Public Roads, the Ministry of Transport is entitled to prohibit a manufacturer of vehicles from placing vehicles or their components on the market if the Ministry finds out that the products at issue could be imminently dangerous to life and health or to road safety. As to recalling unsafe components, the procedure corresponds to the general requirements set out in the GPS Act, however, the competent authority is the Ministry of Transport.

5. Legal consequences of noncompliance

Administrative law sanctions

If a manufacturer or a distributor does not fulfill its recall obligation and life, health or property is at risk, the competent authority may order destruction of the product in addition to imposing a fine on the person who did not fulfill the obligation to recall the product from the market at its expense. The fine imposed by the supervisory body under GPS Act may reach up to CZK 50 million.

Noncompliance with the obligation imposed in MAHs by the Pharmaceuticals Act may be sanctioned by a monetary penalty of up to CZK 20 million. Breach of the vigilance system under the Medical Devices Act is subject to a monetary penalty of up to CZK 500,000.

Violation of food safety regulation may be sanctioned by a monetary penalty of up to CZK 50 million.

When imposing a fine, the degree, manner, duration and consequences of the illegal conduct are taken into account. The procedure to impose a fine can be started within one year from the date the body responsible for imposing the fine learned about the breach of duty, and no later than two years from the date when the breach of duty occurred. No fine may be imposed if three years have elapsed since the breach of duty.

The imposition of fines, due dates, collection and extraction of fines are also governed by special laws and provisions including Act No. 64/1986 Coll. on Czech Trade Inspection, the Czech Administration Procedure Code and the Czech Tax Code.

Criminal law liability

According to the Czech Criminal Code, violation of consumers' rights consisting of: (i) deceiving the consumer in relation to a product's quality, quantity or weight; or (ii) placing a large volume of products with concealed defects on the market may be punished by imprisonment for up to one year or by a fine or a ban on activity or forfeiture of a thing or other property value for the basic violation. If the crime is more severe (eg, in cases of violations as part of an organized group, significant profit or repeat offending), imprisonment may be up to five years, or in particularly severe cases, the offender may be punished by imprisonment for up to eight years. Under the Czech Criminal Code, this offense can be committed by an individual or a legal entity.

In extreme cases, breach of product safety regulations could also amount to the crime of public endangerment, which could be sanctioned by imprisonment for up to eight years. Again, this crime can be committed by an individual or a legal entity.

Sources of information

Czech Trade Inspection: www.coi.cz

Ministry of Industry and Trade: www.mpo.cz

Ministry of Agriculture: www.eagri.cz



Czech Agriculture and Food Inspection Authority: www.szpi.gov.cz

State Veterinary Administration: www.svsscr.cz

Ministry of Health: www.mzcr.cz

State Institute for Drug Control: www.sukl.eu

Ministry of Transport: www.mdcz.cz

Web pages related to consumer protection:

<http://www.spotrebitele.info>

<http://www.dtest.cz>

www.mpo.cz/en/consumer-protection/default.html

Egypt

The Consumer Protection Law No. 67 of 2006 (the “Law”) serves as the foundation of all forms of consumer protection in Egypt, including product safety and recall.

1. Definition of a “consumer product”

The Law and its Executive Regulations make no use of the terminology “consumer product.” The legislation instead defines the terms “consumer” and “product” separately. According to the Executive Regulations, a “consumer” is “any person to whom a product is offered for satisfying a personal or familial need or with whom a transaction or conclusion of an agreement for the said purpose is made,” while “product” is defined as “the goods and services offered by public or private law persons, including the used goods that are contracted upon through the supplier.”

2. Agencies involved in regulating consumer products

The Consumer Protection Authority (CPA) was established under Article 12 of the Law, and was designed to implement the Law’s initiatives and objectives. The CPA, which is headquartered in Cairo, is an independent public entity affiliated with the Ministry of Trade and Industry and acts in the interests of protecting consumers’ rights from general breaches of the Consumer Protection Law by suppliers. While the CPA operates as the primary authority regarding the protection and enforcement of consumer rights, Law No. 1 of 2017 and Ministerial Decree No. 540 of 2007 delegate responsibilities for specific products of a sensitive nature to the appropriate authorities, such as foods and beverage to the National Food Safety Authority and pharmaceuticals to the Egyptian Drug Authority.

3. Reporting requirements and recall procedures

Article 7 of the Law and Article 19 of the Executive Regulations stipulate that if a supplier, importer, manufacturer or distributor (the “Supplier”) discovers a defect in any of its products being sold in the



Egyptian market, it should report this to the CPA within seven days of discovery and advise the CPA of any possible consequences that the defect might cause. The Supplier is also obliged, upon a consumer's request, to change, repair, exchange or refund the product with no additional cost.

A defective product should be reported by the Supplier or his/her representative using the report form provided by the CPA. The form requires the reporter's personal details, the details of the defective product, the name and address of the manufacturer, the date of defect discovery, a detailed technical description of the defect, a description of the potential harm associated with the defect, proposals for their elimination or remedy, a proposal of procedures that enable the consumer to repair, return, exchange or refund the product and any additional information necessary.

Furthermore, Article 20 of the Executive Regulations stipulates that if the defect is likely to cause harm to a consumers' health or safety, the Supplier should inform the CPA immediately upon discovering said defect. Furthermore, the Supplier must immediately cease dealing in the defective product and inform the public of the defect by warning consumers not to purchase or use the products. The Supplier must take necessary measures to suspend the circulation of the product in the market. A recall may be announced in the official Egyptian daily newspapers or be communicated directly to consumers if circumstances permit, all in accordance with any guidelines provided by the CPA.

4. Product-specific regimes

Pharmaceuticals / Medical devices

The Egyptian Drug Authority (the "Authority") is the primary regulatory body for pharmaceuticals and medical devices traded in Egypt. The Authority encompasses three departments, each with specific responsibilities and objectives ensuring the compliance of

drugs and medical devices to the safety standards and regulations of Egyptian law.

The Central Administration of Pharmaceutical Affairs (CAPA) is the sole department within the Authority that is capable of directly interfering with the market to reduce or eliminate the risks posed to consumers by unsafe products. According to Article 1 of the Ministerial Decree No. 540 of 2007, the CAPA has been endowed the authority from the Minister of Health and Housing to issue warnings or recalls on any vaccines, pharmaceutical or biochemical products that are in violation of specific trade or storage standards, or upon the discovery of breaches of law within the factory's production line. Article 1(b) further stipulates that the CAPA is also responsible for issuing recall orders upon the decreed request of such action from the Authority's Department of National Organization of Drug Research and Control and the World Health Organization.

While the CPA still serves as the point of first contact between Suppliers of pharmaceuticals and medical devices and their governing authority, the EDA operates as the point of first contact for consumers concerned with the safety of their drugs or medical products and the authority responsible for protecting them from such risks. Furthermore, the EDA operates as a more effective regulator in regards to pharmaceutical products, due to the structural administrative law distinctions between the two regulators; the CPA is unable to order cessation production of medical products, as Article 2 of the Ministerial Decree stipulates that such powers are granted exclusively to CAPA.

The EDA's website allows for the detailing and reporting of suspected counterfeit medication, while concerns over the safety of licensed medications are to be submitted to the EDA's officer of product safety via email.



Food and drink

Law No. 1 of 2017 on the promulgation of the National Food Safety Authority (the “NFSA Law”) established the NFSA, an entity primarily tasked with upholding international standards of food safety and regulation, and protecting consumers from damages associated with unsafe foods.

Article 3(9) of this law requires the NFSA to enforce the World Health Organization’s endorsed “Hazard Analysis and Critical Control Point” system of ensuring product safety, and for recalling products that are in breach of that system. In addition, Article 3(7) requires the NFSA to set necessary measures and procedures for emergencies that threaten foods exposed to ensuing hazards or risks. It is also responsible for the warning, withdrawal and recall of products susceptible to such risk. These recall systems are to be established by a specific decree of the CPA’s board of directors, which consist of representatives from the ministries of Trade and Industry, Health, Agriculture, Interior, Environment, Supply and Internal Trade, Tourism and the chair of the CPA.

While the CPA’s reporting mechanism is dependent upon Suppliers informing the CPA of discovered defects in their products, the NFSA acts as a point of first contact between the consumers and the responsible authority; its website allows consumers to detail and submit reports of unsafe foods and drinks directly to them. The reporting procedures inquire of the reporter’s personal details, the product in question and its type, the point of sale and/or manufacturing, the nature of the complaint and whether or not it concerns an allegation of food poisoning.

Motor vehicles and parts

There is no specific regulator or regulatory regime for the safety and recall of motor vehicles and parts.

5. Legal consequences of noncompliance

A failure to abide by the Law will result in a fine ranging from EGP 5,000 to EGP 100,000. The minimum and maximum amounts double in the case of a repeat conviction. The Supplier's representative can also be subject to the same fines, jointly with the Supplier.

Any violation of the Law by a Supplier is subject to the jurisdiction of the Economical Court, which was established in 2008 to handle all cases related to commercial and economical matters and criminal actions relating to these.

In addition, the Egyptian Penal Code subjects any person who accidentally causes the death of another person as a result of his/her negligence, imprudence, carelessness or nonobservance of laws, decrees, regulations or systems to imprisonment for a minimum of six months, a maximum fine of EGP 200, or both. If the crime occurs as a result of a serious violation of the norms of the offender's position, profession or trade, he/she shall be liable to imprisonment for a period between one year and five years, or be subject to a fine ranging from EGP 100 to EGP 500. In certain circumstances, the criminal may be subject to both. Furthermore, if the act results in the death of more than three persons, the penalty is imprisonment for a period between one year and seven years.

Additionally, the Penal Code subjects any person who accidentally harms someone as a result of his/her negligence, imprudence, carelessness or nonobservance of laws, decrees, regulations or systems, to imprisonment for a maximum of one year and a maximum fine of EGP 200. If the injury results in a permanent disability or if the crime is a result of the offender's gross breach of duty according to the norms of his/her position, profession or trade, the penalty is imprisonment for a maximum of two years and a maximum fine of EGP 300. In certain circumstances, the criminal may be subject to both. If the crime results in the injury of more than three persons, the penalty is imprisonment for a period between one to five years.



Additional legislative penalties exist that are designed to reprimand suppliers of potentially dangerous medical products. Article 2 of Ministerial Decree No. 540/2007 states that the supplier of a recalled medicine must recall the specified medication within one month of the date of issuing that order. Failure to comply with the CAPA decision within the permitted time may result in a suspension of the product line, or a three-month ban on importation of said medication. Should the product still be produced or imported during this time, the CAPA may revoke the registration of the product and effectively end its capacity to trade in the pharmaceutical market, and confiscate all remaining stock of the medicine without reward.

The NFSA Law does not detail specific penalties for Suppliers found in breach of safety standards, but NFSA employees have the authority to enforce a plethora of penalties dispersed across decades of legislation specific to food categories, such as dairy products, vegetable oils, pasta or meat production. These food category legislations allow employees of the NFSA to enforce a range of penalties, such as fines, suspensions of trade or the revocation of trading licenses.

European Union

The EU has largely harmonized its product safety laws across the (currently) 28 Member States,¹ including in relation to product recall. This chapter provides a summary of that harmonized system, but since the law is actually applied and enforced at Member State level, this chapter should be read together with the individual Member State chapters.

1. Definition of a “consumer product”

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (the “General Product Safety Directive” or GPSD) defines “product” to include not only a good that has been supplied or made available to a consumer, but also a good that was not intended to be used by consumers but that is “likely, under reasonably foreseeable conditions, to be used by consumers.” This definition of consumer products includes new products as well as used or reconditioned products. It also includes products for which the consumer did not have to pay consideration, provided that the products have been supplied or made available in the course of a commercial activity.

However, the GPSD only applies to the extent the risk or obligation at issue is not dealt with in product- or sector-specific EU-derived legislation regarding safety. Some examples of consumer products subject to specific safety-related legislation include toys and cosmetics. However, not all that legislation contains a separate product recall regime, in which case the GPSD regime applies.

2. Agencies involved in regulating consumer products

While the respective authorities in each EU Member State are in charge of enforcing product safety regulations within their jurisdiction, the European Commission also plays an important role in

¹ The UK is due to leave the EU at the end of March 2019.



product recalls. To ensure effective consumer protection and collaboration among the Member State authorities, a European network called the Community Rapid Information System (RAPEX) was established under the GPSD. As a database of all dangerous nonfood products (with the exception of medicines and medical devices) RAPEX seeks to inform EU consumers of the direct or indirect risks posed by these products to health or security. The EEA States (Iceland, Lichtenstein and Norway) also participate in RAPEX. For food products, an equivalent system called Rapid Alert System for Food and Feed (RASFF) was established.

Summaries of all notifications transmitted via RAPEX are published each Friday at

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications.

In almost all recalls, it is mandatory for a Member State authority to inform the European Commission about the product recall when that national authority, on the basis of the hazards posed by a specific product:

- adopts or decides to adopt, recommend or agree to, with producers and distributors, whether on a compulsory or voluntary basis, recalls or other specific measures or actions to prevent or restrict the marketing or use of a product; or
- is notified by the producer or distributor of a serious risk (even if the national authority accepts the voluntary measures taken by the producers and distributors).

The European Commission will forward the information about product hazards and measures taken by the respective Member State authority and the producer or distributor to the relevant national authorities in the other Member States.

If the Commission considers the measures to be insufficient on a national level, it may require the Member States to take specified, more stringent action.

3. Reporting requirements and recall procedures

A producer or distributor who becomes aware that a product it supplied is unsafe is obliged to “immediately” inform the authorities in all Member States where such products are on the market. It is usually appropriate for the producer or distributor to file the notification via the online EU-wide Business Application, which can be found at <https://webgate.ec.europa.eu/gpsd-ba/index.do>. The EU now also has an online risk assessment tool that can be used to generate a risk assessment, which should be submitted with the Business Application: <https://ec.europa.eu/consumers/consumer-safety/rag/>. Detailed Risk Assessment Guidelines for Consumer Products have been produced by the European Commission (see Appendix 5 to Commission Decision 2010/15/EU at https://ec.europa.eu/consumers/consumer-safety/rag/?event=documentation&id=rapex_guid_en.pdf).

The notifying entity should contact the authority in the Member State where its headquarters are located (or, if no affected products were placed on the markets there, in the Member State with the largest number of affected products) to discuss and obtain approval of the notification, and also in most circumstances, follow up with courtesy calls to the authorities in the other affected Member States. Some countries may require a local language translation of the Business Application form or have their own additional form to be completed.

In terms of the timing for making the notification, the Commission’s Notification Guidelines (http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf) state that the notification should be made as soon as the relevant information becomes available, and in any event within 10 days from obtaining reportable information. Even while investigations indicating the existence of a dangerous product are continuing,



notification should be made. If the risk is serious, that timeframe is shortened to three days.

If a competent Member State authority is not satisfied with the notification, it may require the producer or distributor to cooperate with the authority on the actions that have already been taken to prevent the risks posed by the respective product. The authority may otherwise require that further steps be taken. The procedures for such cooperation are set forth on a national level, as administrative rules and practices vary among the EU Member States. These country-specific regulations are discussed in the respective chapters for EU Member States included in this handbook. It is also possible that even after a corrective action is approved by one or more Member States following a notification, other Member States may take a different or more stringent approach and require additional measures to be taken.

There are a number of ways by which the authorities of the EU Member States and the European Commission collaborate and share information with each other regarding product recalls, including through RAPEX (see section 2 above), as well as with other non-EU jurisdictions, such as via the RAPEX-China system.

4. Product-specific regimes

As mentioned in section 1 above, EU law also contains some harmonized product- or sector-specific product safety laws, some of which contain their own product recall regimes or requirements.

Pharmaceuticals / Medical devices

Every holder of a marketing authorization for a medical product (ie, a medicine) is obliged by Directive 2001/83/EC (the “Medicines Directive”) to have in place an effective recall procedure and is required to notify the relevant competent authority of any defect or adverse reaction. In most cases, this authority will be the European Medicines Agency via its online Eudravigilance system. More broadly, EU law contains a very detailed and legally binding

pharmacovigilance system, the scope of which goes far beyond this handbook.

The EU also has a medical device vigilance system, the requirements of which are, at present, primarily contained within Directive 93/42/EEC (Medical Devices), Directive 90/385/EEC (Active Implantable Medical Devices) and Directive 98/79/EC (In Vitro Diagnostic Medical Devices). In general, manufacturers of medical devices must implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. The manufacturer must notify the competent authorities of the following incidents immediately upon learning of them:

- (i) Any malfunction, failure or deterioration in the characteristics and/or performance of a device that might lead to the death of a user or other persons or to a serious deterioration in his state of health
- (ii) Any technical or medical reason connected with the characteristics and/or performance of a device referred to in paragraph (i) above leading to a systematic field safety corrective action by the manufacturer of devices of the same type

Food and drink

Article 14 of Regulation (EC) 178/2002 on General Food Law (the “Food Safety Regulation”) prohibits the placement on the market of food and drink if they are unsafe. Food is deemed to be unsafe if it is considered to be: (i) injurious to health; and/or (ii) unfit for human consumption.

Unsafe food is subject to the withdrawal, recall and notification requirements of Article 19 of the Food Safety Regulation. That Article provides that if a food business operator (as defined in Article 3) has reason to believe that food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements of Article 14 (see above), it shall



immediately initiate procedures to withdraw the food from the market, and inform the competent authorities. If the food in question may already have reached consumers, the food business operator is also under obligation to effectively inform the consumers of the reason for its withdrawal (including details as to why the product is unsafe), and where other measures are insufficient to protect their health, recall products from consumers already supplied to them. Food business operators shall collaborate with the competent authorities on action they should take to avert or reduce the risks posed by the food that they supply or have supplied.

As previously stated, there is a food and feed equivalent of RAPEX, called RASFF, details of which can be found at https://ec.europa.eu/food/safety/rasff_en.

Motor vehicles and parts

Motor vehicle recalls was the second largest product category in RAPEX in 2016 (after toys). The EU's Directive 2007/46/EC (the "Motor Vehicles Framework Directive") requires manufacturers who have been granted an EC vehicle type-approval and are obliged by a regulatory act or the GPSD to recall vehicles already sold, registered or put into service because one or more systems, components or separate technical units fitted to the vehicle presents a serious risk to road safety, public health or environmental protection, to immediately inform the approval authority that granted the vehicle approval. In addition, the manufacturer is obliged to propose a set of appropriate remedies to the approval authority to neutralize the risk to road safety, public health or environmental protection referred to above. The approval authority shall then communicate without delay the proposed measures to the authorities of the other Member States. The competent authorities shall ensure that the measures are effectively implemented in their respective territories.

If the measures are deemed by the authorities concerned to be insufficient or have not been implemented quickly enough, they can immediately inform the approval authority that granted the EC vehicle

type-approval. The approval authority shall then inform the manufacturer. If the approval authority that granted the EC type-approval is itself not satisfied with the measures of the manufacturer, it shall take all protective measures required, including the withdrawal of the EC vehicle type-approval where the manufacturer does not propose and implement effective corrective measures.

If a Member State that has granted an EC type-approval finds that new vehicles (including systems, components or separate technical units) do not conform to the type it has approved, it shall take the necessary measures, including withdrawal of the type-approval, to ensure that the vehicles conform to the approved type. The approval authority of that Member State shall advise the approval authorities of the other Members States of the measures taken. If a Member State identifies any non-conformity, it may request the Member State that granted the EC type-approval to ensure that the vehicles continue to conform to the approved type. When the type-approval authority identifies non-conformity, it must request the manufacturer to submit a plan to remedy the noncompliance, which may include a recall of the vehicles.

5. Legal consequences of noncompliance

The GPSD requires that Member States adopt penalties in case of noncompliance with national rules on product safety “and take all measures necessary to ensure that they are implemented.” Such penalties must be “effective, proportionate and dissuasive.” These country-specific penalties are also discussed in the respective chapters for EU Member States included in this handbook.

Sources of information

Further information on product recall best practice and the relevant European legislation is available on the European Commission’s website at

http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/index_en.htm.



Specific guidance not already mentioned elsewhere in this chapter is available on:

- (a) Notification:
http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf
- (b) Carrying out a corrective action:
http://ec.europa.eu/consumers/archive/safety/rapex/docs/corrective_action_guide_march2012.pdf

France

The French regime on product safety is contained in Articles L. 421-1 to L. 424-1 of the French Consumer Code, as amended by Ordinance no. 2016-301 of 14 March 2016, relating to the legislative section of the consumer code, amending Ordinance no. 2004-670 of 9 July 2004 and no. 2008-810 of 22 August 2008, which implemented General Product Safety Directive 2001/95/EC (GPSD) of the EU Commission.

On 11 February 2012, a nonbinding notice (*avis*) on the implementation of the obligation to report risks and on the measures taken to prevent such risks was adopted (the “Notice”). The Notice replaced a previous notice dated 10 July 2004.

1. Definition of a “consumer product”

According to the French Consumer Code (Article L. 421-2), the French provisions on product safety are applicable to all products, except for “second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.”

2. Agencies involved in regulating consumer products

The authority that is generally competent in France is, at the national level, the General Directorate for Competition, Consumer and Fraud Affairs (*Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* or DGCCRF). Locally, the Departmental Directorates for Social Cohesion and Protection Of Populations (*Direction Départementale de la Cohésion Sociale et de la Protection des Populations* or DD(CS)PP) of the administrative district (*département*) in which the notifying company’s main place of business (*établissement*) is located is also competent.

However, other authorities, depending on the nature of the product at issue, may be competent to address safety issues related to specific products (see Section 4 below).



3. Reporting requirements and recall procedures

Pursuant to the French Consumer Code, a producer or distributor that discovers that the consumer goods it has put on the market are not safe and may create a health hazard must immediately inform the competent administrative authorities and indicate the measures the producer or distributor intends to take to eliminate any risk to consumers.

The French authorities have indicated in the Notice that the compulsory notification of safety issues only applies with respect to end-user goods.

Pursuant to the Order of 9 September 2004 (*arrêté*), the notification must at the very least, contain the following:

- Date of the notification
- Name or company name and the address of the notifying enterprise
- Name and address of the enterprise(s) that provided it with the product (suppliers)
- Name and address of the enterprise(s) to which it supplied the product (distributors)
- Description of the product, particularly the denomination, trademark, batch references and volume concerned for the French market
- Description of the danger and the measures taken by the enterprise
- Any other information that the company considers to be potentially useful for the relevant authorities

The Notice provides that the notification should preferably be made through the EU's Business Application electronic form

(<https://webgate.ec.europa.eu/gpsd-ba/index.do>). If that is not possible, the notification must be made to the relevant DD(CS)PP.

The Notice states that the competent authorities must be notified as soon as the producer or distributor becomes aware that a product is unsafe. In this respect, the French Consumer Code provides that the producer or distributor may not escape its obligations by claiming it was not aware of risks that it could not reasonably have ignored.

We are not aware of specific timeline requirements under French law for recalling defective or dangerous consumer products, other than those contained in the European Commission Decision of 14 December 2004 (see the European Union chapter).

The French Consumer Code provides that the producer must take necessary measures to mitigate risks presented by products, including: (a) withdrawal of products from the market; (b) efficient and appropriate warnings to consumers; and (c) recall of products already sold to consumers (Article L.423-2).

4. Product-specific regimes

Pharmaceuticals / Medical devices

Reporting requirements and recall procedures for pharmaceuticals and medical devices are governed by the French Public Health Code (FPHC). The competent authority in this regard is the National Agency for the Safety of Medicines and Health Product (*Agence Nationale de Sécurité du Médicament et des Produits de Santé* or ANSM)

Pursuant to the FPHC, various actors are legally required to report adverse incidents relating to a medical device² or in-vitro medical

² This includes any incident or risk of incident involving a device that has caused or is likely to cause death or serious damage to the health of a patient, user or third party.



device³ and adverse effects⁴ relating to a pharmaceutical product. These actors include (and may vary depending on the type of product) the manufacturers, distributors, importer, users (ie, healthcare professionals, clinics/hospitals and/or patients) of health products as well as any third party aware of the incident and/or effect. ANSM must be informed about the occurrence of these adverse incidents and/or effects.

The notification can be made in paper form and/or electronically.⁵

ANSM also has the power to require a recall to be carried out by the legal entity or individual responsible for using a pharmaceutical product or medical device, placing it on the market or putting it into service.

Food and drink

There is no specific regime for food and drink. However, the procedure for notification differs from non-food products.

The Notice contains the rules for notifying defects or issues regarding food products.

The competent authority regarding food and drink matters is the Departmental Directorate (for Social Cohesion and) for the Protection of Populations (DD(CS)PP), which is the General Directorate for Competition, Consumer and Fraud Affairs.

³ This encompasses any incident or risk of incident consisting of a failure or deterioration in the characteristics or performance of an in vitro diagnostic medical device, or an inadequacy in the labeling or instructions for use which might lead to or have led to direct or indirect harmful effects on human health.

⁴ An adverse effect is defined as a noxious and unintended response to a pharmaceutical product.

⁵ Forms can be found on the website of ANSM: [http://ansm.sante.fr/Declarer-un-effet-indesirable/Comment-declarer-un-effet-indesirable/Declarer-un-effet-indesirable-mode-d-emploi/\(offset\)/0](http://ansm.sante.fr/Declarer-un-effet-indesirable/Comment-declarer-un-effet-indesirable/Declarer-un-effet-indesirable-mode-d-emploi/(offset)/0) (last accessed on 20 June 2017).

The report must be made to the DD(CS)PP of the district (*département*) where the agri-food operator (import, production, transport, storage or sale to the final consumer) is located and the hazard has been identified.

The list of DD(CS)PPs is available on the websites of the General Directorate for Competition, Consumer and Fraud Affairs and the Ministry of Agriculture and Food.⁶

Practical instructions for reporting and a standard reporting form can be found in the “Guide to the management of food warnings between operators and administrations” (*Guide d’aide à la gestion des alertes d’origine alimentaire entre les exploitants de la chaîne alimentaire et l’administration*) available on the same websites.⁷

Vehicles and their parts

The Notice contains the rules for notifying defects or issues regarding vehicles and their parts.

As stated in the Notice, the alert shall be made using the EU’s Business Application (see further above). If that is not possible, the notification must be made to the General Directorate of Energy and Climate.

The competent authority for motor vehicles matters is the Vehicle Safety and Emissions Branch, part of the General Directorate of Energy and Climate of the Ministry of Ecological and Solidarity Transition.

5. Legal consequences of noncompliance

There are no sanctions for failing to implement a product recall. However, the manufacturer may be held liable from a criminal and/or

⁶ <https://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP>.

⁷ https://www.economie.gouv.fr/files/directions_services/dgccrf/securite/alertes/documents/guide_gestion_alerte020709.pdf.



civil standpoint should an accident occur. A voluntary recall therefore constitutes the best way of limiting the manufacturer's liability. The French administration encourages manufacturers to recall defective products at the earliest possible stage.

Compulsory withdrawal of unsafe products

In the absence of any voluntary recall, the French authorities may order the withdrawal of products. Pursuant to Article L.521-17 of the French Consumer Code, in the case of serious and imminent danger caused by a product, the ministry in charge of consumer affairs and/or other relevant ministries may order, for a period not exceeding one year, the suspension of manufacture, import, export and placement on the market, and order the withdrawal or the destruction of said product should it constitute the only way to stop the danger. The French authorities may also order the circulation of warnings or notices on the precaution of use, as well as the recall of the product for its replacement, modification or partial/total refund.

In addition, decrees may be adopted ordering the withdrawal from the market or the recall of unsafe products in order for them to be modified, exchanged or totally or partially reimbursed. The French authorities can also order the destruction of the products where this constitutes the only way to stop the danger. Such decrees may be taken even in the absence of "serious and imminent" danger and are not limited to a one-year period.

Failure to comply with administrative orders is criminally sanctioned in Article L.532-1 of the French Consumer Code by a fine, which may reach up to EUR 1,500 (EUR 7,500 for legal entities).

Criminal liability

If a defective product is likely to cause or actually causes physical injury, criminal sanctions may apply. Pursuant to the French Criminal Code (Articles 223-1 and 223-2), directly exposing a person to an immediate risk of death or injury that may lead to a mutilation or a permanent infirmity, by the deliberate violation of a particular

obligation of safety or of prudence provided by law, is sanctioned by one year's imprisonment and a fine of up to EUR 15,000 (EUR 75,000 for legal entities).

Causing death by recklessness, imprudence, inattention, carelessness or failure to fulfill an obligation of safety or caution provided by law is sanctioned by three years' imprisonment and a fine of up to EUR 45,000 (EUR 225,000 for legal entities), pursuant to Articles 221-6 and 221-7 of the French Criminal Code. The French Criminal Code also sets forth that, for a clearly deliberate violation of a specific obligation of safety or prudence, the sanctions incurred could be imprisonment for up to five years and a EUR 75,000 fine (EUR 375,000 for legal entities).

In addition, pursuant to Articles 222-19 and 222-21 of the French Criminal Code, the fact of causing, by recklessness, imprudence, inattention, carelessness or failure to apply an obligation of safety or of caution provided by law or regulations, an incapacity to work for more than three months is sanctioned by a two-year prison sentence and a fine of up to EUR 30,000 (EUR 150,000 for legal entities). This provision also sets forth that for a clearly deliberate violation of a particular obligation of safety or of prudence, the sanctions incurred could be imprisonment for up to three years and a EUR 45,000 fine (EUR 225,000 for legal entities).

Lastly, Article 222-20 (and 222-21) of the French Criminal Code provides that causing, by deliberate violation of a particular obligation of safety or prudence provided by law, incapacity to work for less than three months is punished by one year imprisonment and a fine of up to EUR 15,000 (EUR 75,000 for legal entities).

Various sanctions may apply in case of noncompliance with the requirements set forth in the FPHC in relation to pharmaceutical products and medical devices. The sanctions below relate to both of these types of products.



Criminal sanctions may be imposed as follows:

1. Two years of imprisonment and a fine up to EUR 150,000 against determined legal entities or individuals (eg, the marketing authorization holder, or the distinct entity marketing the product, the manufacturer, the importer or the authorized representative, depending on the type of product, etc.) that:
 - did not inform ANSM of an adverse incident or effect of which they were aware; or
 - have not informed ANSM regarding a product recall it has carried out.

This fine is multiplied by five for legal entities having committed the offense (ie, EUR 750,000).

Additional sanctions may be imposed (eg, publication of the decision).

2. Two years' imprisonment and a fine of up to EUR 150,000 if a recall imposed by ANSM is not carried out by the legal entities. This fine is multiplied by five for legal entities having committed the offense (ie, EUR 750,000).
3. A fine of up to EUR 1,500 (which may be increased to EUR 3,000 in the event of a second or subsequent infringement) against healthcare professionals who did not inform ANSM of an adverse incident or effect of which they were aware.

In addition, for the infringements described under point 1 above, ANSM can impose an administrative fine against legal entities of up to EUR 150,000 for an individual and up to 30% of the company's latest turnover made on the product or group of products, up to a maximum of EUR 1 million. Additional sanctions may also be imposed by ANSM in this respect (eg, publication of the decision on ANSM's website).

France

If the same infringement is sanctioned by both a criminal and an administrative fine, the overall amount of fines that could be imposed cannot exceed the highest maximum amount of the two.

Sources of information

Ministry of Economic Affairs – (Departmental Directorate for the Protection of Populations) DDPP de PARIS

Tel.: (+33) 1 40 27 16 00

Fax: (+33) 1 42 71 09 77

Email: ddpp@paris.gouv.fr

Website: <https://www.economie.gouv.fr/dgccrf>

Direction Générale de l'Alimentation Bureau de la Surveillance des Denrées Alimentaires et des Alertes Sanitaires

Tel.: (+33) 1 49 55 84 05 or 01 49 55 50 85 or 01 49 55 81 91

Fax: (+33) 1 49 55 84 23

Email: alertes.dgal@agriculture.gouv.fr

Direction Générale de l'Energie et du Climat, Sous-direction de la sécurité et des émissions de véhicules

Tel.: (+33) 1 40 81 21 22

Fax: (+33) 1 44 97 09 01

Email: de.dgec@developpement-durable.gouv.fr

A list of the Departmental Directorates for social cohesion and protection of populations (DD(CS)PP) is available here:

<https://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP>

ANSM - National Agency for the Safety of Medicines and Health Products

Tel.: (+33) 1 55 87 30 00

Email list depending on the matter: <http://ansm.sante.fr/Les-contacts-utiles-a-l-ANSM#Email>



Germany

The German Product Safety Act (*Produktsicherheitsgesetz* — “ProdSG”) is the German law implementing the EU’s General Product Safety Directive 2001/95/EC (GPSD) and is the main German law covering the recall of consumer products.

1. Definition of a “consumer product”

In the ProdSG, “consumer products” are “new, used or refurbished products which are intended for consumers or which may be used by consumers under reasonably predictable conditions even when not intended for them. Consumer products also include products made available to the consumer when a service is being rendered.”

This definition includes all kinds of products for use or consumption (excluding food and medical devices), end and spare products, supply parts and supply material, provided that the respective item is “intended for consumers or may be used by consumers under reasonably predictable conditions.” For example, a product qualifies as a consumer product if either of the following applies:

- It is marketed to both private consumers and commercial customers
- It was originally designed for commercial customers only, but “migrates” into private use (eg, laser pointers and certain do-it-yourself equipment), even without the manufacturer’s intention or approval

A product does not necessarily actually have to be used by consumers to qualify as a “consumer product,” as long as private use is possible. However, the mere possibility that a consumer might misuse a commercial product and might try to use it for private purposes is not sufficient, if such a potential misuse cannot be reasonably foreseen.

The term “consumer product” in the ProdSG also covers products that are not transferred to the consumer, but only “made available” in

connection with rendering certain services. However, this definition only refers to situations where the product is used by the consumers themselves during such services, such as shopping carts, workout equipment in gyms, slides in a children's playground, etc. If the consumer is only passively exposed to a product during certain services (eg, to a hairdryer at the hairdresser's) or is transported by a product, this will not, by itself, be sufficient for a product to qualify as a "consumer product," unless the product is used by private consumers as well.

2. Agencies involved in regulating consumer products

The governmental agencies with jurisdiction to supervise or order the recall of certain products are determined according to the state laws of the 16 German states (*Länder*). In most cases, the district authorities dealing with the supervision of commercial enterprises (*Gewerbeaufsichtsämter*) are competent, and notices of recalls would have to be filed with the district authority having jurisdiction at the location of the manufacturer's German headquarters. However, there are several statutes that provide for special jurisdiction of certain governmental agencies for certain types of products (eg, the Federal Motor Transport Authority for motor vehicles and the Federal Network Agency for radio and telecommunications terminal equipment).

When looking for the competent German authority in any given case, the www.icsms.org website offers "Search Authority" as a first step (<https://webgate.ec.europa.eu/icsms/public/authoritySearch.jsp?locale=en>).

3. Reporting requirements and recall procedures

Notification obligation

The ProdSG obliges the manufacturer, its authorized representative, the importer and the dealer to notify the competent authority without delay if they know, or if they ought to know, on the basis of information in their possession or their experience, that a consumer product they have placed on the market presents a danger to the health



and safety of consumers. In particular, they must notify the authority with jurisdiction at their place of business of the measures they have taken, or intend to take, to prevent such danger.

This notification duty requires that the notifying party have concrete indications that a product constitutes a danger to the health and safety of persons, eg, because they have received reports of incidents. Typically, a manufacturer will investigate the root cause and prepare a risk assessment before considering a notification. However, notification of a hazardous product may not be delayed on the basis that testing has not been finalized.

There is no prescribed format for notification (see Annex I of the GPSD for the details and the form of the notification). The easiest way to file a notification is to use the electronic notification system called “Business Application” offered by the European Commission (<https://webgate.ec.europa.eu/gpsd-ba/index.do>). Of course, it is also possible to notify the competent authority directly.

Recall requirements

Under German law, a manufacturer might be obligated to carry out a product recall for three different legal reasons:

- The manufacturer might be obligated to recall dangerous products in order to avoid liability for damages under German civil law
- Managers (and to a certain extent the employees of the manufacturer) who fail to recall dangerous products in time might be subject to personal criminal prosecution under German criminal law if an immediate recall would have prevented subsequent damage, especially damage to health
- The manufacturer, its authorized representative, the importer and the dealer might be obligated under German public law to notify the competent public authority about a dangerous product and about the measures taken (including a recall) to protect the

public from such danger, or they might even be ordered to carry out a recall by the competent public authority

The obligation to carry out a recall under civil and criminal law is not limited to “consumer products” as defined above, but also applies to all kinds of products for private or commercial use.

There are no specific rules as to what kinds of measures have to be taken to address a particular product danger. It is therefore up to the manufacturer and the other responsible parties to evaluate the risks posed by the product in question and decide upon an adequate course of action that ensures such product dangers are effectively addressed. These actions may include silent warranty activities; distribution of notices to consumers, dealers and/or distributors; or an effective public recall (eg, by letters, press announcements, posters and mass media broadcast).

The competent authority will evaluate whether the measures taken by the manufacturer or other responsible parties are sufficient to effectively protect consumers’ health and/or safety. In doing so, the competent authority will take into account the type of danger; the possible damage; the likelihood of damage; and the number, age and type of consumers concerned. If the competent public authority believes that the responsible party is not voluntarily taking adequate measures, it may issue orders requiring such action from the responsible party or, if necessary, take such measures itself (eg, issue a public warning). In cases of serious danger to the safety and health of persons, the competent public authority has a statutory duty to order a recall or withdrawal from the market and to prohibit making the products available on the market.

4. Product-specific regimes

There are specific product recall regimes that apply to particular products and sectors, for example: (a) medicinal products/medical devices; (b) food and drink; and (c) vehicles and their parts.



(a) Pharmaceuticals / Medical devices

Safety surveillance of medical devices, so-called “materiovigilance,” is determined by a distinct set of rules, similar to those applicable to “pharmacovigilance” — the safety surveillance of medicinal products. Pursuant to the new Medical Devices Regulation (EU) 2017/745 (binding as of 2020, but reflective of the rules and best practices to be observed under the currently applicable Directive 93/42/EEC and the guidance document MEDDEV 2.12-1 rev 8), manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. In connection with this system, manufacturers have to report any “(serious) incidents” they become aware of to the competent authorities, ie, any malfunctions or deteriorations in a medical device’s characteristics or performance that led, might have led or might lead to the death of a patient [...] or a permanent serious deterioration of his or her state of health.

If as a result of a risk assessment a (field safety) corrective action (FSCA) has to be taken, which is also subject to compulsory reporting to the authorities, the manufacturer may either issue advisories (dear doctor letters), update the instructions for use (IFU) or entirely recall a device from the market, depending on the seriousness of the risk. If a manufacturer is not located within the EU or EEA, it has to appoint an authorized representative tasked with discharging all materiovigilance obligations.

(b) Food and drink

The ProdSG does not apply to food products, as these are separately regulated, with regard to their health and safety, in the German Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch* — LFGB).

The laws and regulations are mainly in line with EU provisions. It is helpful to understand that the LFGB is supplemented by other relevant provisions, eg, the Ordinance on Commodities

(*Bedarfsgegenständeverordnung* — BGV). Both the LFGB and the BGV provide the regulatory basis to ensure the safety of food, feed and commodities, which are defined as products that are meant for prolonged body contact. Further specific acts and regulations deal with hygiene and provide details for product groups such as tobacco, spread, fish, meat, poultry, beverages, milk, frozen goods, water, wine, etc.

According to Section 44a of the LFGB, food business operators are required to inform the competent authorities if they learn about the presence of undesired substances in or at food or feed. In order to protect against health hazards, competent authorities may order recalls of unsafe food or feed.

(c) Motor vehicles and parts

The Federal Motor Transport Authority (*Kraftfahrt-Bundesamt* — KBA) is the authority in charge of vehicle registration and safety. Having one central authority is not typical for Germany, as administrative surveillance and enforcement are typically distributed among the federal states.

The KBA's main tasks are type-approval of vehicles, market surveillance and enforcement, and the management of several vehicle- and driver-related registers, such as the Central Vehicle Register, the Register of Driver Fitness and the Central Register of Driving Licenses.

Recalls of vehicles and vehicle parts are to be notified to the KBA, which manages and oversees such recalls. In the case of a recall, the KBA also provides the addresses of holders of potentially affected vehicles to the manufacturers of such vehicles. The KBA has established its own “Codex for the implementation of the Product Safety Law (ProdSG) to road vehicles,” which is available on the internet (but only in German)

(https://www.kba.de/DE/Marktueberwachung/Kodex/kodex_pdf.pdf?__blob=publicationFile&v=4).



5. Legal consequences of noncompliance

Failing to appropriately notify the competent public authority in a timely manner of an unsafe product constitutes an administrative offense and is subject to an administrative fine of up to EUR 10,000.

Compliance with the duties described in the previous sections, however, does not protect a manufacturer from civil or criminal liability if the manufacturer willfully or negligently fails to take the necessary measures to recall dangerous products in time and if, due to this omission, persons are hurt or goods are damaged. To avoid liability, a manufacturer must not only comply with the notification requirements under the applicable public law statute, but must also make sure that all measures are taken that are necessary to prevent injuries or damage to persons or property due to a dangerous product. In practice, these measures can easily go beyond what would have been required by the public authority, since German courts — including criminal courts — set very strict duties of care for manufacturers.

These duties include the obligation of a manufacturer to immediately recall products as soon as it finds out that one of its products presents serious dangers to persons or property, even if those dangers could not be foreseen when the product was placed on the market and even if the product fully complied with the applicable product safety standards. For example, the managers of a manufacturer of leather spray were sentenced to imprisonment and fines for failing to immediately recall a leather spray that caused pulmonary edema to some consumers. In that case, it was unclear what chemical substance in the spray had caused the damage, and the managers decided to delay a public recall until their laboratories could deliver a clear explanation. The German Supreme Court for Criminal Matters explicitly confirmed that the managers were not released from criminal liability by the mere fact that the German public authorities had not yet considered it necessary to carry out a recall. In order to avoid personal criminal liability in that case, a manager would instead

have had to immediately call an extraordinary board meeting and to decide in favor of a recall, which would have to be carried out within one to two days.

As a consequence, if the question arises as to whether a certain product contains a danger that might render it necessary to carry out a recall in Germany, the manufacturer will not only have to comply with the notification duties under applicable public law, but will also have to carefully evaluate the risk of becoming liable under German law (including the possible criminal liability of its managers) for damage that could have been prevented had an immediate product recall been implemented.



Hong Kong

The Consumer Goods Safety Ordinance (CGSO), supplemented by the Consumer Goods Safety Regulation, contains the general regulatory framework for consumer goods liability and mandatory recall in Hong Kong.

1. Definition of a “consumer product”

Consumer goods under the CGSO means goods that are ordinarily supplied for private use or consumption. It excludes goods in transit, consumer goods manufactured for export and goods controlled by specific legislation, such as food, pharmaceutical products, electrical products, and toys and children’s products.

2. Agencies involved in regulating consumer products

The responsible enforcement agency under the CGSO is the Customs and Excise Department (C&E), which also regulates the safety of toys and children’s products.

As detailed further below, other agencies involved in regulating specific sectors are the Food and Environmental Hygiene Department in respect of food products; the Department of Health in respect of pharmaceuticals and traditional Chinese medicines; and the Electrical and Mechanical Services Department in respect of electrical goods.

3. Reporting requirements and recall procedures

The CGSO provides the C&E with the power to issue various safety control notices, including a mandatory recall notice requiring the immediate removal of unsafe goods from sale and the retrieval of those goods already supplied, or, where the consumer goods do not comply with an approved or established safety standard or may be unsafe with a significant risk of causing serious injury.

The recall notice from C&E will specify the goods to be withdrawn from supply, and will require items already supplied to be retrieved in the manner and to the extent reasonably possible.

No provision is made for the voluntary recall of products under the CGSO, but the C&E publishes guidelines and recommendations on voluntary recall procedures from time to time. The latest guidelines on voluntary recall of consumer goods were published in September 2017, which also apply to toys and children's products (see further below). Notification prior to a voluntary recall is advised under the latest guidelines, although it is not a mandatory requirement.

Recall procedures under the CGSO do not apply where the types of goods in question are separately governed by specific legislation.

Electrical products

Hong Kong is unusual in having a separate recall regime for electrical products, which in many other jurisdictions are not distinguished from general consumer goods. The Electricity Ordinance and Electricity Products (Safety) Regulation (EPSR) together outline the relevant safety standards applicable to electrical products, defined to mean any current-using equipment, lighting fitting or accessory that uses low or high voltage electricity. The body responsible for enforcing these provisions is the Electrical and Mechanical Services Department (EMSD).

The EPSR empowers the Director of Electrical and Mechanical Services to serve a written notice on the supplier of any electrical product which he/she considers to be noncompliant with the applicable safety requirements, requiring that supplier to notify the purchasers of its hazardous defects, accept a return of that product and provide a refund. The director may additionally require the supplier to publicize the recall by television announcements and/or newspaper advertisements.



The EMSD has published a guidance note encouraging manufacturers, importers and suppliers to develop their own recall procedures and initiate voluntary recall of their electrical products where necessary. The guidance note provides the specific information to be included in a voluntary recall, and requests a notification and submission of a recall plan to the EMSD. It is not uncommon for the EMSD to request regular written updates during the recall process. A report on the effectiveness of the recall (i.e., the quantity of stock returned or repaired) and any proposed action to prevent future recurrence of the problem should be submitted to the EMSD after the recall is completed.

Toys and children's products

Under the Toys and Children's Products Safety Ordinance, the C&E may require the immediate withdrawal and retrieval of a toy or children's product that does not comply with the relevant safety standards if he/she reasonably believes that there is a significant risk of such product causing serious injury. A person who is served with a recall notice and fails or refuses to comply commits an offense.

The C&E published a set of guidelines on the voluntary recall of consumer goods, toys and children's products in September 2017. Notification prior to a voluntary recall is advised under the latest guidelines, although it is not a mandatory requirement.

4. Product-specific regime

Pharmaceutical products

The Pharmacy and Poisons Ordinance and the Pharmacy and Poisons Regulations provide a specific recall regime for pharmaceutical products, which is enforced by the Department of Health.

The Department of Health may alert the public of defects in a drug and instruct the relevant licensee (typically, the local manufacturer and/or the local supplier for foreign-manufactured products) to recall

and dispose of the product. The Department of Health has published extensive guidelines governing the recall of pharmaceutical products.

Licensees are required to notify the Department of Health of any problem with a pharmaceutical product within 24 hours, or within 72 hours where the defect does not pose a significant hazard to health, after receipt of a complaint or report of a problem. Such notification should be sent prior to implementing a recall.

If the licensee decides to initiate a recall, then it is required to notify the Department of Health by submitting a recall notification with additional information, including a proposed recall strategy, which should be agreed by the Department of Health before implementation.

During the recall, the licensee is required to submit an interim report and a final report to the Department of Health within seven and 14 days respectively after commencement of the recall. After completion of the recall, a report of the results of the investigation into the problem and the proposed remedial action to prevent a recurrence of the problem should also be submitted to Department of Health in a timely manner. If the Department of Health is not satisfied with the recall or the remedial action, it may require further recall action or investigation, or an audit.

Since all dealers of pharmaceutical products in Hong Kong are required to obtain a license, failure to comply with the Department of Health's directions on a recall may result in the relevant license being suspended or revoked.

Medical devices

There is no overarching legislation that regulates medical devices in Hong Kong (except for devices that contain pharmaceutical products or emit ionizing radiation, which are regulated by specific legislation). The government recognizes the need to have, and has been developing, a proposed statutory framework to impose "pre-market



control” and “post-market control” for all medical devices, as well as “use control” for specific high-risk medical devices.

Currently, there is an administrative control system of medical devices under the Medical Device Administrative Control System (MDACS) managed by the Medical Device Control Office of the Department of Health. The MDACS comprises a voluntary listing of medical devices with the Department of Health, and an adverse incident report system. A manufacturer who wishes to apply for inclusion of a device under the MDACS list is required to designate a “local responsible person” who will be charged with a number of obligations in relation to the device, including the receipt and handling of customer complaints, the reporting and investigation of adverse incidents, the tracking of specific high-risk medical devices, the initiation and management of any recall, etc.

Given the lack of a mandatory framework, medical devices (which do not contain pharmaceutical products or emit ionizing radiation) are not subject to mandatory recall procedures. That said, medical devices that are voluntarily listed on the MDACS are expected to comply with the notification requirements set forth in the guidance notes issued by the Medical Device Control Office, which includes a requirement to report any adverse incidents within 10 days.

Food and drink

Under the Food Safety Ordinance, the Food and Environmental Hygiene Department (FEHD) may make a food safety order directing that any food supplied be recalled or be isolated, destroyed or otherwise disposed of. In cases of public health emergencies, the FEHD may alert the public before a decision on whether to recall the product has been reached.

In most cases in Hong Kong, food recalls are carried out on a voluntary basis. The FEHD’s role in a voluntary recall is to monitor progress and assess the adequacy of actions taken by the food supplier (with the local supplier bearing the prime responsibility). In the

guidelines published by the FEHD on voluntary food recalls, suppliers are requested to immediately notify the FEHD of an intended recall by using the prescribed notification form. Retailers should remove the relevant food from the shelves immediately and store them in a place inaccessible to customers, and should keep a proper record of the quantity of food withdrawn for return to the supplier. After recovery of the food product, the FEHD will check with the food supplier to see if the food can be suitably corrected or reprocessed before release to the market; otherwise, the product must be destroyed.

Food suppliers carrying out a voluntary recall are required to provide a progress report to the FEHD at regular intervals, and produce a final report within a time frame specified by the FEHD upon completion of the recall. The FEHD may consider taking further action, such as extending the recall action or implementing a mandated food safety order, if the supplier's report is unsatisfactory.

Motor vehicles

The Transport Department oversees the safety of motor vehicles pursuant to the Road Traffic Ordinance and the Road Traffic (Construction and Maintenance of Vehicles) Regulations.

There are no statutory recall or notification procedures for motor vehicles and their parts, but the Transport Department requires all vehicle models to go through the vehicle type approval process. Authorized dealers have to provide relevant particulars, such as information on the braking system, standard of the safety belts and specification of safety glass, to prove that the construction of the model concerned is safe. The vehicle model also has to pass the vehicle examination to ensure compliance with the legislation and its subsidiary regulations before it may be sold, registered, licensed and driven on the road in Hong Kong. It is an offense to sell, supply, hire, use or cause to be used on any road in Hong Kong a vehicle that is not soundly and properly constructed from materials that are in good and serviceable condition.



The Transport Department monitors recalls by overseas manufacturers and publishes detailed safety recall information on its website. When a recall affects vehicles that are used in Hong Kong, the Transport Department will liaise with local dealers for information relevant to Hong Kong to facilitate the recall exercise.

5. Legal consequences of noncompliance

Failure to comply with a product recall notice under any of the regimes outlined in this chapter constitutes a criminal offense and may result in a fine and imprisonment.

Legislation for consumer goods in Hong Kong does not provide for civil fines or penalties. Civil compensation can be sought by way of legal action based on contract and tort principles under common law.

Sources of information

Customs and Excise Department:

http://www.customs.gov.hk/en/consumer_protection/goods_safety/index.html

Centre for Food Safety of the Food and Environmental Hygiene Department:

http://www.cfs.gov.hk/english/import/import_icfsg_08.html

Drug Office of the Department of Health:

http://www.drugoffice.gov.hk/eps/do/en/consumer/news_informations/drug_regulatory_system.html

http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Pharmaceutical_Products_Recall_Guidelines.pdf

Medical Device Control Office of the Department of Health:

<http://www.mdco.gov.hk/english/mdacs/mdacs.html>

Transport Department:

http://www.td.gov.hk/en/public_services/vehicle_typeapp_examination/vehicle_examination/index.html#2

Hungary

Hungary's product safety regulations comply with, and are based on, the provisions of General Product Safety Directive 2001/95/EC (GPSD) and Regulation (EC) No. 765/2008 on the requirements for accreditation and market surveillance relating to the marketing of products. Act LXXXVIII of 2012 on the market surveillance of products effective as of 1 September 2012 (the "Market Surveillance Act") and Government Regulation 6/2013 (IV. 29) on the detailed rules regarding the market surveillance activities connected therewith (the "Product Safety Regulation") establish the Hungarian product safety rules.

1. Definition of a "consumer product"

The Market Surveillance Act states that a "product" is "any movable article, which is intended for consumers or users, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned, excluding food products, feeding stuffs, living animals or plants, products of human origin or products of plant or animal origin directly connected to the reproduction of plants or animals, and products and services under the scope of the Act on electricity, supply of natural gas, and district heating."

The act defines a "consumer" as "a natural person who buys, orders, receives, uses or consumes goods for purposes beyond his or her professional and business activity, or who is the target of a commercial communication or offer in connection with goods, or a person to whom the product is distributed for consuming or usage purposes beyond his or her professional and business activity." A "user" is defined as "a person who buys, orders, receives, uses or consumes products for purposes within his or her professional and business activity, or who is the target of a commercial communication or offer in connection with products."



2. Agencies involved in regulating consumer products

Product safety issues, including product recalls, are generally dealt with, in the first instance, by one of the 197 city level consumer protection inspectorates responsible for recalls and other complaints. The inspectorates function as separate departments within the District Offices (*Járási Hivatal*). The Government Office of Pest County (the “Consumer Protection Authority”) has the power to review the lawfulness of one of those first instance authorities at the national level. The Consumer Protection Authority operates under the supervision of the minister responsible for consumer protection (currently the Minister of National Development). However, several other authorities may have jurisdiction with respect to products of a specific nature (see Section 4 below).

3. Reporting requirements and recall procedures

Distributors, importers or producers are required to monitor the safety of their products and to notify the competent market surveillance authority of dangerous products.

The producer, importer or distributor must withdraw or recall products that it knows or should have known, either on the basis of information in its possession or because of the distributor’s or producer’s professional knowledge, are dangerous to consumers from the market and simultaneously inform the market surveillance authority (and the producer and/or importer if applicable) of the implemented measures, the reasons for implementing such measures and the results thereof. Under Hungarian law, “withdrawal” (*kivonás*) means any measure aimed at preventing a product in the supply chain from being made available on the market, whereas “recall” (*visszahívás*) means any measure aimed at achieving the return of a product that has already been supplied or made available to the end user.

The notification must be made to the market surveillance authority, which is obliged to immediately inform the Consumer Protection Authority of any goods not in compliance with the safety

requirements through the Central Market Surveillance Information System (KPIR), which is created and managed by the Consumer Protection Authority in order to share information with other Hungarian market surveillance authorities.

The Consumer Protection Authority is also Hungary's contact point for the Community Rapid Information System (RAPEX), whose aim is the rapid exchange of information among EU Member States regarding serious risk. Depending on the seriousness of the risk caused by a particular product and on the number of Member States affected, the Consumer Protection Authority will either only inform the Hungarian market surveillance authorities through the KPIR or it will inform both the Hungarian authorities and the authorities of the other Member States through RAPEX.

The applicable laws do not provide a list of what must be included in notifications to the market surveillance authorities. However, based on certain provisions regarding the information that the competent authorities must circulate among themselves and the minimal requirements for the content of notifications to the Consumer Protection Authority in the case of serious risk, it appears that the market surveillance authority will require the notification to include: (a) the identification data of the person who prepared the notification form; (b) the identification data of the producer of the product; (c) the product's identification data and the location of its placement in the market; (d) the quantity of the product; (e) the name of the company distributing the product, including all companies in the distribution chain within the country; (f) a full description of the danger created by the product; (g) all available information relevant to tracing the product; and (h) a description of the measures taken by the producers and distributors. The notification can be made electronically or in hard copy using the form that can be accessed at <http://fogyasztovedelem.kormany.hu/node/7822>.



4. Product-specific regimes

Pharmaceuticals / Medical devices

The regime for the recall and withdrawal process of pharmaceuticals is governed by Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (the “Medicines Act”) and Decree 52/2005 (XI. 18.) of the Ministry of Health on the Registration of Medicinal products for Human Use (the “Registration Decree”) for pharmaceuticals and Decree 4/2009. (III.17.) on Medical Devices (the “Medical Devices Decree”) as well as Decree 8/2003. (III. 13.) on IVD Medical Devices (the “IVD Decree”). The rules enshrined in the Product Safety Regulation shall also be complied with. However, instead of the Consumer Protection Authority, the National Institute of Pharmacy and Nutrition (OGYÉI) has the authority, power and competence to deal with product recall cases in the pharmaceuticals and medical device market.

Pursuant to the Medicines Act, the manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling medicinal products in the distribution network promptly and at any time.

Manufacturers shall record and investigate any complaint concerning a defect and shall inform OGYÉI of any defect that could result in a recall or a restriction on supply, and, so far as possible, indicate the countries of destination. Pharmacovigilance notifications should be made online on specific forms through the Eudravigilance system as defined by the relevant laws. Notifications for product recall can be made electronically or in hard copy. There is no specific form that should be used.

Under the Medical Devices Decree and the IVD Decree, the manufacturer, its authorized representative or the distributor and the healthcare service provider via the person responsible for the incidents, shall inform OGYÉI — electronically or in hard copy by

using the specific form in the relevant laws — of any unexpected events or accidents mentioned below involving a Class I, IIa, IIb or III device, provided that the unexpected event or accident: (a) may lead to a serious public health risk (which shall be reported as soon as possible but at least within two days); (b) may lead to or might have led to the death of a patient or user, or to a serious deterioration in his/her state of health (which shall be reported as soon as possible but at least within 10 days upon notice); or (c) relates to other issues not listed in subparagraphs (a) and (b) above (which shall be reported as soon as possible but at least within 30 days upon notice). If OGYÉI receives the notification by a person other than the manufacturer or its authorized representative, OGYÉI shall inform the manufacturer or its authorized representative on the unexpected event or accident as soon as possible but at least within eight days upon receipt of the notice.

The manufacturer or its authorized representative shall take the necessary corrective measures to correct any defect. The manufacturer or its authorized representative shall inform OGYÉI if the medical device is to be recalled from the entire market as a result of the unexpected event or accident.

Identical rules apply for the recall of IVD medical devices pursuant to the IVD Decree.

Food and drink

There are separate rules applicable for the recall of foodstuffs that may be dangerous to human health. The main rules are laid down by Regulation no. 178/2002 of the European Parliament and of the Council on the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety at an EU level, which is supplemented by Act XLVI of 2008 on the Food Supply Chain and on the Supervision of the Food Supply Chain (the “Food Supply Act”) at the national level. According to the Food Supply Act, the National Food Supply Chain Security Office (NÉBIH) shall be responsible for



market surveillance of foodstuffs, including product recalls in that market.

If a food business operator considers or has reason to believe that a food that it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform NÉBIH thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal and, if necessary, recall products already supplied to consumers when other measures are not sufficient to achieve effective health protection.

A food business operator shall immediately inform NÉBIH if it considers or has reason to believe that a food that it has placed on the market may endanger human health. Operators shall inform NÉBIH of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with NÉBIH where this may prevent, reduce or eliminate a risk arising from a food. Notification can be made electronically or in hard copy. There is no specific form to be used.

Food business operators shall collaborate with NÉBIH on action taken to avoid or reduce risks posed by a food that they supply or have supplied.

Motor vehicles and parts

The definition of “product” in the Market Surveillance Act includes vehicles and their spare parts. Thus, the Market Surveillance Act and the Product Safety Regulation are applicable in a recall of those products. Besides these laws, Decree no. 5/1990. (IV.12) on the Assessment of Public Vehicles contains provisions regarding safety concerns (the “Vehicles Decree”).

Pursuant to the Product Safety Regulation, the minister responsible for transportation (currently the Minister of Development) shall be responsible for market surveillance of vehicles and their spare parts, including product recall procedures.

Pursuant to the provisions of the Vehicles Decree, EC type-approved vehicle manufacturers shall inform the authority issuing the approval of any vehicles, spare parts or separate technical units sold and registered in the relevant registry if any of those need to be recalled because of risks relating to the security of transportation, or public health or environmental concerns. The notification can be made electronically or in hard copy using the form that can be accessed under <http://fogyasztovedelem.kormany.hu/node/7822>.

5. Legal consequences of noncompliance

The market surveillance authorities encourage producers or distributors to voluntarily comply with their product safety obligations. If, however, a producer or distributor fails to comply, the market surveillance authority may undertake any of the following:

- Prescribe that the products be provided with a warning of the risks the products present
- Order that consumers or users be notified of the risk originating from using the products, in due time and in an appropriate manner, through radio or television broadcasts or through the press
- Constrain or prohibit the advertising or placement of the products on the market and introduce measures that are necessary to ensure compliance with the prohibition
- Order the withdrawal of the products already placed on the market and the notification of such withdrawal



- Order the recall of the products and, if reasonable, organize the products' recall from consumers or users and the products' destruction, taking environmental considerations into account
- Order the producer/importer or distributor in question to terminate the deficiencies and disparities detected within a prescribed period of time, provided that the producer/importer or distributor is obliged to inform and give due notice to the market surveillance authority of the measures taken in order to terminate the deficiencies and disparities
- Ban, restrict or impose conditions regarding the supply and offering of products until the infringement is eliminated
- Impose fines from HUF 15,000 to (i) HUF 500 million or (ii) HUF 2 billion if the breach endangers or jeopardizes the health, physical integrity or life of consumers or users

Sources of information

Pest Megyei Kormányhivatal

1141 Budapest, Komócsy u. 17-19.

Hungary

Tel:+36 1 460-2231

Email: fogyved@pest.gov.hu

Website: <http://fogyasztovedelem.kormany.hu/taxonomy/term/12>

OGYÉI

1051 Budapest, Zrínyi u. 3.

Hungary

Tel.: +36 1 8869-300,

Email: ogyei@ogyei.gov.hu

Website: https://www.ogyei.gov.hu/main_page/

Hungary

NÉBIH

1024 Budapest, Keleti Károly utca. 24

Hungary

Tel.: +36 1 336-9000

Email: ugyfelszolgalat@nebih.gov.hu

Website: <http://portal.nebih.gov.hu/nyitoldal>



India (AZB & Partners)

There is no general statute or regulatory scheme on product recalls in India. However, there are a few industries, such as pharmaceuticals and food, which are required to comply with specific statutory requirements pertaining to product recalls. Despite this lack of clear statutory or regulatory guidance, product recalls do occur across other industries and are usually voluntary, strategic actions with a view to limit potential liability due to defective products in the market.

1. Definition of a “consumer product”

The term “consumer product” is not defined under the Consumer Protection Act, 1986 (the “Consumer Protection Act”). However, the Consumer Protection Act refers to the term “goods.” Similarly, the term “goods” is defined under the Sale of Goods Act, 1930, as every kind of movable property other than actionable claims and money, including stock and shares, growing crops, grass, and things attached to or forming part of the land.

2. Agencies involved in regulating consumer products

The Bureau of Indian Standards (BIS), established under the Bureau of Indian Standards Act, 1986 (the “BIS Act”) and the Bureau of Indian Standards Rules, 1987 (the “BIS Rules”) are the key regulatory bodies established to regulate product safety and development of product standards.

The BIS develops and sets out quality standards and certification requirements for various consumer products in India, which may be either mandatory or voluntary, depending on the category of goods. Certain goods such as cement, identified electronic goods, pneumatic tires, and certain valves and cylinders, where the BIS has prescribed mandatory standards, require manufacturers and importers to ensure compliance with these standards before such goods are imported, distributed or sold in India. The Bureau of Indian Standards Act, 2016 (the “BIS Act 2016”), which has been approved by the parliament and

notified in 2016 for general information, will replace the BIS Act upon coming into force. The BIS Act 2016 allows the central government to notify certain goods, articles, processes, systems or services that will need to comply with prescribed standards and carry a standard mark.

There are also industry-specific regulators for the pharmaceutical, automotive and food sectors, which are discussed in section 4.

3. Reporting requirements and recall procedures

Except for certain specific products, there are no general laws on product recall in India, and therefore manufacturers are free to devise their own procedures to implement a product recall. These procedures may be based on their experience in other jurisdictions. Depending on the industry, recalls are generally carried out by the manufacturers in conjunction with the dealers, vendors or distributors. However, as obligations such as duty of care under tort law and consumer protection laws continue to apply under Indian law, manufacturers across various industries typically adopt a voluntary product recall in order to avoid or limit potential liability, even in the absence of any specific statutory guidance to govern such recalls.

Where possible, the affected customers are generally contacted directly, informed of the recall exercise and offered replacements for their defective products.

4. Product-specific regimes

Pharmaceuticals / Medical devices

Pharmaceuticals and medical devices are regulated by the Drugs and Cosmetics Act, 1940 (the “Drugs Act”) and the Drugs and Cosmetics Rules, 1945 (the “Drugs Rules”). The Drugs Rules provide for licensing as well as controlling authorities at the central and state level to grant and renew licenses to manufacture, sell and distribute drugs as specified from time to time. These authorities have the power to suspend and cancel licenses if the conditions under the licenses, which



may include devising a prompt and effective recall system for defective products, are not met by the licensees. The implementation of these standards and related requirements under the Drugs Act and the Drugs Rules are carried out by central and state authorities, including drug laboratories, drugs controllers, licensing authorities and inspectors based centrally or regionally.

The Central Drugs Standard Control Organization (CDSCO) is the central authority for discharging functions assigned to the central government under the Drugs Act and Drugs Rules. Some of the major functions of the CDSCO include regulatory control over imported and locally manufactured drugs and setting out standards applicable to drugs and cosmetics. The CDSCO also has the power to regulate, restrict or prohibit the manufacture, sale or distribution of drugs, medical devices or cosmetics that are likely to involve any risk to human beings or animals.

Licensees that sell, stock, exhibit or offer for sale or distribute drugs under the Drugs Act must comply with the Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products detailed under the Drugs Rules. These require the licensee to devise a prompt and effective product recall system of defective products, including a standard operating procedure. It also contains requirements for reporting and storage of the recalled products.

Further, one of the conditions of a license issued under the Drugs Rules is that if the licensing authority finds that a batch of drugs or other substances does not conform to the standards of strength, quality and purity prescribed by the Drugs Act or the Drugs Rules, then the licensee must withdraw or recall the batch on being directed to do so by the authority.

The Medical Device Rules, 2017 (the “Medical Device Rules”), which are proposed to come into force on 1 January 2018, empower the licensing authority to order the recall of medical devices that do not conform to the prescribed standards. The Medical Device Rules will

apply to substances used for in-vitro diagnosis and surgical materials, blood and blood component collection bags, mechanical contraceptives, disinfectants and insecticides as notified under the Drugs Act, and other devices notified from time to time under the Drugs Act.

The Medical Device Rules also impose an obligation on manufacturers or authorized agents who have reasons to believe that a medical device is likely to be unsafe to: (a) initiate procedures to remove such medical devices from the market while indicating the reasons for such recall; and (b) inform the competent authority of details thereof.

Food and drinks

The Food Safety and Standards Act, 2006 (FSSA) governs the manufacture, storage, distribution, sale and import of food to ensure availability of safe and wholesome food for human consumption. The Food Safety and Standards Authority of India (the “Food Authority”) established under the FSSA has issued various regulations under the FSSA, including those for the licensing of food businesses, food additives, packaging, labelling, sampling and analysis.

In the event a food business operator considers that a food item that it has processed, manufactured or distributed does not comply with the FSSA, it must immediately initiate procedures to withdraw the food in question and inform the competent authority. “Food business operator” in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring compliance with the FSSA and rules and regulations made thereunder.

The Food Safety and Standards Regulations, 2017 specifically regulate the process of recalls, creation of recall plans and monitoring of the recall process by manufacturers, importers and wholesalers. Under the Food Recall Regulations, the Food Authority can initiate a food recall and provide that recalled food be dealt with in the manner prescribed. In the case of such recall, the food business operators are



required to provide a weekly report to the Jurisdictional Commissioner of Food Safety or the Food Authority informing them of the progress of the recall in the prescribed manner. The food business operator is required to retain proper and complete documentation on food recall for inspection and verification by the relevant authorities.

Motor vehicles

Under the Motor Vehicles Act, 1988 (MVA), the Ministry of Road Transport and Highways is the primary authority for regulation of the automotive industry in India. It has overarching powers under the MVA, including implementing standards on automotive safety, construction and equipment of motor vehicles, which have to be complied with by automobile manufacturers. Pursuant to these powers, the Ministry of Road Transport and Highways, in consultation with the Automotive Industry Standards Committee and other committees, has set out automotive technical standards and specifications to be complied with by motor vehicles manufactured or sold in India.

Until the Motor Vehicle Amendment Bill 2016 (the “Motor Vehicle Bill”) is notified, the Voluntary Code of Vehicle Recall dated July 2012 (the “Voluntary Code”), which contains guidelines for a voluntary recall of vehicles containing safety defects, may be followed. The Voluntary Code contains provisions relating to intimation to the government about the recall procedure and the methods for notifying the customers regarding the recall process. However, the Voluntary Code does not provide a specific process to be followed for recall of vehicles and the manufacturers are free to devise their own recall procedures.

The Motor Vehicle Bill proposes to introduce a recall procedure wherein the central government may recall any motor vehicle that may cause harm to the environment or to the driver or occupants of such motor vehicle or other road users in addition to imposing any monetary penalty on such manufacturer. The Motor Vehicles Bill

further provides that the manufacturer whose vehicles are recalled will have to: (a) reimburse the buyers the full cost of the vehicle, or replace the defective vehicle with another vehicle with similar or better specifications; and (b) pay such fines and other dues as may be prescribed. Where the manufacturer notices defects in the motor vehicles manufactured by him, the manufacturer may initiate a voluntary recall after intimating the central government, and thereby avoid the payment of any prescribed fines. The Motor Vehicles Bill is still pending approval before the Lower House of the Indian Parliament.

5. Legal consequences of noncompliance

Under the Consumer Protection Act, the appropriate authority has the right to issue orders to: (a) remove defects in the product; (b) replace the product; (c) return any consideration paid by the consumer; and (d) award compensation, including punitive damages, to the consumer. Authorities with powers under the Consumer Protection Act are not empowered to impose imprisonment, except in cases where there is noncompliance with an order made by an appropriate authority. In such case, imprisonment for a term that may extend up to three years may be imposed.

Drugs

Failure to comply with any obligations imposed on an importer or manufacturer under the Drugs Act and Drugs Rules may result in the cancellation or suspension of the license to manufacture, sell or distribute drugs.

Food

There is no specific penalty prescribed under the FSSA for failing to adhere to provisions relating to food recall. However, related penalties, including penalties for sale of substandard and/or unsafe food products that do not comply with provisions of the FSSA, may apply if the food business operator does not meet recall obligations.



These penalties include payment of stipulated fines and imprisonment in certain cases.

Motor vehicles

The Voluntary Code does not provide for penalties for noncompliance in relation to product recalls. However, the Voluntary Code contains a recommendation that if a manufacturer fails to announce a vehicle recall despite there being clear evidence of safety defects, the government may issue appropriate directions to the vehicle manufacturer. Monetary penalties are proposed to be imposed on manufacturers, importers and wholesalers under the Motor Vehicles Bill.

Sources of information

Central Drugs Standard Control Organization:

<http://www.cdsc0.nic.in/forms/Default.aspx>

Food Safety and Standards Authority:

<http://www.fssai.gov.in/home>

Ministry of Road Transport and Highways:

<http://www.morth.nic.in>

Bureau of Indian Standards:

<http://www.bis.gov.in/>

Indonesia

Indonesian Law No. 8 of 1999 (the “Consumer Protection Law”) is the umbrella regulation that provides the principles and basic rules of consumer protection in Indonesia.

1. Definition of a “consumer product”

The Consumer Protection Law defines a “consumer” as an individual who uses goods, services, or both, per that are not to be traded and that are available to the public for the purposes of the individual, his or her family and/or other living creatures. “Consumer products” are defined as goods or services that are used by consumers.

2. Agencies involved in regulating consumer products

Depending on the type of product recalled, different government offices and agencies are involved. For example, for general consumer goods, the Directorate for Supervision of Goods and Services of the Ministry of Trade has the authority to supervise recalls. For food, cosmetics and drug products, the National Agency of Drug and Food Control (BPOM) has the authority to supervise recalls. For health equipment, recalls are within the authority of the Ministry of Health and for automotive product, the Ministry of Industry has the authority to supervise recalls.

3. Reporting requirements and recall procedures

Voluntary recall

Voluntary recall means a recall initiated by the company. Under the Consumer Protection Law and the Indonesian Criminal Code, companies are required to make full disclosure of product defects. Furthermore, if a product is defective or contaminated, or if it violates applicable standards or is fraudulently marketed, the producer or distributor must recall the product. The Consumer Protection Law stipulates that a business actor who commits a violation, such as selling defective products or services without proper disclosure, is



prohibited from selling those goods or services and must withdraw them from distribution.

A voluntary recall should be considered in order to prevent criminal liability under Indonesian consumer protection laws. Moreover, although there is no specific requirement to notify the authorities (except for drugs, which will be addressed in section 4), notification should be considered in certain cases to prevent criminal prosecution where there is potential for serious harm or imminent personal injury to the public. Failure to give notification in such a case may cause the authorities to initiate administrative action (eg, ordering a mandatory recall), or a criminal investigation leading to a possible prosecution. By notifying and involving the authorities, a producer or distributor may be deemed to exhibit good faith, which may dissuade the authorities from pursuing a criminal prosecution.

Mandatory recall

For mandatory recalls (ie, recalls ordered by the relevant authorities), certain procedures must be followed. According to Ministry of Trade Regulation No. 20/M-Dag/PER/5/2009 on Provisions and Procedures on Goods and/or Services Supervision (MOT Regulation No. 20), the procedures for recalling goods are authorized by the Directorate for Supervision of Goods and Services of the Ministry of Trade. If, based on the results of laboratory tests, surveys or research of periodic control and/or specific control, goods prove hazardous to health, security or safety of consumers, or give rise to personal injury, the authorized official will order the business actor to stop production and withdraw the goods from circulation after consulting a team specifically formed for that purpose. The company whose products are recalled should report periodically on the execution of the product recalls.

Aside from security and consumer safety, a product may be recalled for the following reasons:

- The products do not meet national standards stipulated in MOT Regulation No. 20
- The products do not meet labelling requirements
- The products do not meet standard clause requirements
- The products do not meet after sales services requirements
- The way of selling the products and the advertisements contain false statements, or deceptive or misleading content

No specific procedures to be followed in implementing a recall are prescribed by MOT Regulation 20. Usually, the steps to be taken in a product recall are as follows:

- Once a safety issue arises, the recalling party should immediately prepare for the product recall and also start liaising with the officials of the Ministry of Trade on the availability of the official in charge to receive and review the notice, as well as to ascertain their expectations of the notice.
- Once the notice has been received by the Ministry of Trade, the recalling party may start communicating the safety issue and the product recall to its consumers and, if it opts to do so, the recalling party may make an announcement of the recall in two daily newspapers, as normally suggested (not mandated) by the Ministry of Trade.
- Afterwards, the recalling party should prepare a summary of the tracking/results of the recall to be submitted to the Ministry of Trade after expiry of the recall period or after the recall is completed.



For drugs, cosmetics and food products, the procedure for mandatory recalls (as well as voluntary recalls) is authorized by BPOM. BPOM is authorized to take administrative measures against those who violate the provisions of the Drug Law and Health Law. The administrative measures include: (a) warnings; (b) prohibition of circulation; (c) destruction of products that prove dangerous to human health and life; (d) temporary termination of production; (e) imposition of fines; and/or (f) revocation of production licenses or permits.

4. Product-specific regimes

The following regulations provide more detailed requirements for recalls of the following types of products.

Food and beverage products

Ministry of Industry Regulation No. 75/M-IND/PER/7/2010 on Good Manufacturing Practices for Processed Food Products provides for the following requirements when recalling food products, both voluntarily and mandatorily:

- A product shall be recalled if it suspected of causing diseases or food poisoning
- The manufacturer is responsible for carrying out the recall and preparing a recall procedure
- Other products that were produced under the same condition as the hazardous product must also be recalled
- The public should be informed about the likelihood of hazardous products being distributed
- Recalled products must be monitored until they are destroyed or used for other purposes, and may not be repurposed for human consumption

- Production of hazardous products must be stopped until the relevant problems have been resolved

Pharmaceutical products

BPOM Regulation No. HK.04.1.33.12.11.09938 dated 2 December 2011 on Criteria and Procedures of Recall of Drugs that Do Not Meet the Standards and/or Requirements governs the recall of pharmaceutical products.

Recalling products that do not conform to standards are classified into classes I, II and III, in terms of descending severity.

- Class I recall, the most severe case, is caused by the following:
 1. Failure to fulfill safety requirements
 2. Microbe contamination in injection preparation or eye drops
 3. Chemical contamination that causes serious health effects
 4. Labels that are not aligned with content
 5. Various products being mixed in a single packaging
 6. Wrong active ingredient being used in a multicomponent product causing a serious effect on health

For class I cases, a recall is required to be reported to BPOM within 24 hours after the product is determined to be noncompliant. An initial progress report of the recall must be delivered to BPOM within 72 hours after initiation of the recall.

- Class II recall, which is for less-severe cases, is caused by the following:
 1. Incomplete or misprinted labels
 2. Inclusion of incomplete or wrong brochure or leaflet



3. Microbe contamination in non-sterile product
4. Other chemical or physical contamination
5. The product not fulfilling specification on ingredient, weight, dissolution, potency, portion, pH, water level or stability
6. The product having expired

For class II cases, a recall is required to be reported to BPOM within five working days after the product is determined to be noncompliant. An initial progress report of the recall must be delivered to BPOM within five working days after initiation of the recall.

- Class III recall, which is for the least-severe cases, is caused by the following:
 1. Failure to apply the batch number or expiry date
 2. Certain failures to fulfill technical requirements of liquid oral products
 3. Damage to packaging
 4. Failure to fulfill other standards that do not fall within classes I and II

For class III cases, a recall is required to be reported to BPOM within seven working days after the product is determined to be noncompliant. A progress report of the recall must be delivered to BPOM within 10 working days after initiation of the recall.

- For all classes of recalls, BPOM shall supervise the recall process and the nonconforming products shall be destroyed within 15 working days after all nonconforming products have been received and the result of the recall has been reported to BPOM.

5. Legal consequences of noncompliance

If a company fails to recall a product and that product causes harm to consumers, the company could be subject to civil and criminal penalties. This is a general rule that applies to all products.

Civil penalties

Civil compensation and liability for damage incurred by consumers is assessed under Article 1365 of the Civil Code and Article 19 of the Consumer Protection Law. Article 1365 of the Civil Code stipulates, “Every unlawful action that causes damage to other persons, obliges the person whose fault caused such loss to compensate for such loss.” Based on Article 1365, a consumer harmed by a defective product could request damages from a business actor through an Indonesian court.

Article 19 of the Consumer Protection Law stipulates as follows:

- Business actors are liable for damage, pollution and/or consumer losses caused by the consumption of goods and/or services produced or marketed
- This compensation can be in the form of a refund or replacement of goods and/or services of the same type or comparable value, or healthcare and/or benefits according to prevailing laws and regulations
- Payment of compensation does not eliminate possible criminal charges based on the element of fault, unless the business actor can prove that the consumer was at fault

Based on Article 19 of the Consumer Protection law, a consumer could request compensation (eg, healthcare treatment costs) from a business actor for losses arising from use of the defective product.



Criminal penalties

Under Article 62 of the Consumer Protection Law, criminal penalties of up to five years' imprisonment or fines of up to IDR 2 billion may be imposed for violation of Article 8(4) of the Consumer Protection Law on selling defective products.

Italy

Consumer product safety is regulated by Articles 102 to 113 of the Consumer's Code (Legislative Decree no. 206/2005) (CC), which implements the General Product Safety Directive 2001/95/EC (GPSD).

1. Definition of a “consumer product”

Consumer products to which product safety provisions apply are those products defined under Article 3(e) of the CC, which reproduces the definition in the GPSD: “any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.”

Second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used are excluded from the scope of this definition.

In addition to the general rules provided for by the CC, certain product-specific national laws integrate the applicable legal framework. For example, Legislative Decree no. 54/2011 implements Directive 2009/48/EC on the safety of toys, adopted by the EU to update the existing rules on toy safety in light of technological and scientific progress and to coordinate them with the latest sets of rules issued by the EU (including the GPSD).

Finally, regulations and guidelines issued by the competent Italian authorities (eg, the Ministry of Economic Development) may set forth additional provisions applicable to specific practices and/or product categories.



2. Agencies involved in regulating consumer products

Pursuant to the CC, the competent surveillance authority in Italy is the Ministry of Economic Development. Alternative competent authorities, depending on the nature of the product involved, are the Ministry of Health, the Ministry of Economy and Finance, the Ministry of Welfare, the Ministry of the Interiors and the Ministry for Infrastructures and Transport (see section 4 below).

3. Reporting requirements and recall procedures

Companies must “immediately” inform the competent authority if they become aware of a product hazard, specifying what measures they have undertaken to prevent any risks to consumers. The CC does not specify what “immediately” means. However, “immediately” almost certainly has the same meaning as under the GPSD, ie, without delay, and in any case within 10 days after the company has reportable information, or three days in the case of serious risk.

The CC also does not specify when a product defect presents a hazard that must be reported to the market surveillance authorities. The CC does adopt the GPSD definitions of “safe product” and “dangerous product.” Pursuant to the CC, the manufacturer and/or distributor must inform the competent authorities about products that pose risks for consumers and thus do not comply with general safety requirements.

The company makes the decision as to whether a product defect reaches a hazard level that must be reported to the competent surveillance authority. Manufacturers and distributors should consider having a written procedure for how they carry out a risk assessment and take corrective actions for potentially unsafe products. However, although the company makes the initial risk assessment to evaluate whether a report is required, the competent authorities may independently evaluate the product hazard, disagree with the company’s decision and adopt any alternative or additional measure they deem necessary to limit or prevent sales of the unsafe product.

If a report is required, the manufacturer and/or distributor must file its report to the *Dipartimento per l'Impresa e l'Internazionalizzazione* of the Ministry of Economic Development. As mentioned above, the report may alternatively be filed with other ministries, such as the Ministry for Infrastructures and Transport for automobiles or the Ministry of Health for pharmaceutical or food products. The report can be filed by completing the EU's Business Application form online (usually when the notification involves other EU member states), accessible on the European Commission website, or in any other way, such as by registered letter or courier, and can also be filed by fax or email to speed up the procedure.

Where not using the EU's Business Application model, the report to the surveillance authorities must contain at least all the information required by the notice form attached to the GPSD.

In implementing a corrective action, notification to consumers may be necessary. Pursuant to Article 104 of the CC, manufacturer must adopt any proportionate measures, depending on the product (including the nature of the product, the number of products distributed and the potential to make individual notifications), to allow the consumer to be informed about the product's risks, and must undertake any action required to avoid such risks, including recall campaigns. Where individual notifications are not commercially feasible, public notifications via the media are strongly recommended.

If a product recall is implemented, the CC does not specify to what extent and for how long the recall campaign will run. The company must monitor the effectiveness of the communication methods used and verify whether the corrective actions undertaken, including the product recall, have reached a sufficient level in terms of contacts and response. A positive assessment of such elements is needed before the corrective action can be formally ended. Statistics and data on recall campaigns of similar products may be helpful to establish the grounds of such an assessment. If such data is not available, market surveillance authorities may help in determining a sufficient target



level for contacts and/or response. Once the target level has been reached, the corrective actions may be formally ended.

4. Product-specific regimes

Medicinal products for human use

Medicinal products for human use are regulated by Legislative Decree no. 219/2006, which transposes Directive 2001/83/EC and Directive 2003/94/EC into Italian legislation.

Decree no. 219/2006 provides for the withdrawal from the market or the recall from the patients of medicinal products (i) that are harmful, (ii) that lack therapeutic efficacy, (iii) that present an unfavorable risk-benefit balance for the patient, (iv) that present a qualitative and quantitative composition different from those declared, (v) for which the controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or (vi) for which some other requirement or obligation relating to the grant of the manufacturing authorization has not been fulfilled. If any of the above circumstances exist, the withdrawal can also be ordered unilaterally by the Italian Medicines Agency (AIFA).

The decree requires supply chain operators to adopt an adequate and effective system to allow them to withdraw the medicinal products from the market at any time. When implementing a withdrawal, the economic operator shall notify AIFA and the other interested EU Member States' Health Authorities. The notification can be made by using the form available on the AIFA website (http://www.agenziafarmaco.gov.it/sites/default/files/MODELLO_A-SEGNALAZIONE_DIFETTI_27.12.2016.pdf). AIFA shall then inform the European Medicines Agency accordingly. If a medicinal product is suspected of presenting a serious risk to public health and it has reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the

patients. Those announcements shall contain sufficient information on the suspected quality defect or counterfeiting and the risks involved.

Medical devices

Italian legislation (ie, Legislative Decree nos. 46/1997, 507/1992 and 332/2000) implementing the relevant EU Directives (ie, Directives 93/42/EEC, 90/385/EEC and 98/79/EC) provides for the withdrawal/recall of medical devices under certain circumstances. In particular, the manufacturer is required to withdraw/recall, at its own responsibility and cost, a medical device that (i) may cause the death of patients, operators and third parties and/or (ii) may compromise the health and/or safety of patients, operators or other persons. The manufacturer is also required to immediately inform the Ministry of Health. The notification can be submitted online by submitting the special form accessible on the Ministry of Health's website (<http://www.salute.gov.it/DispoVigilancePortaleRapportoOperatoreWeb/>). Healthcare organizations and healthcare professionals are also required to inform the Ministry of Health if they discover any medical devices triggering the concerns mentioned above under points (i) and (ii). The Ministry of Health might order the manufacturer to immediately withdraw/recall the unsafe device and shall immediately inform the European Commission and the other EU Member States' Health Authorities.

Food and drink

Food and drink safety is primarily regulated by European Regulation 2002/178/EC, which is directly applicable in Italy and addresses all stages of production, processing and distribution of any food. Italian Legislative Decree no. 190/2006 punishes noncompliance with Regulation 2002/178/EC, which provides, under certain circumstances, for the obligation to withdraw/recall food and drink that do not comply with the applicable safety requirements established in the regulation.



If a food business operator considers or has reason to believe that a food/drink that it has imported, produced, processed, manufactured or distributed does not comply with the food safety requirements, it shall immediately implement a withdrawal campaign and inform the Ministry of Health accordingly. The notification shall be made using the forms provided by the Regulation 2002/178/EC, accessible directly on the Ministry of Health's website (http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1146&area=sicurezzaAlimentare&menu=sistema). Where the product may have already reached the consumers, the operator shall effectively and accurately inform the public of the reason for the withdrawal, and if other measures are not sufficient to achieve a high level of health protection, it shall recall products already supplied to consumers.

Motor vehicles and parts

Ministerial Decree no. 32721/2008, implementing Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, includes specific provisions for the withdrawal/recall of vehicles and their parts.

Manufacturers have an obligation to withdraw/recall vehicles and their parts if they entail a serious risk to (i) road safety, (ii) public health and/or (iii) environmental protection. The manufacturer shall immediately inform the Ministry of Transport (acting as the national Approval Authority) and propose remedies in order to neutralize any potential risks. The Approval Authority shall communicate the proposed measures to the other Member States' Approval Authorities immediately. If the Approval Authority that granted the EC type-approval is itself not satisfied with the manufacturer's measures, it may take all protective actions deemed appropriate, including withdrawal of the EC type-approval, for as long as the manufacturer does not propose and implement effective corrective measures. In this case, the protective measures shall be communicated to the

manufacturer, the other Member States' Approval Authorities and the European Commission.

5. Legal consequences of noncompliance

Violation of the product safety rules may result in administrative or criminal liability for the manufacturer and/or distributor. Pursuant to the CC, the sale of unsafe products is punishable by imprisonment for up to one year and fines of up to EUR 50,000. Failure to comply with reporting requirements may result in an administrative fine of up to EUR 40,000. Other violations of the CC relating to the manufacturer's and/or distributor's failure to comply with their cooperation obligations may be sanctioned by fines of up to EUR 40,000, provided that the relevant conduct does not qualify as a different criminal offense.

Product-specific laws and regulations that might be applicable in a specific case may provide for additional sanctions.

The imposition of administrative or criminal sanctions will not bar additional consumer tort claims seeking damages under Articles 114 to 127 of the CC concerning product liability or under general tort law.

Failure to comply with the obligations set out in section 4 is punishable as follows:

- (a) Medicinal products - a fine of up to EUR 38,000
- (b) Medical devices - imprisonment for up to one year and a monetary penalty of up to EUR 100,000
- (c) Food and drink - a fine of up to EUR 18,000

There are no specific sanctions for noncompliance with safety requirements/adoption of corrective measures concerning vehicles and their parts, so the sanctions provided by the CC apply.



Sources of information

Ministry of Economic Development

Dipartimento per l'Impresa e l'Internazionalizzazione

Direzione generale per il mercato, la concorrenza, il consumatore, la vigilanza e la normativa tecnica

Divisione VII - Qualità dei prodotti e dei servizi e professioni non organizzate in ordini o collegi - Sicurezza e conformità dei prodotti

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Japan

There are several laws that govern product recall in Japan, including the Consumer Product Safety Law and several other product specific laws.

1. Definition of a “consumer product”

The definition of “consumer product” is found in the relevant law covering the particular type or category of product. The main laws specifically addressing products and product recalls are as follows:

- The Consumer Product Safety Law (*Shohiseikatsuyoseihin Anzen-ho*), which defines “consumer products” as “all products to be used for ordinary consumers, excluding those regulated under other laws” and covers almost all consumer products
- The Liquefied Petroleum Gas Security and Fair Trade Law (*Ekikasekiyugasu no Hoan-no-Kakuho Oyobi Torihiki-no Tekisei ni-kanseuru Houritsu*), which covers liquefied petroleum-gas-related products, such as various heating appliances and products powered by liquefied petroleum gas
- The Gas Business Law (*Gasu Jigyo-ho*), which covers gas-related products such as instantaneous gas water heaters, gas stoves, bath boiler with gas burners, gas bath burners and similar products
- The Electric Appliance and Material Safety Law (*Denkiyohin Anzen-ho*), which covers electrical products mainly for businesses, such as thermal fuses, plugs, electric heaters, electric massagers, electric stoves, electric washing machines, electric irons, electric refrigerators, electric stand lights and other electrical appliances for businesses



2. Agencies involved in regulating consumer products

The Ministry of Economy, Trade and Industry (METI) was in charge of enforcing the abovementioned laws until 1 September 2009, when the Consumer Affairs Agency (CAA) was established and replaced METI with respect to enforcing the Consumer Product Safety Law. In the event of a consumer product safety issue, the CAA requires manufacturers, importers and sellers of products to comply with prescribed safety standards and reporting requirements within 10 days of the acknowledgment of a Serious Product Incident. The CAA also has authority to conduct investigations and issue orders to manufacturers to improve their internal supervision system for product safety. METI still has responsibility for issuing recall orders if companies do not voluntarily recall products that do not meet the relevant safety standards, or cause accidents. METI also remains responsible for enforcing the other laws listed above.

The intention of establishing the CAA was to combine the consumer-related authorities previously scattered among various ministries and agencies, and allow the CAA to compile and analyze consumer-related information, publish warnings and reports to the general public, and order private enterprises and governmental agencies to take appropriate actions upon the occurrence of consumer safety issues.

3. Reporting requirements and recall procedures

Reporting requirements under the Consumer Product Safety Law

In the wake of the deaths of multiple consumers from carbon monoxide poisoning from automatic gas water heaters, the Consumer Product Safety Law was amended in November 2006 to expand the reporting obligations of manufacturers and importers, especially in relation to Serious Product Incidents. Within 10 days after acknowledging a “Serious Product Incident,” manufacturers and importers must file a Serious Incident Report to the CAA, including a

brief description of the accident and possible causes. The Consumer Product Safety Law defines a “Serious Product Incident” as, among other things, fire, carbon monoxide poisoning, physical injury requiring 30 days or more for recovery, and other serious physical injuries. In general, the CAA discloses these reports on its website within one week after submission.

As the Consumer Product Safety Law covers almost all consumer products, such as personal computers, cell phones, televisions, bicycles, skis and pressure cookers, this reporting requirement has become a critical compliance matter not only for Japanese manufacturers, but also for foreign capitalized firms in Japan that are not in the service industries.

In addition to these mandatory reporting requirements, METI issued an administrative guideline on voluntary action plans for product safety on 4 March 2011, which requires manufacturers, importers, sellers, leasing companies, construction companies and repair companies to also file a report relating to a product safety incident with the National Institute of Technology and Evaluation (the “NITE Report”), an independent administrative organization in charge of product safety issues. The difference between the NITE Report and the Serious Incident Report is that the former needs to be filed by sellers, leasing companies, construction companies and repair companies as well as manufacturers and importers, while the latter only needs to be filed by manufacturers and importer. Furthermore, the NITE report is required for less serious accidents, including minor accidents and near-miss cases, while the Serious Incident Report is only required for the Serious Product Incident. Under this new guideline, the NITE Report should be submitted within 10 days after the acknowledgment of an accident that could lead to either a Serious Product Incident or even cause a lesser injury.

This administrative guideline and the requirement to file a NITE report are unchanged even after the establishment of the CAA.



In contrast to the CAA reporting requirement, a NITE Report is not mandatory, but is recommended. Therefore, there are no legal sanctions for not filing it. However, METI or the CAA will take more stringent action against companies that do not submit a NITE Report and can employ a range of enforcement actions, such as recall orders under the Consumer Product Safety Law or the other product safety laws. In addition, even if a product does not fall within the scope of consumer products as defined under the Consumer Product Safety Law, it is recommended that companies, including manufacturers and importers, file a NITE Report. For example, if electric power lines for businesses are defective and could lead to a Serious Product Incident, or if they have caused a physical injury, it is often recommended that the manufacturer, importer or seller acknowledge such an issue by filing a NITE Report.

Other than these reporting requirements, which are mainly connected to the Consumer Product Safety Law, the other product safety laws for specific categories of products generally do not require companies to report to a regulatory body, unless the CAA or the other agencies issue a reporting order to them. Therefore, in most cases, companies that know of product defects or accidents involving consumer products should comply with the required reporting to the CAA and NITE under the Consumer Product Safety Law and METI's guideline, both of which impose a relatively short period of 10 days after the acknowledgment of an accident.

Although manufacturers and importers do not have a legal duty to report incidents to the CAA that are not “serious,” administrative guidelines issued by METI strongly recommend that incidents that are not themselves serious, but which could lead to serious incidents, be reported to NITE. This recommendation by METI is not a legal duty, but should be followed in practice.

Recall procedure

Generally, recalls in Japan are done voluntarily by each manufacturer or importer. Such recalls are usually initiated by a Serious Incident

Report filed with the CAA, as triggered by a Serious Product Incident. Upon such a filing, companies start communicating with the CAA about how to deal with the incident and the necessity of a recall. During such discussions, the CAA communicates with METI and if METI determines the incident was due to a defect in the product design or manufacturing process, it will recommend a voluntary recall. If the manufacturer or importer does not obey such a recommendation, METI will issue an involuntary recall order under the Consumer Product Safety Law or other safety laws, depending on the type of product. As most companies follow METI's recall recommendation, METI has issued recall orders in only two cases since the amendment to the Consumer Product Safety Law.

It is recommended that, before the commencement of a recall, a manufacturer or importer file a recall report specifying the identity of the company, product types, method of recall and reasons for the recall. Subsequently, it is recommended that such company file a periodic recall status report, usually on a monthly or bimonthly basis.

4. Product-specific regimes

Pharmaceuticals / Medical devices

Pharmaceuticals, quasi pharmaceuticals, cosmetics, medical devices and regenerative medicine products (collectively, "Pharmaceuticals and Medical devices") are subject to the product recall regulations under the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices (the "PM Law"), whose regulator is Ministry of Health, Labor and Welfare (MHLW).

The key elements of the product recall regulations under the PM Law are as follows:

- Holders of marketing authorization for Pharmaceuticals and Medical devices, or persons with special foreign approval (collectively, "Holders" or "Special approved persons") shall, when they learn of the occurrence or spread of hazards to public



health and hygiene suspected to be caused by using the Pharmaceuticals or Medical devices, dispose of, recall, discontinue selling and provide information on such product, and take other necessary measures for the prevention of the occurrence or spread of hazards to public health and hygiene

- Proprietors of pharmacies, hospitals or clinics for human beings or human-reared animals; sellers of pharmaceuticals, quasi-drugs or cosmetics; persons selling, leasing or repairing medical devices; sellers of regenerative medicine products; physicians, dentists, veterinarians or other medical professionals, (collectively, “Relevant Medical Professionals”) shall make efforts to cooperate in providing measures required by Holders or Special approved persons
- When Holders or Special approved persons learn of the occurrence of any disease, disability or death suspected to be caused by the side effects of using Pharmaceuticals and Medical devices that they manufactured and sold or received approval for, the occurrence of any infectious disease suspected to be caused by the use of such items, and other matters on the efficacy and safety of Pharmaceuticals and Medical devices, such Holders or Special approved persons shall report the same to the MHLW
- Relevant Medical Professionals shall, where they learn of the occurrence of any disease, disability or death suspected to be caused by the side effects of using Pharmaceuticals and Medical devices, or the occurrence of any infectious disease suspected to be caused by the use of such items, and when it is found to be necessary in order to prevent the occurrence or spread of hazards to public health and hygiene, report the same to the MHLW
- Holders, Special approved persons or manufacturers of Pharmaceuticals and Medical devices, etc., exported pursuant to the PM Law shall, when they recall Pharmaceuticals and Medical devices, etc., that they marketed, manufactured or

received approval for, report that they have started to recall such products and the status of the recall to the MHLW

Food and drink

All food and drink except for the pharmaceuticals and quasi pharmaceuticals specified in the PM Law, additives, natural flavoring agents, apparatus for food and additives, and containers and packaging (collectively “Food and Drink”) are subject to the product recall regulations under the Food Sanitation Act (FSA). The MHLW oversees the FSA. Furthermore, Food and Drink, toys that are likely to harm the health of infants when they touch them, and the cleaning agents used for cleaning vegetables, fruits or tableware may be subject to the order by the Minister of Health, Labor and Welfare, or a prefectural governor, to dispose of or take other necessary measures to eliminate the food sanitation hazards under Article 54 and 62 of the FSA.

The key elements of the product recall regulations under the FSA are as follows:

- A food business operator shall, on her/his own, endeavor to ensure the safety of Food and Drink that she/he collects, produces, imports, processes, cooks, stores, transports, sells, provides to many and unspecified persons, or uses in business (“Food for Sale”) and for that purpose, she/he shall endeavor to obtain the knowledge and technologies necessary to ensure the safety of Food for Sale, conduct voluntary inspections of Food for sale and take other necessary measures. “A food business operator” means a person or corporation who is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or producing, importing, or selling apparatus or containers and packaging, or a person or corporation who provides food to many and unspecified persons on an ongoing basis at schools, hospitals or other facilities



- A food business operator shall endeavor to record any necessary information, such as the name of a person who has sold Food for Sale or the raw materials thereof to the food business operator, and retain such records, within the limit necessary for preventing food sanitation hazards resulting from Food for Sale
- A food business operator shall endeavor to take any necessary measures appropriately and immediately in order to prevent food sanitation hazards resulting from Food for Sale, such as the provision of the record to the State or prefectures, and the disposal of the Food for Sale that caused the food sanitation hazard

Motor vehicles and parts

Automobiles, tires and child seats are subject to the product recall regulations under the Road Transport Vehicles Law (the “RTV Law”). The Ministry of Land, Infrastructure, Transport and Tourism (MLITT) oversees the RTV Law.

The key elements of the product recall regulations under the RTV Law are as follows:

- An automobile manufacturer or importer shall, if the structure, equipment or function is not likely to or does not conform to the safety standard required under the RTV Law and the cause of the unconformity is in the process of design or manufacture of automobiles, inform the Minister of Land, Infrastructure, Transport and Tourism of the status of such structure, equipment and function, the said cause of the unconformity, the improvement measures to be taken and the measures to notify the users of the affected automobiles, cause and improvement measures, etc.
- The Minister may, if she/he finds that the improvement measures to be taken do not diligently conform to the safety

standards, order the automobile manufacturer or importer to change the improvement measures

- The automobile manufacturer or importer who reported shall also report an update to the Minister regarding the improvement measures taken

5. Legal consequences of noncompliance

Failing to file a Serious Incident Report does not itself constitute a violation of the criminal provisions in the Consumer Product Safety Law. The CAA may issue an order requiring a manufacturer or importer to report information on product safety issues if it learns of such incidents from other sources, including consumers. Additionally, METI may issue a recall order to prevent further serious accidents. Furthermore, the Minister of Health, Labor and Welfare may issue a recall order to prevent further accidents under Article 69-3 and/or 70(1) of the PM Law and under Article 54 of the FSA. The Minister of Land, Infrastructure, Transport and Tourism may also issue a recall order under Article 63-2 of the RTV Law.

If a company does not comply with such an order, an individual acting on behalf of the company could face imprisonment of up to one year and/or a fine of JPY 1 million. Under the PM Law and the FSA, an individual acting on behalf of the company could face imprisonment of up to three years and/or a fine of JPY 3 million. Under the RTV Law, an individual acting on behalf of the company could face imprisonment of up to one year and/or a fine of JPY 3 million.

The company itself could face a fine of up to JPY 100 million under the PM and JPY Laws. Under the RTV law, the company could face a fine of up to JPY 200 million.



Sources of information

CAA

<http://www.caa.go.jp/>

METI

www.meti.go.jp/

MHLW

<http://www.mhlw.go.jp/>

MLITT

<http://www.mlit.go.jp/>

NITE

www.jiko.nite.go.jp/

Kazakhstan

Consumer product safety in Kazakhstan is mainly regulated by Law of the Republic of Kazakhstan No. 274-IV, dated 4 May 2010, On Protection of Consumers' Rights (the "Consumer Protection Law") and Law of the Republic of Kazakhstan No. 603-II, dated 9 November 2004, On Technical Regulation (the "Technical Regulation Law").

1. Definition of a "consumer product"

There is no definition of a consumer product under Kazakhstani law. Generally, the Consumer Protection Law covers all kinds of products, works and services consumed for personal domestic needs.

2. Agencies involved in regulating consumer products

The main governmental agencies that deal with safety aspects of consumer products are the Agency for Regulation of Natural Monopolies, Protection of Competition and Consumers Rights of the Ministry of National Economy (the "Agency") and the Committee on Technical Regulation and Metrology of the Ministry of Investments and Development. In accordance with Article 6 of the Consumer Protection Law, other governmental authorities may also be involved in regulating consumer products.

3. Reporting requirements and recall procedures

Under the Consumer Protection Law, if the manufacturer or seller obtains information that the use, storage, transportation or utilization of a consumer product brings or may bring harm to human life, health, property or the environment, the manufacturer or seller must immediately suspend producing and/or selling the product until the reasons for the harm are eliminated. Should it be impossible to eliminate the reasons for the harm, the manufacturer or seller must withdraw the product from production or sale; report to the relevant governmental authorities on the finding; notify consumers of the potential hazard to their lives, health, property or the environment through mass media; and recall the product from consumers.



Under local rules, the manufacturer or seller must publish the notice about the potential hazard to life, health, property or the environment in the official newspapers and/or TV/radio channels within three days if there is risk of damage to life, health, property of consumers or environment (10 days in other cases). Product recall procedures must be commenced within five days with regard to food products and within 14 days with regard to other products.

The law is unclear as to which governmental authorities a report should be made. We interpret the law such that the manufacturer or seller must report to the Agency and the authorities regulating the particular areas of circulation of the defective products (eg, in instances where medical drugs are affected, the manufacturer or seller must also report to the Ministry of Health of the Republic of Kazakhstan).

The manufacturer or seller must pay in full all consumer damages connected with the recall of a product. Kazakhstani legislation does not provide detailed regulation of the product recall procedure, nor does it provide for an allocation of responsibilities between the manufacturer and the seller (or sellers) in the case of a product recall. However, if the manufacturer or seller fails to take the actions referred to above, the governmental authorities may step in and compel the manufacturer or seller to take the necessary actions.

4. Product-specific regimes

Pharmaceuticals and medical devices

Special procedures exist for the recall of pharmaceuticals and medical devices. The recall procedures for pharmaceutical products and medical devices are regulated by the Code On Health of Population and Healthcare System (the “Healthcare Code”) and the Rules On Prohibition, Suspension, Recall and Limitation of Pharmaceuticals, Medical Equipment and Medical Devices approved by the Order of the Minister of Healthcare and Social Development dated 27 February 2015.

The main differences from the general procedures can be summarized as follows:

- The recall process is conducted under the instructions and guidance of the healthcare regulator (the Ministry of Healthcare). The marketing authorization holder can initiate the recall procedure by applying to the regulator
- The regulator is entitled to recall pharmaceuticals and medical devices in a number of cases specified by the Healthcare Code (eg, products do not comply with safety and quality requirements; identification of side effects that may be dangerous to health; information about recall in other countries in connection with side effects dangerous to health)
- Upon receipt of information that could serve as a ground for recall, the regulator should conduct an investigation or, depending on the circumstances, an expert examination of the relevant pharmaceuticals. If the regulator takes the decision on the recall, all interested entities (manufacturer, distributors, drugstores, etc.) should be notified about the recall and take measures aimed at removing the relevant products from the market

Food and drink/Motor vehicles and parts

No special regime applies to the recall of these types of products, so the normal procedure set out in section 3 above applies.

5. Legal consequences of noncompliance

The Code on Administrative Offenses establishes liability for misleading consumers as to the features or qualities of the product. In the case of such a violation, officials of legal entities are subject to a fine ranging from 10 to 200 monthly calculation indices (MCI) (KZT 22,690 – KZT 463,800), with termination of a license or suspension or ban of the relevant activity for up to three years.



The Criminal Code establishes liability for production or sale of goods, works or services that do not meet safety requirements, as well as for the issue or use of an official document certifying the alleged compliance of defective goods, works or services with the relevant safety requirements if these acts have caused harm to human health by inadvertence. Such liability arises for officials of legal entities and results in any of the following: (a) a fine ranging from 300 to 5,000 MCI (KZT 680,700 – KZT 11,345,000) or correctional works in the same amount; (b) custodial restraint for up to three years (a form of restriction of liberty in which an offender serves his or her punishment at his or her place of residence subject to an obligation not to change the place of residence, place of work or place of study without notifying the specialized governmental authority; an obligation not to attend certain places; an obligation not to leave the place of residence during non-study or off-duty time; and an obligation not to travel to other localities without the permission of the specialized governmental authority); (c) arrest for up to 75 days; (d) public works for up to 240 hours; or (e) imprisonment for up to eight years, with or without deprivation of the right to hold certain posts or perform certain activities for up to three years.

Depending on the type of product or products, additional or separate liability may also be imposed. For example, under the Administrative Code, sale of non-registered pharmaceuticals, if it has not resulted in harm to human health, may result in fines up to 1,500 MCI (KZT 3,403,500) with suspension of the activity and confiscation of products and income received in the result of the relevant activity. Further, under the Criminal Code, sale of falsified pharmaceuticals or medical devices, if it has resulted in serious negative consequences, may result in: (i) fines up to 2,000 MCI (KZT 4,538,000) or correctional works in the same amount; (ii) custodial restraint for up to two years; or (iii) imprisonment for up to two years with confiscation of property, with or without deprivation of the right to hold certain posts or perform certain activities for up to two years.

Specific sanctions will depend on the circumstances of a case.

Noncompliance with recall procedure regulations may also result in civil liability requiring full compensation of damages to the consumer on whose life, health or property the harm was inflicted by the manufacturer or seller.



Malaysia

Malaysia does not have a specific single law governing the recall of consumer products. There are, however, various laws and regulations governing consumer rights, under which Malaysian regulators have a general power to order the recall of a wide range of consumer products.

1. Definition of a “consumer product”

There is no specific definition of “consumer product” in Malaysian legislation concerning consumer rights or transactions.

The primary legislation in Malaysia that governs consumer rights is the Consumer Protection Act 1999 (CPA), the provisions of which apply to all goods or services that are offered or supplied to one or more consumers in trade. A “consumer” is defined in the CPA as a person who “acquires or uses goods or services of a kind ordinarily acquired for personal, domestic or household purpose, use or consumption, and does not acquire or use the goods or services ... primarily for the purpose of resupplying them in trade, consuming them in the course of a manufacturing process, or in the case of goods, repairing or treating, in trade, other goods or fixtures on land.” The term “supply” in relation to goods is defined as “to supply or resupply by way of sale, exchange, lease, hire or hire purchase.”

Therefore, within the context of the CPA a “consumer product” is a product that is supplied by way of sale, exchange, lease, hire or hire purchase to a person, for personal, domestic or household purposes, during the course of trade.

2. Agencies involved in regulating consumer products

The government agency that is generally concerned with the regulation of consumer products is the Consumer Affairs Division within the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC). The functions of the MDTCC include the establishment of product safety standards, the enhancement of

consumer protection rules and legislative provisions and the management of consumer complaints. The MDTCC maintains branches in each state within Malaysia, as well as the federal territories of Labuan and Kuala Lumpur.

The involvement of other governmental agencies may also be warranted for the regulation of certain specific types of consumer products. For example, the Malaysian Communications and Multimedia Commission (MCMC) is entrusted with regulatory and other functions in relation to goods and services associated with the media and telecommunications industries.

3. Reporting requirements and recall procedures

As discussed more fully in section 4, apart from specific guidelines and regulations concerning toys, cosmetic products, drugs and medical devices, there are generally no laws or regulations of general application that impose mandatory reporting obligations or recall procedures for defective consumer products in Malaysia. The CPA does, however, grant a power to the MDTCC to declare, in the Malaysian Gazette, any goods or any class of goods to be prohibited if those goods or classes of goods have caused, or are likely to cause, injury to any person or property, or are otherwise unsafe. The CPA can require the supplier to recall the prohibited goods at the supplier's own expense and within any specific period.

Under the CPA, "supplier" means a person who, in trade, engages in any of the following:

- (a) Supplies goods to a consumer by transferring ownership or the possession of the goods under a contract of sale, exchange, lease, hire or hire-purchase to which that person is a party
- (b) Supplies services to a consumer, and includes:
 - where the rights of the supplier have been transferred by assignment or by operation of law, the person for the time being entitled to those rights



- a financier who has lent money on the security of goods supplied to a consumer, if the whole or any part of the price of the goods is to be paid out of the proceeds of the loan and if the loan was arranged by a person who, in trade, supplied the goods
- a person who, in trade, assigns or procures the assignment of goods to a financier to enable the financier to supply those goods, or goods of that kind, to the consumer
- a person who, in trade, is acting as agent for another person where that other person is not supplying in trade

Whether a person or entity is considered a supplier is a question of fact. Generally, the retailer would be the supplier, since the retailer supplies the goods to the consumers.

Apart from the above, consumer product recalls are essentially conducted at the discretion of the supplier. Nevertheless, a supplier may liaise with the MDTCC when the supplier decides to conduct a voluntary recall of its products as a gesture of goodwill.

4. Product-specific regimes

Pharmaceuticals and medical devices

Under the Control of Drugs and Cosmetics Regulations 1984 (CDCR), every licensed manufacturer, importer and wholesaler is required to have a product recall procedure for pharmaceutical products. Regulation is conducted by the National Pharmaceutical Regulatory Agency (NPRO), which is under the purview of the Ministry of Health (MOH).

Unlike the regime for general consumer products, which has no specific procedural recall requirements, the MOH has issued the Guidelines on Good Distribution Practice, which sets out some requirements for the recall procedure of pharmaceutical products.

These requirements include the appointment of responsible persons for implementing and overseeing the recall, the information to be included in a recall notice and the process for storage of the recalled products.

Medical devices

Recalls of medical devices are under the purview of the Medical Device Authority (MDA), which is also under the MOH. Under the Medical Devices Act 2012, any licensed establishment may recall any defective medical device at any time. The MDA also has power to order any establishment to recall any medical device at any time due to patient safety and public health.

The Minister of Health, under the Medical Devices Act, may make regulations necessary for the purposes of a voluntary recall and the criteria, conditions and procedures for a mandatory recall. However, to date, no such regulations have been made.

Under the Good Distribution Practice for Medical Devices (GDPMD) issued by the MDA, every establishment must have a documented procedure to effectively and promptly recall medical devices known or suspected to be counterfeit. The GDPMD does specify some requirements for recalls, which include informing and consulting with the manufacturer and/or authorized representative and reporting to the MDA.

Food and drink

Under the Food Act 1983 (FA), the Deputy Director General of Health under the MOH may, by notice in writing, order any person who prepares, packages, labels, advertises or sells any food to recall, remove or withdraw from sale food from any food premises within a period specified in the notice.

The Minister of Health may further make regulations relating to the recall of foods from food premises under the FA. However, no such regulation relating to the recall of food and drink has been made.



Therefore, the regime for food and drink is similar to that for consumer products under the CPA, the regulatory authority has merely a discretionary power to order a recall.

Vehicles and their parts

There are no specific recall regimes that apply to vehicles and their parts. Given that the definition of “goods” under the CPA includes vehicles, any such recall of vehicles and their parts would be made under the discretionary power of the Minister of DTCC to require a supplier to recall any goods if they have caused or are likely to cause injury to any person or property, or are otherwise unsafe.

5. Legal consequences of noncompliance

The main sanctions are fines and revocation of licenses to distribute the particular product, as provided by specific regulations.

Mexico

The main body of law applicable to consumer product recalls in Mexico is the Federal Law of Consumer Protection (the “CPL”). The CPL was enacted on 24 December 1992 with the purpose of promoting and protecting the rights of consumers, and seeking fairness and legal certainty in relations between suppliers and consumers.

1. Definition of a “consumer product”

The CPL has no specific definition of a consumer product. However, in Mexico, a consumer product is generally defined as goods and services offered or sold by a manufacturer to a consumer. The CPL defines a consumer as an individual or legal entity that acquires, carries out or enjoys goods, products or services as a final end user.

2. Agencies involved in regulating consumer products

The Federal Consumer Protection Bureau (*Procuraduría Federal de Protección al Consumidor* or Profeco) is the Mexican authority that has jurisdiction over consumer products after importation and upon retail. If the product in question is subject to a specific Official Mexican Standard (*Norma Oficial Mexicana* or NOM), then, in addition to Profeco, the authority with jurisdiction over the relevant product may regulate the specific product.

NOMs are enacted and enforced in accordance with the provisions set forth in the Federal Law of Metrology and Standardization (the “Standardization Law”).

3. Reporting requirements and recall procedures

The CPL requires a supplier (ie, the manufacturer, importer and distributor of goods, products and services) to “...immediately report to the relevant authorities if it determines that any of its products may imply a risk for the life or health of consumers.” The phrase “imply a risk for the life of health of consumers” is broadly defined in the



regulations to the CPL to include situations that: (i) interrupt life or may interrupt the continuity of life; or (ii) suspend or may suspend the regular functioning of a human organism. These situations may occur if the relevant product: (a) possesses corrosive, reactive, explosive, toxic, flammable, radioactive or infectious characteristics; or (b) is considered, by itself, a hazardous product, due to the speed that it develops, the energy that it conducts or other similar causes.

In addition, Profeco may order consumer products be recalled from the market when it (or the relevant authority) determines that such goods pose a risk to the life or health of consumers. As noted above, a product poses a risk to consumers' life or health when its use interrupts or may interrupt human life, or suspends or may suspend the proper functioning of a human organism.

Profeco may order consumer products be recalled based on any of the following factors:

- Information provided to the public in recall or other notices published by consumer protection agencies of other countries indicating that such products are potentially hazardous
- Voluntary recalls conducted by a supplier
- Upon verifying that the product fails to comply with an applicable NOM, Profeco may carry out this verification in the context of a National Program of Verification of a particular NOM or when it decides to inspect a specific seasonal product (eg, school supplies during the months of July and August)

Regarding risk to consumers' life or health, the General Health Law (GHL) and the Regulations on Health Inputs (RHI) also contain provisions whereby the sanitary authorities, such as the Federal Commission for the Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios* or COFEPRIS) and the National Service of Health and Agrifood Quality (*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* or

SENASICA) may order as precautionary measures the recall, seizure, prohibition of use or destruction of products, either as a result of a public complaint or a notice by the producer or retailer of the good in compliance with its reporting obligations.

Similarly, under Article 57 of the Standardization Law, if a product does not meet the specific requirements set forth in a NOM, as determined by the relevant authority, this authority may order that the sale or distribution of such products be suspended or withdrawn from the market. In such a case: (i) the person involved in the sale or commercialization of the non-compliant product must refrain from selling such product; and (ii) producers, manufacturers, suppliers, importers and their distributors must immediately recover the non-compliant products from the market.

As noted above, when a supplier or manufacturer determines that any of its products imply a risk to the life or health of consumers, it should immediately notify the relevant authorities. However, the CPL does not set forth the specific procedure to be followed to make such notice or to conduct a product recall. In practice, notices of recall filed with Profeco include the following information:

- The safety risk imposed by the product to be recalled
- The name of the distributor/retailer that sells the product in Mexico
- The number of units sold in Mexico
- The actions and remedy (see below) to be followed as part of the recall
- A point of contact in Mexico (telephone number and email)
- Photographs of the product

As a practical matter, when a recall is necessary, the manufacturer should endeavor to recall as many products as possible in the shortest



period of time in order to diminish its liability, and should offer consumers of products an exchange or repair of the product free of charge, an indemnity, or both. As noted above, the manufacturer may also request assistance from Profeco in conducting the product recall.

When Profeco and other agencies in charge of regulating consumer products or food and drug safety, including COFEPRIS and SENASICA, become aware of products that pose a risk to the health and safety of consumers, they are required to publish a notice of recall (*llamado a revision*) or an alert (*alerta*) at the government-maintained Rapid Alert Network website (*Red de Alerta Rápida*) located at www.alertas.gob.mx. COFEPRIS operates its own portal for sanitary alerts at <http://www.gob.mx/cofepris/acciones-y-programas/alertas-sanitarias>.

4. Product-specific regimes

There are product-specific obligations found in different NOMs, mainly in those regulating good manufacturing practices for different categories of products. These obligations are different in nature to the precautionary measures noted above (seizure, destruction or prohibitions of use).

Pharmaceuticals / Medical devices

The recall-related obligations for medicines are established in NOM-059 for Good Manufacturing Practices for Medicines (“NOM-059”) and for medical devices in NOM-241 for Good Manufacturing Practices for Medical Devices (“NOM-241”). For both types of products, the competent authority to inspect its compliance is COFEPRIS. When COFEPRIS is notified of the risks that motivate the recall, it will upload a sanitary alert to its web page.

Both regulations require adopting and having in place a specific Standard Operation Procedure (SOP) that ensures the appropriate and effective recall of the products that are commercialized. The trigger is the suspicion or knowledge that the authorized product (i) is not

meeting the specifications for its approval or (ii) has lost its efficacy and safety.

The recall shall be notified to COFEPRIS and a final report has to be produced.

Food and drink

The recall of food and beverages is regulated, scarcely in comparison to medicines or medical devices, in NOM-251 for Good Hygiene Practices for Food, Beverages and Dietary Supplements (“NOM-251”). The competent authority to inspect its compliance is COFEPRIS. When COFEPRIS is notified of the risks that motivate the recall, it will upload a sanitary alert to its web page.

Similarly, the relevant obligations foresee that: (i) the legal entities involved in the commercialization of the products shall adopt and operate an action plan for products that could become a risk for human health; and (ii) each recall shall be registered.

Motor vehicles and parts

The recall of automotive-related products is subject to the general recall framework and procedure set forth under the CPL.

5. Legal consequences of noncompliance

If a supplier does not comply with the abovementioned obligation under the CPL and Profeco determines that a provision of the CPL has been violated, Profeco may carry out any of the following:

- (i) Impose fines ranging from MXN 222.16 to MXN 3,732,360.02
- (ii) Order the permanent or temporary cessation of the supplier’s activities

As of February 2012, consumers that are harmed by a product may bring a class action (*acción colectiva*) before Mexican civil courts. Profeco is also entitled to file this kind of action.



The sanctions that could be imposed in relation to products that belong to specific recall regimes are the following:

- (a) For failing to comply with obligations developed in NOMS, the sanction could be a fine of up to MXN 1,600,800.
- (b) For failing to comply with a precautionary measure that was ordered by the regulator, the sanction could include the closure of the premises and/or a fine of up to MXN 1,280,640.

Sources of information

The Federal Consumer Protection Bureau (*Procuraduría Federal de Protección al Consumidor or Profeco*)

www.profeco.gob.mx/

The Federal Commission for the Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios or COFEPRIS*)

<http://www.gob.mx/cofepris/>

Myanmar

The complete Myanmar regime for product-related consumer protection is contained in the Consumer Protection Law 2014 (CPL).

1. Definition of a “consumer product”

There is no definition of “consumer product” in Myanmar law. “Consumer” is defined in the CPL as “a person who consumes or utilizes goods or services for non-trading”. “Goods” are defined as “tangible or not fully tangible, moveable or immovable property or edible or non-edible things that can be merchandized for human use and consumption.” “Services” is defined as “fulfilment of human requirements by way of enterprises or services in the public community.” In Myanmar, it is thus possible to conclude that “consumer product” means either goods or services consumed or used by consumers within the meaning of the CPL.

2. Agencies involved in regulating consumer products

The highest body is the Consumer Protection Central Committee (CPCC), which is appointed by the government to implement the CPL, and appoint and hear appeals from the Consumer Dispute Settlement Body (CDSB). The CDSB is the equivalent of the court of first instance, and hears initial complaints from consumers. The CDSB has significant powers, including ordering the recall of goods from the market where there is a violation of the CPL.

As the CPCC has limited resources, the Department of Trade Promotion and Consumer Affairs, Ministry of Commerce, also handles investigations and complaints.

3. Reporting requirements and recall procedures

There are no reporting requirements in law, although it would be advisable to voluntarily report and recall defective products to lessen potential liability in actions for negligence.



No recall procedure has been developed yet under the CPL, although the CDSB has clear power to order a recall.

4. Product-specific regimes

Pharmaceuticals / Medical devices

The Myanmar Food and Drug Board of Authority (FDA) was formed under The National Drug Law 1992 (NDL). The NDL prohibits the sale of unregistered, counterfeit or adulterated drugs, among other things. However, the NDL does not lay down detailed procedures that relate to the recall of such drugs.

In practice, the FDA makes inspections and will confiscate drugs that fall into such categories. While there is no specific power granted to government agencies to recall drugs from the market, this does happen following an inspection that reveals defective drugs.

There is no special legislation relating to medical devices.

Food and drink

Edible (and presumably drinkable) matter is specifically included in the CPL definition of goods (see above).

In 1997, the FDA was expanded by the National Food Law (NFL) to include a number of food experts. The functions and duties of the FDA were also expanded to include establishing policies to ensure quality assurance in relation to food. A number of offenses were created relating to the production or sale of unsafe food. There is though no power to order a recall of such food. However, as with the FDA drug inspections, the FDA does conduct food inspections from time to time and orders the destruction of food that is in breach of the NFL.

Vehicles and their parts

There is no legislation that specifically provides for a recall regime for vehicles and their parts. However, they would come within the ambit of the CPL.

5. Legal consequences for noncompliance

There are a variety of penalties for offenses under the CPL, ranging from warnings and fines to up to three years' imprisonment.

Penalties for breach of the NDL range from fines to up to seven years' imprisonment, and for breach of the NFL, range from fines to up to three years' imprisonment.



The Netherlands

EU Directive 2001/95/EC on General Product Safety is implemented into Dutch law by the Consumer Goods Act (CGA) and rules based on the CGA, which became effective on 1 December 2005. In addition, the Consumer Goods Act Decree on General Product Safety (the “Decree”) contains obligations on producers to adopt measures to avoid safety and health risks, such as an obligation to withdraw products from the market, to adequately and effectively warn consumers or to recall products from consumers.

1. Definition of a “consumer product”

“Consumer product” is not defined under Dutch law.

The CGA refers to “commodities,” which is defined as movable property, including food and beverages, as well as immovable property designated in a governmental decree. Commodity also includes products that are used on a professional basis. However, the notification obligation for producers and distributors only relates to commodities that could be used by consumers.

The Decree defines “product” as a good, not being a food or beverage, intended for a consumer or which could in all reasonableness be expected to be used by a consumer and goods that, within the scope of a trade activity, against payment or for free, will be delivered or made available, irrespective of whether it is new, second hand or renewed.

2. Agencies involved in regulating consumer products

On the instructions of the Ministry of Agriculture, Nature and Food Quality and the Ministry of Health, Welfare and Sport, the Netherlands Food and Consumer Product Safety Authority is the supervisory authority with respect to compliance with obligations arising from the CGA.

The Decree stipulates that other supervisory authorities are the Minister of Infrastructure and Environment, the Governmental Road Transport Agency and the Minister of Economic Affairs.

Specific product regimes have other supervisory authorities (see section 4 below).

3. Reporting requirements and recall procedures

Notification obligation

Article 21b CGA obliges manufacturers or distributors to notify the competent authorities immediately if they know or, on the basis of the information in their possession, ought to know, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement. In particular, they must detail the measures they have taken or will take to prevent risk to the consumer. Notification takes place by reporting the unsafe products to the Netherlands Food and Consumer Product Safety Authority using the EU's Business Application form (<https://webgate.ec.europa.eu>).

There are no specific rules as to what kind of measures must be taken to warn of certain product dangers. It is, therefore, left to the manufacturer's discretion to evaluate the risks that the products in question pose and to decide on an adequate course of action that ensures that the inherent danger is effectively communicated, such as through notices to consumers, dealers, distributors or a public recall (by letters, press announcements, posters, mass media, etc.).

The competent authority will evaluate whether the measures are sufficient to protect consumers' health and safety. In this evaluation, the public authority will take into account, among other matters, the type of risk, the possible damage, the likelihood of damage and the number, age and category of consumers involved. If the authority finds that adequate measures are not taken, it can issue orders requiring certain actions from the responsible manufacturers or distributors. Not complying with such an order is a criminal offense.



In addition, manufacturers or distributors may be instructed by the authorities to recall unsafe products in order to protect the public from dangers pursuant to the CGA (and its Decrees), on pain of criminal prosecution under Dutch criminal law (particularly the Act on Economic Crime or WED). This is not limited to consumer products.

Under the Decree, manufacturers or distributors and their directors may be prohibited by the relevant authority from trading in unsafe products in order to prevent distribution of these products, on pain of criminal prosecution under the WED.

The competent Dutch authorities are not authorized to recall products themselves. They are, however, authorized to issue public warnings. The threat of such a public warning is often sufficient to have the manufacturer or distributor initiate a “voluntary” recall.

4. Product-specific regimes

Pharmaceuticals / Medical devices

A specific regime for medical devices can be found in the Medical Devices Act and the Medical Devices Decree. With regard to pharmaceuticals, the Medicines Act, the Medicines Decree and the Medicines Regulation are of relevance. Upcoming legislation concerning medical devices includes EU Regulations 2017/745 and 2017/745.

The Healthcare Inspectorate of the Ministry of Health, Welfare and Sport is the applicable regulator with regard to pharmaceutical and medical devices. Pharmaceutical defects must be reported to the Medicines Evaluation Board as well.

Notifications of pharmaceutical defects are made using the notification form, which can be found on the following website of the Healthcare Inspectorate of the Ministry of Health (<https://fd2.formdesk.com>).

Quality defects in pharmaceuticals with marketing authorization via the central procedure have to be notified only to the EMA using the below procedure:

<http://www.ema.europa.eu>

In case of parallel distribution, notifications to the Healthcare Inspectorate of the Ministry of Health as well as to the EMA are required.

Notifications of medical devices take place by reporting incidents or field safety corrective actions to the Healthcare Inspectorate using the notice templates, which can be found on the following websites:

<https://www.igz.nl>

<http://ec.europa.eu>

With regard to pharmaceuticals, the classification of the risk will determine whether a recall is necessary and whether the recall will take place on the level of patients, pharmacists or wholesale. The commercial license holder has to perform the recall; the regulator cannot perform a recall. The regulator has to approve the recall letter. The recall letter must be sent in a special orange envelop which is only used for medicine recalls.

With regard to medical devices, producers are obliged to perform post-market surveillance. They have to follow the European guidelines on a Medical Devices Vigilance System when performing a recall. The regulator is entitled to order the recall or other corrective actions. The Medical Device Act does not contain a recall obligation. However, under the Directive, a Member State is obliged to take appropriate measures in case of unsafe medical devices.



Food and drink

A specific recall regime for Food and Drink exists in EU Regulation 178/2002, also known as the General Food Law (GFL). The GFL was effected into Dutch Law on 1 January 2005.

The Netherlands Food and Consumer Product Safety Authority is responsible for compliance with laws and regulations for producers, distributors and retailers of food and drink.

The main differences between this regime and the regime for general consumer products are that, pursuant to Article 19 GFL, (i) a recall could be mandatory and (ii) a notification obligation arises as soon as the food business operator considers or has reason to believe (instead of “knows or ought to know”) that a food is not in compliance with the food safety requirements. Notification takes place by filling out a digital form provided by the Netherlands Food and Consumer Product Safety Authority on the following website:

<https://formdesk.minlnv.nl>

Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal and, if necessary, recall products already supplied to consumers when other measures are not sufficient to achieve a high level of health protection.

Motor vehicles and parts

The CGA and Road Traffic Act 1994 apply to vehicles and their parts. The Governmental Road Transport Agency is the applicable regulator with regard to motor vehicles and their parts. The regime does not differ from the regime for general consumer products summarized in section 3 above.

5. Legal consequences of noncompliance

Failure to notify the competent public authority of an unsafe product timely and adequately, or to take appropriate measures, may result in an administrative fine. Under certain circumstances, it could furthermore constitute a criminal offense. With regard to non-food and the special regimes food and drink and vehicles, the Netherlands Food and Consumer Product Safety Authority has the authority to impose fines. With regard to pharmaceuticals and medical devices, that authority lies with the Healthcare Inspectorate.

If a case is prosecuted and both the criminal nature of the act and the accountability of the manufacturer have been established, the criminal court has the discretionary power to order the manufacturer to pay damages to the state. Victims may also formally join the criminal suit against the manufacturer and claim damages themselves.



Peru

Product safety is regulated mainly by Law No. 29571, Consumer Protection and Defense Code (the “Consumer Code”) and Supreme Decree No. 050-2016-PCM, which provides the rules and procedures that should be followed to inform consumers and the corresponding authorities about any risk detected in products already placed on the market and the measures adopted to reduce the risks. Depending on the type of product (for example, pharmaceuticals), product safety may also be further regulated by other legislative acts.

1. Definition of a “consumer product”

The Consumer Code does not contain an explicit definition of “consumer product.” Through the definitions of “consumers” and “products,” the Consumer Code by implication defines a consumer product as any movable or immovable good, tangible or intangible, of national origin or not, acquired, used or enjoyed by consumers. Consumer products can be new, used or reconditioned.

Consumers are defined as the natural or legal persons that acquire, use or enjoy the products as final recipients for their own benefit or the benefit of their social or family group, in a field outside their profession or business. Microenterprises — companies with no more than 10 workers and with annual revenues up to 150 UIT (taxable units), equivalent to PEN 607,500 at the time of going to press — are also considered as consumers, provided that they are acquiring products or services that are not related to their core activities.

There are special regulations governing certain kinds of products, such as food and beverages, cosmetics, pharmaceuticals, toys and telecommunications equipment, among others. There are also technical regulations regarding carbon zinc batteries, tires and footwear.

2. Agencies involved in regulating consumer products

The National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI) is the authority responsible for enforcing the Consumer Code and certain aspects of related regulations (for example, those relating to labeling requirements).

INDECOPI is not a regulator and is not entitled to enact regulations regarding consumer products. It does have the authority to verify compliance with consumer protection regulations and impose the corresponding sanctions in case of infringements. INDECOPI is entitled to establish national policy on consumer protection, propose legislation on consumption, develop and implement actions to strengthen consumer protection, apply alternative dispute resolution mechanisms such as conciliation or mediation, implement an information and orientation system to educate consumers on their rights and coordinate the implementation of warning systems against dangerous products, among other things.

3. Reporting requirements and recall procedures

According to the Consumer Code, if a producer realizes that a product presents a risk that consumers were not warned about at the time of placement on the market, it is obliged to adopt all reasonable measures to eliminate or reduce the risk in the immediate term. This obligation is further developed by Supreme Decree No. 050-2016-PCM, which provides the rules and procedures that should be followed to inform consumers and the corresponding authorities of the measures adopted to reduce the risks. The main obligations under the Supreme Decree are as follows:

- Disseminate a warning to consumers within five business days from the date the hazardous nature of the product was detected
- Send a notice to the Consumer Protection Authority within five business days from the date the hazardous nature of the product was detected



- Provide reasonable measures to reduce the detected risks, which may include providing substitutes and/or remedies, and withdrawing the products from the market, to mitigate or eradicate the existing risk, based on its nature

After being informed that a product placed on the market involves a risk for consumers, INDECOPI alerts consumers through its web page and informs them about the measures adopted by the producers to reduce the risks associated with the product.

4. Product-specific requirements

Supreme Decree No. 016-2011-SA, through which the Regulations for the Register, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products were approved, contains certain provisions regarding the recall of the products under its scope.

The Supreme Decree states that if, because of an inquest, the Health Authority concludes that a certain product does not comply with the technical specifications in its Sanitary Registration and that such nonconformities affect its security and/or effectiveness, the holder of the Sanitary Registration of the associated product must recall and destroy the corresponding lot within 60 calendar days. If the provider fails to proceed in accordance with this, the Health Authority will order the seizure of the lot and will alert consumers on that regard.

5. Legal consequences of noncompliance

If a producer fails to comply with the provisions related to recall of products, it may be sanctioned by INDECOPI, which is entitled not only to impose fines, but also to require producers to comply with corrective actions, such as repairing the product (if possible), replacing it (if repair is not possible) or refunding the amount paid by the consumer if neither repair nor replacement is possible.

Fines are applied as follows:

- Minor violations are sanctioned by an admonition or a fine of up to 50 UIT (taxable units), which is equivalent to PEN 202,500
- Serious violations are sanctioned by a fine of up to 150 UIT (taxable units), which is equivalent to PEN 607,500
- Very serious violations are sanctioned by a fine of up to 450 UIT (taxable units), which is equivalent to PEN 1,822,500

INDECOPI is also entitled to order the reimbursement of any direct and immediate costs that consumers had to incur due to the infringement.

This administrative responsibility does not exclude the obligation of the producer to compensate consumers for damages claimed before civil courts. INDECOPI is not entitled to grant compensation, for example, if a consumer suffers any injury due to a defective product.

Also, if the product that should have been recalled is a pharmaceutical, sanitary product or medical device, failing to conduct the recall would also lead to a sanction being imposed by the Health Authority, equivalent to PEN 12,150.

Sources of information

INDECOPI

www.indecopi.gob.pe



Philippines

Consumer protection and product liability in the Philippines are primarily governed by the Consumer Act of the Philippines (the “Consumer Act”).

1. Definition of a “consumer product”

“Consumer products and services” is defined in the Consumer Act as goods, services and credits, debts or obligations that are primarily for personal, family, household or agricultural purposes. The definition includes food, drugs, cosmetics, devices and other health products.

“Consumer” is defined in the Consumer Act as a natural person who is a purchaser, lessee or recipient, or a prospective purchaser, lessee or recipient, of consumer products, services or credit.

2. Agencies involved in regulating consumer products

The following government agencies are involved in regulating consumer products in the Philippines:

- The Department of Health (DOH) with respect to food, drugs, cosmetics, devices, substances and other health products
- The Department of Agriculture (DA) with respect to agricultural products
- The Department of Trade and Industry (DTI) with respect to all other consumer products that are not regulated by the DOH or the DA

3. Reporting requirements and recall procedures

There is no law or regulation on the procedure for a voluntary recall for products other than health products (see section 4 below). Moreover, there is no law or regulation under which a manufacturer or distributor is required to notify the relevant government agency of a voluntary recall. However, one likely benefit of immediately and

voluntarily notifying the relevant government agency of a voluntary recall is that notification may be considered a sign of good faith and a mitigating circumstance, should a government agency determine that the product is defective, hazardous or unsafe and considers imposing sanctions on the manufacturer or distributor in the event that a complaint is filed against it.

Although there is no requirement to notify the relevant government agency of a voluntary recall, a manufacturer or distributor who discovers that its product is defective, hazardous or unsafe is obligated to do the following: (a) notify the public of the defect or failure to comply with the product safety standards; (b) bring the defective, hazardous or unsafe product into conformity with the applicable product standards or replace the product with a similar or equivalent product that complies with the applicable product standards; and (c) refund the purchase price of the defective, hazardous or unsafe product.

With respect to compulsory recall of consumer products and other health products, under the Consumer Act the DTI or the DA (as appropriate) may issue an order for a product's recall, prohibition or seizure from public sale or distribution if, upon its own initiative or upon a petition from a consumer and after due notice and hearing, the product is found to be injurious, dangerous and unsafe.

The DTI or DA will give the manufacturer or distributor due notice of the proceeding and the chance to be heard. After the hearing, the DTI or DA will notify the manufacturer or distributor of its findings. If the DTI or DA determines the product to be substandard or materially defective, it may order the recall, prohibition or seizure from public sale or distribution of the defective product. The ban on the sale and distribution of the product will stay in force until the manufacturer or distributor can prove that measures to ensure the product's safety have been established.



In addition to ordering the recall, prohibition or seizure of the product that is found to be injurious, dangerous and unsafe, the DTI or DA may also order the manufacturer, distributor or seller of the defective product to take the following actions, among others:

- Notify the public of the defect or failure to comply with the product safety standards
- Give notice of the same to each distributor or retailer of the defective product

4. Product-specific regimes

Medicines/medical devices/food

The Philippine Food and Drug Administration (FDA, formerly known as the Bureau of Food and Drugs), an agency under the DOH, issued FDA Circular No. 2016-012 (the “FDA Circular”), which governs the recall of health products. Health products refer to food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, household/urban hazardous substances and/or a combination and/or a derivative thereof, as well as products that may have an effect on health and which require regulations as determined by the FDA.

The FDA Circular currently classifies recalls according to the following categories:

- Class I recall - product defects/conditions that are potentially life-threatening or could result in a severe health risk, health impairment or effects such as permanent damage to health or death
- Class II recall - product defects/conditions that could cause poisoning or a temporary/medically reversible adverse health problem or mistreatment

- Class III recall - product defects/conditions that may not pose a significant hazard to health, but whose withdrawal may have been initiated

The FDA Circular provides that a Product Recall Committee (PRC) shall be created in each of the four centers of the FDA, that is, Center for Drug Regulation and Research, Center for Food Regulation and Research, Center for Cosmetic Regulation and Research and Center for Device Regulation, Radiation, Health and Research. The PRC shall oversee the recall system.

Under the FDA Circular, the triggers for recall may come from the FDA's post-marketing surveillance (PMS), such as the following:

- Health product quality/complaints processing
- Adverse Events (AEs) monitoring and Events-based Surveillance Response (SR) reports
- Sampling, testing and verifying health products
- Post-licensing inspection, monitoring and investigations
- Post-evaluation of acknowledged notifications
- Monitoring of advertisement and promotional articles
- Coordination with regulatory agencies and international partners

Below is a summary of the recall procedure:

- The trigger will be reviewed by the PRC for health hazards to determine if the product should be recalled
- If the PRC decides to recall the product, it will prepare a Product Recall Resolution (PRR) containing information on: (a) the trigger and other evidence; (b) the result of the health hazard evaluation; and (c) the recall classification



- The PRC shall meet with the Market Authorization Holder (MAH) within 48 hours to present the PRR and to agree on the appropriate recall strategy. If there is no agreement between the PRC and the MAH, the PRC shall issue a Product Recall Order (PRO), and the recall shall be implemented by the FDA at the expense of the MAH
- The MAH's recall strategy must be consistent with the Risk Management Plan and shall include: (a) extent of the recall; (b) recall communications containing the identified list of establishments, as per distribution records, to be contacted and contents of such communication; (c) recall operation instructions and timeline; (d) recall status reporting to the FDA; and (e) disposal strategy
- The FDA and MAH shall undertake appropriate communication activities to protect the public, such as issuance of FDA Advisory notifications and notifications by the MAH to all concerned parties and establishments
- The MAH shall be responsible for conducting the recall. It shall submit recall status reports to the PRC in accordance with the recall strategy. For Class I recall, the product should be immediately pulled out of the selling area
- The recall is deemed complete upon retrieval of all products subject to the recall as verified by the FDA. The MAH is required to submit a Final Recall Status Report, which will include details on the final inventory and disposition of the recalled products
- Upon the MAH's submission of supporting documents proving that the recalled products have either been destroyed (ie, Certificate of Destruction, photographs of the destruction activity, copy of the signed FDA report of destruction), redressed (ie, copy of the signed FDA inspection report of redressing, actual labeling material) or returned to the source

country (ie, notice of return, copy of the signed FDA inspection report and returned shipment documents), a Termination Letter shall be issued in favor of the MAH once the PRC has determined that the product recall has been completed

While the FDA Circular does not provide for a voluntary recall procedure, the MAH may voluntarily report a product it believes to be violating. Such voluntary report will trigger the recall procedures under the FDA Circular.

Vehicles and their parts

There is no specific recall-related regime for vehicles and their parts, therefore they are subject to the regime set out in section 3 above.

5. Legal consequences of noncompliance

Health products

Under the FDA Circular, any violations thereof shall be a ground for filing the appropriate administrative charges, which may result in administrative sanctions such as imposition of fines, suspension, cancellation or revocation of any market authorization issued by the FDA.

Health products and other consumer products

Under the Consumer Act, a manufacturer or distributor of a consumer product (including health products) who fails to comply with a recall order issued by the relevant government agency may be subject to a fine from PHP 1,000 up to PHP 10,000, imprisonment from two months up to one year, or both, according to the court's discretion. If the offender is a foreign national, he/she must be deported after serving the associated sentence and paying the associated fine without further deportation proceedings.

Any director, officer or agent of a corporation who authorized or ordered such noncompliance will be subject to the same penalties as those applicable to the corporation.



If the violation is committed by or in the interest of a foreign juridical person duly licensed to engage in business in the Philippines, such license to engage in business in the Philippines might be immediately revoked.

The foregoing penalties are in addition to the administrative, civil and criminal liabilities that may be imposed for the manufacture or distribution of defective, substandard, unsafe or hazardous products.

Poland

The Act on General Product Safety dated 12 December 2003 (Journal of Laws of 2003, No. 229, item 2275; the “Act”), along with its accompanying secondary legislation, is the basic legal regulation that specifies general requirements relating to product safety obligations of producers and distributors, as well as the terms and procedure for exercising supervision to ensure the safety of products introduced onto the market.

1. Definition of a “consumer product”

The Act does not contain an explicit definition of “consumer product,” but rather contains an implied definition, since it defines products as new, used or repaired or regenerated movables that are devoted for consumer use, or such items that may be used by consumers even if not devoted for such use. Such items are supplied or made available by the producer or distributor, either for payment or free of charge. Pursuant to the Act, a product does not include used objects that have been introduced onto the market as antiques or as objects requiring repair or renovation prior to use, if the supplier informed the consumer about the properties of the objects.

2. Agencies involved in regulating consumer products

The President of the Office for Protection of Competition and Consumers supervises general product safety within the scope specified in the Act (the “Supervisory Authority”). The Supervisory Authority performs its tasks through the Trade Inspectorate. Supervision over general product safety includes, but is not limited to the following:

- Periodic monitoring and evaluation of the effectiveness of inspection with respect to product compliance with the general safety requirements, taking into account the types of products being inspected and the threats subject to verification



- Approving a periodic product inspection plan within the scope of compliance with general safety requirements and monitoring the implementation of such a plan
- Conducting proceedings on general product safety
- Keeping a register of dangerous products and collecting data concerning products that do not meet specific safety requirements
- Gathering information concerning product safety, transferring it to the proper authorities and monitoring the manner in which such information is used
- Gathering notifications transmitted by the producers and the distributors concerning information that a marketed product is unsafe

3. Reporting requirements and recall procedures

Producers and distributors are obliged, within the scope of their business activity, to cooperate with the Supervisory Authority and the Provincial Inspector of the Trade Inspectorate in order to avoid or eliminate product safety risks posed by the products they sell or distribute. A producer or distributor that is informed that a product introduced onto the market is unsafe should inform the Supervisory Authority and provide information identifying the product or a batch of products in detail, a description of the risk posed by the product, information identifying the marketing and distribution of the product, and a description of steps taken to prevent the risks connected with the product. A copy of the notification form is available at: <https://uokik.gov.pl/download.php?plik=10259>.

The Act defines a “producer” very broadly. A “producer” is not only the manufacturer of goods but also each entity that acts as producer by attaching to the product any markings such as its name, trademark or trade name. Also, a company that performs repairs will be considered a producer. If the producer does not carry out business activity in the

EU, the importer of the product will be responsible for the products and any potential liability.

The Act requires a producer to introduce onto the market only those products that are safe, warn consumers of the risks connected with the product during the normal or foreseeable period of use, and instruct consumers on how to avoid such risks. However, warning consumers of the risks connected with a product does not release a producer or distributor from other obligations, such as the obligation to participate in monitoring the safety of products introduced onto the market and to work closely with the Supervisory Authority and the Provincial Inspector of the Trade Inspectorate to prevent risks caused by the products that are not safe.

A producer, acting with due diligence, is obliged to take steps to eliminate the threats posed by its products, including, if necessary, withdrawal of the product from the market, proper and effective warnings to consumers or withdrawal of the products from the consumers. Such steps may include attaching to the product or its packaging the name and address of the producer or a marking that identifies the product or, if required, the batch of the product; testing samples of products introduced onto the market; and analyzing consumer complaints and, if required, recording such complaints and advising distributors on a continuous basis of the corrective actions taken.

Although there are no precise requirements as to the form of a warning producers might be required to provide, the Act provides that the warning must be “proper and effective.” Whether a given warning meets such requirements is assessed on a case-by-case basis. The most common practice is publishing announcements in newspapers, trade magazines and placing notes in shops that sell the products in question.

A “distributor” is defined as an entity that acts as a go-between between the manufacturer and the consumer. A distributor differs from the producer in that its activity does not affect the product’s



safety properties. The distributor is obliged to act with due diligence in order to ensure the safety of the products it distributes, in particular by not delivering products that it knows or should know, given the information possessed by it according to its professional expertise, do not meet safety requirements. The distributor, within the scope of its business activity, is obliged to participate in the monitoring of the safety of products introduced onto the market. In particular, it should gather information from consumers regarding threats or risks posed by the products and provide that information to producers, the Supervisory Authority and the Trade Inspectorate. Distributors must also maintain documents necessary to establish the origin of the product and make the same available to the Supervisory Authority and the Trade Inspectorate.

4. Product-specific regimes

Pharmaceuticals / Medical devices

Marketing of pharmaceuticals and medical products is regulated under the provisions of the Polish Act of 6 September 2001 — Pharmaceutical Law (Journal of Laws of 2016, item 2142 as amended; the “PPL”).

The safety of pharmaceuticals and medical products marketed in Poland is supervised by the Polish Chief Pharmaceutical Inspector, who may suspend the trade of any pharmaceutical or medical product in case of a justified suspicion that such product may be unsafe, or even withdraw such product from the market. The procedure of withdrawal is regulated by the PPL along with the ordinance of the Polish Minister of Health of 12 March 2008 on the detailed rules and procedures for the suspension and withdrawal of pharmaceuticals and medicinal products from the market (Journal of Laws No. 57, item 347).

Notification of suspicion that a pharmaceutical or medicinal product does not meet set quality requirements shall be made to the Voivodship Pharmaceutical Inspector. Among entities that must notify, using a special form, are the following:

- Managers of a healthcare facility, physicians or dentists employed by a healthcare facility
- Managers of a pharmacy or pharmacy point
- Entities entitled to market the pharmaceutical or medicinal product
- Entities responsible for the pharmaceutical or medicinal product, manufacturers or importers
- Physicians running an individual medical practice, individual specialized medical practice or group medical practice
- Nurses and midwives running an individual nursing and midwifery practice, individual nursing and midwifery practice or group practice of nurses and midwives

The form is available at:

http://www2.mz.gov.pl/wwwfiles/ma_struktura/docs/zal1_prod_leczni_czych_14032008.pdf.

The notifying entity must secure the pharmaceutical or medicinal product suspected of failing to meet the quality requirements by placing it or its residues, including the package, in a permanently sealed package labeled “Pharmaceutical or medicinal product secured — suspected of failing to meet the quality requirements.” In case notifying entities do not possess the pharmaceutical or medicinal product, they should file a written statement on the cause of non-possession of the pharmaceutical or medicinal product or its residue, including packaging.



Food and drink

Marketing of new food products in Poland is regulated under the provisions of the Polish Act of 25 August 2006 on food and nutrition safety (Journal of Laws of 2017, item 149 as amended), Act of 16 December 2005 on products of animal origin (Journal of Laws of 2017, item 242 as amended).

In case of suspicion that a food product which does not meet the requirements is in circulation, the competent state district or border sanitary inspector shall decide on temporary suspension of marketing or withdrawal from the market until proceedings conducted by the Polish Chief Sanitary Inspector are finished.

Motor vehicles and parts

Marketing of vehicles and their equipment and parts is regulated under the provisions of the Polish Act of 20 June 1997 — Road Traffic Law (Journal of Laws of 2017, item 1260 as amended).

An entity marketing a vehicle, equipment or parts without the relevant approval is obliged to withdraw them from the market at its own expense. In case of noncompliance, a cash fine may be imposed.

In addition, in some circumstances, an entity that places a piece of equipment or parts on the market may be obliged at its own expense to publish any of the following:

- Nationwide coverage in the mass media
- Information on the withdrawn equipment or parts, at the places where they were marketed, about the product recall, including the date of recall, which should not be less than three months and not longer than 12 months previously

5. Legal consequences of noncompliance

Producers or distributors that fail to meet the requirements set out in the Act are subject to severe fines. The Supervisory Authority may impose a fine of up to PLN 100,000.

Anyone who: (i) markets a non-food product as a food; and (ii) does not withdraw from the market spoiled food and food that has been adulterated and that is harmful to human health or life, is subject to a financial penalty of up to 30 times the average monthly salary.



Russia

Product safety is regulated mainly by Law No. 2300-1 dated 7 February 1992 “On the Protection of Consumer Rights,” as amended, dealing with the protection of consumers’ rights (the “Consumer Rights Law”), and by Federal Law No. 1 84-FZ dated 27 December 2002 “On Technical Regulation,” as amended, dealing mainly with standards for safety requirements (the “Technical Regulation Law”). Product safety for certain products are also regulated at supranational level, eg, regulations adopted by the Eurasia Economic Union of Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan (formerly the Customs Union).

1. Definition of a “consumer product”

The Consumer Rights Law does not contain a definition of a “consumer product.” However, a definition may be derived from the definition of a consumer, ie, an individual intending to purchase or use, or purchasing or using, a product for personal, family or other uses not connected with further business activity. Therefore, a consumer product is understood as a product intended for personal, family or other use not related to the business activity of the user.

2. Agencies involved in regulating consumer products

Consumer product safety issues, including product recalls and control and supervision over compliance with the mandatory requirements of technical regulations, are dealt with by the Federal State Service for the Protection of Consumers’ Rights (also known as Rospotrebnadzor).

State control over compliance of products with state standards and technical regulations with respect to non-consumer products is administered by the Federal Agency for Technical Regulation and Metrology (also known as Rosstandard) unless otherwise provided by the relevant technical regulations.

Both Rospotrebnadzor and Rosstandard routinely publish information about noncompliance of particular products on their website (according to their competence).

3. Reporting requirements and recall procedures

In accordance with the Consumer Rights Law, a manufacturer is obliged to suspend production of a product, and, where necessary, the manufacturer and/or seller is obliged to recall the product where, even if the established rules for the use, storage or transportation of products have been followed, the manufacturer and/or seller has learned that the product inflicts or may inflict harm on the life, health or property of an individual. Moreover, if the cause of harm cannot be eliminated from the product, the manufacturer must cease the production of such product. The Consumer Rights Law does not clarify what constitutes a case where product recall is necessary. However, should the manufacturer fail to suspend production of a product that is unsafe, the State Agency should take measures aimed at the recall of the product from the domestic market or from consumers.

The manufacturer and/or seller must compensate the full losses caused to the consumer as a result of the product recall.

The Consumer Rights Law does not provide more detailed regulation of the recall procedure, nor does it allocate responsibilities between the manufacturer and seller in the case of a product recall.

Under the Technical Regulation Law, a product must be recalled if it does not comply with the requirements of the relevant technical regulations. A technical regulation is a document adopted by an international treaty of the Russian Federation, a federal law or a decree of the president or the government of the Russian Federation or the competent authority that establishes mandatory requirements to be applied to and met by the objects of technical regulation (products, buildings and constructions, and product-related processes such as manufacturing, storage and transportation). Technical regulations are



adopted for the purposes of: (i) protecting the lives and health of citizens, property of individuals and legal entities and government property; (ii) protecting the environment and the lives and health of animals and plants; and (iii) preventing actions that may mislead purchasers of products.

Under the Technical Regulation Law, if, as the result of a product's noncompliance with technical regulations, the product harms or may harm the life or health of a citizen or the property of an individual or a legal entity, state property, or the environment, the manufacturer and/or seller is required to compensate for the harm inflicted and take measures aimed at preventing harm to other persons, their property and the environment. Should the manufacturer and/or seller receive information that a product in circulation does not comply with technical regulations, the manufacturer and/or seller is required to inform the state authority — the Federal Agency for Technical Regulation and Metrology — of the same within 10 days of receipt of this information. If this information is received by the seller, the seller is required to notify the manufacturer of the same within 10 days of receipt of the information. If such information is received by the state authority from a third person, the authority is required to inform the manufacturer and/or seller of the same within five days.

Within 10 days of this information being received, the manufacturer and/or seller is required to verify the information. The state authority is entitled to request the materials relating to such verification from the manufacturer and/or seller. The manufacturer and/or seller is also required to take measures to ensure that the possible harm from the product's circulation does not increase while the verification is being carried out.

If the information on noncompliance of the product with the technical regulations has been confirmed, the manufacturer and/or seller is required (including on the basis of an order from the state authority) to develop a preventative plan and seek the state authority's approval of the plan. The plan must include actions for notifying purchasers of the

product of the possible harm and of methods to help ensure its prevention, as well as timeframes for such actions. The state authority is entitled to request information and materials regarding the plan and its execution. If the manufacturer and/or seller fails either to develop such a plan or to take the preventative actions specified therein, the state authority and any third persons who are aware of such violation are entitled to file a claim with a court requesting a mandatory product recall. Should the claim be sustained by the court, the respondent to the claim will be required to undertake certain product recall actions within the timeframe established by the court and to notify purchasers of the product via the mass media of the court's decision within one month of its issuance.

If prevention of harm requires additional expenses, the manufacturer and/or seller is required to carry out the necessary actions using its own resources. Should this be impossible, the manufacturer and/or seller is required to announce a product recall and to compensate for the losses caused to the product purchaser as a result of the recall.

Removal of defects as well as the transportation of the product for defect removal and its return to the purchasers shall be at the manufacturer's and/or seller's cost.

During the entire period of undertaking preventative measures, the manufacturer and/or seller is required to provide product purchasers with access to up-to-date information regarding the progress of the measures.

When carrying out the recall of a noncompliant product, the manufacturer and/or seller is bound by the mandatory civil code and consumer law provisions with regard to liability towards the purchaser and remedies available to the purchaser. For instance, Russian laws do not allow the manufacturer and/or seller to restrict the remedies available to the purchaser to repairs or partial replacement or exchange for a voucher. The seller and/or manufacturer is not prohibited from offering such solutions to the purchasers, but the



purchasers may elect to use other remedies, including repayment of the purchase price.

4. Product-specific regimes

Pharmaceuticals / Medical devices

The safety and quality of medicinal preparations is governed by Federal Law No. 61-FZ dated 12 April 2010 “On Circulation of Medicines” and controlled by the Federal Service for Surveillance in Healthcare (also known as Roszdravnadzor).

A technical regulation for medicinal preparations has not been adopted and, as we understand, will not be adopted, despite the fact that the need to adopt this document has been debated for over a decade. Therefore, quality of medicinal preparations is not ascertained against a technical regulation, but it is rather ascertained in comparison with a normative documentation, adopted with respect to each medicinal preparation in the course of its state registration in Russia.

Normative documentation contains various measures that a medicinal preparation has to meet and descriptions of methods of analysis. Compliance of a medicinal preparation with its normative documentation is confirmed as a part of mandatory confirmation of its conformity, when its samples are tested in an independent accredited laboratory using methods of analysis, set forth in the normative documentation. Results of this testing are then compared with the measures also set forth in the normative documentation.

Noncompliance of a medicinal preparation with applicable quality requirements may not be cured while the medicinal preparation remains on the market due to the nature of these goods. Therefore, after the noncompliance of a medicinal preparation is confirmed, its recall is normally initiated.

Article 59 of Federal Law No. 61-FZ “On Circulation of Medicines” requires that poor quality medicinal preparations must be removed

from circulation and destroyed. As far as we know, the Russian authorities enforce this requirement and fine those legal entities, which, upon receipt of the medicinal preparations being recalled, hand them over further up in the distribution chain to be ultimately delivered to the manufacturer for centralized destruction instead of destroying them themselves. Therefore, a usual recall of medicinal preparations, ie, when pharmacies deliver medicinal preparations to the distributors and the chain of distributors then delivers them to the manufacturer, is not recommended in Russia. Each participant of the delivery chain of the relevant medicinal preparation should, by itself, organize destruction of the medicinal preparations in its possession.

Please note that recall in Russia is not the only procedure, which may interrupt circulation of a medicinal preparation in Russia. The other procedures are (i) cancellation of declaration of conformity or certificate of quality and (ii) suspension of use of a medicinal preparation based on pharmacovigilance information (ie, when it is discovered that a medicinal preparation of good quality is more dangerous to the patients than it has been assessed initially).

In case the relevant company continues trading poor quality medicinal preparations, it bears a risk that its pharmaceutical license will be canceled, and that it may be subject to administrative liability, while its responsible officials may even be subject to criminal liability.

Food and drink

Safety requirements for food products are specified in the Technical Regulation of the Customs Union TP TC 021/2011 “On the Safety of Food Products.”

Rospotrebnadzor is the authority responsible for control over safety of food products.

The general notification and recall requirements described in section 3 above also apply to food products.



Vehicles and their parts

Safety requirements for vehicles and their spare parts are specified in the Technical Regulation of the Customs Union TP TC 018/2011 “On the Safety of the Wheeled Vehicles.”

Rospotrebnadzor and Rosstandard are responsible for control over safety requirements in Russia concerning vehicles and their spare parts.

The general notification and recall requirements described in section 3 above also apply to vehicles and their parts.

5. Legal consequences of noncompliance

Failure of the manufacturer and/or seller either to develop a plan for preventing harm as required by the state authority or to perform the actions for preventing harm specified in the plan may entail administrative fines of up to RUB 500,000 imposed on a legal entity. If the manufacturer and/or seller does not develop a plan or does not implement the plan, a claim requesting a mandatory product recall may be filed with a court by the state authority or a third person. Nonperformance of the court decision by the manufacturer and/or seller may entail criminal liability.

Noncompliance with the recall procedure regulations may also entail civil liability, requiring the manufacturer and/or seller to provide full compensation of losses to any consumer whose life, health or property was harmed.

Failure to comply with the relevant safety requirements for food products, vehicles and their spare parts entails the same consequences as for common consumer products. The practical difference in enforcement of the safety requirements is demonstrated in the more active approach taken by the Russian authorities towards suspension of those products’ circulation and their withdrawal from the market as soon as potentially serious noncompliance becomes known or an incident occurs.

Singapore

Product recalls in Singapore are governed by two regimes.

The first consists of product-specific regimes relating to: (a) medical devices; (b) cosmetic products; (c) therapeutic products; (d) food; (e) vehicles; and (f) weighing and measuring instruments.

The second consists of general product regimes relating to goods generally.

Two types of product recall are provided for in each of these regimes: (a) voluntary recalls directed by the product owner/license holder, manufacturer or importer; and (b) compulsory recalls directed by the relevant governmental agencies.

1. Definition of a “consumer product”

There is no express definition of a “consumer product” in consumer-related legislation in Singapore.

However, for the purposes of product recalls, there are specific definitions of various products, for instance “goods” under the Consumer Protection (Trade Descriptions and Safety Requirements) Act, which are defined as ships, aircraft, vehicles, animals, plants and all kinds of movable property.

2. Agencies involved in regulating consumer products

The main government agency involved in product recalls, for goods generally, is the Standards, Productivity and Innovations Board of Singapore’s (SPRING) Consumer Product Safety Department.

The following acts are administered by the Director of Consumer Protection at SPRING and its officers: (a) the Consumer Protection (Trade Descriptions and Safety Requirements) Act, which regulates the supply of safe goods in Singapore; (b) the Consumer Protection



(Safety Requirements) Regulations; and (c) the Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011.

Officers of the Consumer Product Safety Department of SPRING Singapore have been appointed as officers of consumer protection.

3. Reporting requirements and recall procedures

The reporting requirements and recall procedures differ according to the different regimes.

Focusing on general goods, the Consumer Product Safety Department of SPRING Singapore ensures the safety of controlled goods. In addition, only registered controlled goods bearing the Safety Mark may be sold on the market. Controlled goods consist largely of electrical, electronic and gas appliances, as well as products used in homes. The Safety Mark signals that the goods to which it is affixed meet specified safety requirements and are generally safe for normal use.

Under the Consumer Protection (Safety Requirements) Regulations, the Department can require the supplier to effect a recall of registered controlled goods. It can also require the supplier to keep the Department informed of the progress of the recall and to take necessary steps to inform the users of the potential danger if the supply of these goods is prohibited or if these goods do not have the Safety Mark affixed to them.

Under the Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011, thousands of additional consumer goods are regulated (not including the controlled goods covered by the Consumer Protection (Safety Requirements) Regulations). These goods fall into two categories:

- (a) Category One goods are any consumer goods for which there are existing international safety standards. The relevant international standards are those set by the International Organization for Standardization (ISO), the International Electrotechnical

Commission (IEC), the European Committee for Standardization or ASTM International.

- (b) Category Two goods are any other consumer goods not covered by Category One and may be subject to national or regional standards.

Where these controlled or uncontrolled consumer goods do not conform to the international safety requirements, SPRING Singapore may issue a public notice declaring such goods unsafe. This public notice will be published in at least four daily newspapers in the English, Malay, Chinese and Tamil languages. SPRING Singapore will also be able to direct the supplier to control or cease the supply of such goods and inform consumers of their potential dangers.

In other recall situations for controlled and uncontrolled goods, where the product presents a safety issue that is not technically a violation of a specific safety requirement, it is strongly recommended that the company notify and consult SPRING Singapore. The company may then choose to conduct a voluntary recall exercise. This would demonstrate that the company is a responsible corporation that prioritizes consumer safety. It may also prove to be a significant mitigating factor should there be grounds for prosecution by the authorities. SPRING Singapore has the discretion, however, to conduct an inquiry and give appropriate instructions to the company (ie, order a mandatory recall), and any noncompliance with such instructions may amount to an offense under the Consumer Protection (Trade Descriptions and Safety Requirements) Act.

The company may wish to notify the public of the product recall. This will also help to minimize potentially adverse publicity for the company and potential damage to its product and corporate reputation (for example, if adverse incidents occur and the company is perceived to have failed to take proper measures to avoid these incidents).

Types of product recall notices include letters to the company's retailers, posters to be affixed at the retailers' premises and press



releases. There is no specific legislation on any particular publications in which the product recall notice should be published. In addition to the leading English-language newspaper in Singapore, the company may also wish to take out a notice in Mandarin-, Malay- or Tamil-language newspapers to ensure that the non-English-speaking public is made aware of the product recall. The recall notice will need to be translated accordingly.

Particulars that should be included in such product recall notices include: (a) the name of the product in question, the model number and relevant photographs; (b) the date of manufacture and/or shipping of the products to the retailers; (c) the number of units of the product shipped to Singapore; (d) information on the defect; (e) the measures adopted by the company to address the defect (for example, voluntary product recall and replacement parts); (f) the procedures implemented by the company to effect the measures; and (g) the name of a contact person and the relevant contact details (for example, a toll-free number) for more information.

4. Product-specific regimes

Pharmaceuticals / Medical devices

Medical devices, cosmetic products and therapeutic products fall under the definition of “health product” under the Health Products Act. They are regulated by the Medical Device Branch, the Cosmetics Control Unit and the Therapeutic Products Branch of the Health Sciences Authority (HSA), respectively.

Under the Health Products Act, a manufacturer, registrant, supplier or importer of a health product that recalls or seeks to recall the health product shall inform the HSA within the prescribed time about the recall or intended recall, as well as the reasons for such recall. Upon such notification, the HSA may issue a written notice, mandating that the manufacturer, registrant, supplier or importer of the health product publish or ensure the publication of a statement to people that the

HSA may specify or to the public at large notifying them of the health product recall and other matters as the HSA deems fit.

Under the Guidance on Medical Device Recall issued by the HSA, a dealer or registrant of medical devices that intends to carry out a recall of a medical device should submit a preliminary report consisting of comprehensive information on the recall within 24 hours from making the decision to recall. Subsequently, the dealer or registrant is also required to submit a final report to the HSA within 21 days from the start date of the recall. The notifications and reports should be submitted based on the HSA's prescriptions in the Guidance.

Under the Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007, if a party that is responsible for placing a cosmetic product on the market is conscious of anything that indicates a defect in the product or that relates to an adverse effect resulting from the use of the product, the person shall report the defect or adverse effect to the HSA.

Under the Health Products (Therapeutic Products) Regulations 2016, once a party is conscious of any defects in its therapeutic product, it should collect the necessary information to ascertain the extent of the defect and the health risks that consumers of the product may incur. Moreover, the party must notify the HSA of, as well as the reasons for, an intended recall within 24 hours from the commencement of the intended recall (this excludes Sundays and public holidays).

Food and drink

The Food Control Division of the Agri-Food & Veterinary Authority of Singapore (AVA) is responsible for regulating food in Singapore.

There is no specific legislation or guidelines concerning reporting requirements and recall procedures. Parties involved may nevertheless wish to notify the public through notices in mainstream newspapers so as to minimize adverse publicity and potential damage to corporate reputation.



Vehicles and their parts

The Land Transport Authority (LTA) is responsible for regulating vehicles in Singapore.

There is no specific legislation or guidelines concerning reporting requirements and recall procedures. However, parties who have sold vehicles that are linked to any safety-related vehicle recall should inform the LTA and relevant vehicle owners, take the appropriate measures to address the flaws and keep the LTA apprised of the progress of the remedial works.

5. Legal consequences of noncompliance

In Singapore, the legal consequences of noncompliance differ according to the type of product in question.

Controlled goods

Under the Consumer Protection (Safety Requirements) Regulations, any person who fails to effect a recall ordered by the authorities in relation to goods to which the Safety Mark is not affixed is guilty of an offense and shall be liable for a fine not exceeding SGD 2,000, imprisonment for a term not exceeding 12 months, or both.

In addition, a registered supplier who either fails to effect a recall of registered controlled goods as required by the authorities or fails to notify all suppliers who obtained controlled goods from that registered supplier, directly or indirectly, is guilty of an offense and shall be liable for a fine not exceeding SGD 2,000, imprisonment for a term not exceeding 12 months, or both.

Uncontrolled goods

Under the Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011, any person who fails to comply with an order made by SPRING Singapore to control or cease the supply of goods that do not conform to safety standards, and inform consumers of their potential dangers, shall be liable for a fine not exceeding

SGD 2,000, imprisonment for 12 months, or both. Subsequent offenses could result in a penalty of SGD 10,000, imprisonment for two years, or both.

As there is no specific legislation requiring notification to the authorities or stipulating guidelines or protocols in which the product recall exercises are to be conducted, there are no specific remedies or offenses imposed.

Pharmaceuticals / Medical devices

Under the Health Products Act, a person, who (a) fails to notify the HSA about a recall or intended recall of a health product; (b) does not comply with a notice issued by the HSA; or (c) provides the HSA with information or document(s) that they know to be untrue or misleading, shall be liable for a fine not exceeding SGD 20,000, imprisonment for 12 months, or both.

Under the Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007, failure to notify the HSA about any defects in or side effects from the use of a cosmetic product constitutes an offense. The same goes for furnishing the HSA with information that one knows is untrue or misleading. A person guilty of either offense shall be liable for a fine not exceeding SGD 20,000, imprisonment for 12 months, or both.

Under the Health Products (Therapeutic Products) Regulations 2016, a person who fails to comply with a recall notice issued by the HSA within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice, shall be liable for a fine not exceeding SGD 20,000, imprisonment for 12 months, or both.



South Africa

The recall of products is generally regulated by section 60 of the Consumer Protection Act, No. 68 of 2008 (CPA), read together with the Consumer Product Safety Recall Guidelines (the “Recall Guidelines”) and any applicable industry codes.

1. Definition of a “consumer product”

The term “consumer product” is not specifically defined in the CPA or Recall Guidelines; however, the range of products covered under the CPA and Recall Guidelines is broad and covers, among other things, the following:

- (a) Anything marketed for human consumption
- (b) Any tangible objects
- (c) Any literature, music, photograph, motion picture, game, information, data, software, code or other intangible product written or coded on any medium, or a license to use any such intangible product
- (d) A legal interest in land or any other immovable property
- (e) Gas, water and electricity

(Collectively referred to as “Consumer Products”)

The recall procedure contained in the CPA and Recall Guidelines applies to all transactions occurring within South Africa that involve Consumer Products, including transactions that are generally exempt from the application of the CPA and notwithstanding where the Consumer Products were manufactured.

All suppliers, manufacturers, importers, distributors and retailers (collectively referred to hereinafter as “Suppliers”) are required to comply with the recall procedure as set out in the CPA and Recall Guidelines.

2. Agencies involved in regulating Consumer Products

The responsibility for enforcing of the CPA and Recall Guidelines primarily lies with the National Consumer Commission (NCC).

3. Reporting requirements and recall procedures

A Supplier may be required to conduct a voluntary safety recall in the event that a potential health or safety hazard is identified in a Consumer Product.

As soon as a potential health or safety hazard is identified, a Supplier is required to undertake the following:

- (a) Conduct a comprehensive risk analysis of the health and/or safety hazard(s) associated with the Consumer Product.
- (b) Stop distribution and remove the Consumer Product from the marketplace.
- (c) Cease production or, if possible, modify the manufacturing process for the Consumer Product to remove the health and/or safety hazard from further items.
- (d) Notify the NCC of the hazard(s) and intended recall by submitting a Recall Notification Form (which can be found at the end of the Recall Guidelines)⁸ within two days of commencing the recall action. It is recommended that a Supplier notify the NCC when the Supplier officially resolves to call back or withdraw a Consumer Product from the market or supply chain or to request consumers or other Suppliers to return a Consumer Product for a refund, replacement, modification or something similar.

⁸ http://www.gov.za/sites/www.gov.za/files/35434_gen490.pdf.



- (e) Notify any other relevant regulators of the hazard(s) and intended recall.
- (f) If the Supplier or NCC resolves that a recall is required based on the risk analysis, prepare a Recall Strategy with the assistance and guidance of the NCC, following which the Recall Strategy may be adopted by the Supplier. The Recall Strategy is required to set out certain information, including the nature of the hazard(s), information as to how the Supplier will communicate the hazard(s) and recall to consumers and other Suppliers, and the recall procedure. The recall procedure as set out in the Recall Strategy may take any form, including a complete recall from the market or a corrective action program in terms of which the Supplier simply rectifies the hazard(s) by the replacement or modification of a part of the Consumer Product.
- (g) Implement the Recall Strategy by:
 - (i) notifying the consumers and other parties in the supply chain of the hazard(s), the recall and the steps required to be taken by consumers and other parties to participate in the recall as set out in the Recall Strategy, by way of written notices (the “Recall Notice”). Although there is no prescribed form, the Recall Guidelines set out minimum requirements with which the Recall Notice has to comply
 - (ii) giving effect to the recall action as set out in the Recall Strategy
 - (iii) providing the NCC and other regulators with regular updates on such dates as agreed and set out in the Recall Strategy
 - (iv) placing information relating to a product recall prominently on the Supplier’s website.

When a Supplier has successfully implemented the Recall Strategy or taken all reasonable steps to effectively mitigate the risk posed by the Consumer Product, the recall may be closed. Closure of a recall does not affect the rights of consumers in relation to the product and the public can continue to access information about the recall through the Supplier's recall website or any form designed by the NCC. However, when a recall is closed, the Supplier no longer needs to actively promote the recall and the regulatory oversight ceases. The NCC requires a Supplier to submit a final report (the "Final Report") before the recall can be closed. The Recall Guidelines set out the requirements of the Final Report in detail.

Alternatively, if a Supplier is not prepared to initiate a voluntary recall, the NCC may order a compulsory recall to protect the public from unsafe Consumer Products. When this occurs, the NCC may issue a written notice stipulating the manner in which the recall is to occur. The NCC will monitor compliance with all such notices.

In addition, section 15(3) of the National Regulator for Compulsory Specifications Act No. 5 of 2008 (the "NRCS Act") stipulates that if the National Regulator for Compulsory Specifications of South Africa (NRCS) finds that a commodity or product, which includes motor vehicles and related accessories and certain food products, does not conform to any applicable 'compulsory specifications' as stipulated by the NRCS, the NRCS may take action to ensure the recall of such commodity or product.

4. Product-specific regimes

Pharmaceuticals / Medical devices

In addition to the CPA, recalling pharmaceuticals and medical devices (Medical Products) is regulated by the Medicines and Related Substances Act, No. 101 of 1965 (MRSA), read together with the Guidelines for Recall/Withdrawal of Medicines, Medical Devices and IVDs (In Vitro Devices) (the "Medical Recall Guidelines").



The responsibility for enforcing the MRSA and Medical Recall Guidelines lies with the Medical Control Council (MCC), Registrar of Medicines and Cluster: Food Control, Pharmaceutical Trade and Product Regulation: Directorate: Inspectorate and Law Enforcement (the “Inspectorate and Law Enforcement”).

The purpose of the Medical Recall Guidelines is to define the action to be taken when Medical Products are to be removed from the market for reasons relating to their safety, quality, efficacy or performance (known as ‘defects’).

The responsibility for the recall lies with the holders of the certificates of registration, parallel importers and distributors of Medical Products (the “Medical Suppliers”).

Upon becoming aware of a defect that may require a recall, a Medical Supplier is required to inform the Registrar of Medicines, whereafter the Medical Supplier and the MCC will jointly decide if there is a need for a recall.

Recalls can be either voluntary or compulsory. The MCC can therefore order a recall should it become aware of defects in a Medical Product, notwithstanding the views of a Medical Supplier.

No recall, regardless of the level, should be undertaken by a Medical Supplier without consultation with the MCC and agreement on the recall strategy. Only if there are potential significant health hazards to patients during weekends or public holidays may a Medical Supplier disseminate information on the recall, which includes precautionary measures to quarantine stock pending the initiation of the recall approved by the MCC.

Recalls are classified into both a class (according to the level of health hazard involved (risk to the patient)) and a type (denoting the depth or extent to which the product should be recalled from the distribution chain). The decision as to the classification of a recall is to be taken by the MCC in consultation with the Medical Supplier.

The nature and extent of the recall strategy and required action will depend on the categorization of the recall.

Once the recall has been handled satisfactorily, the MCC will determine the recall closed, subject to any follow-up actions.

Food and drink

In addition to the CPA and the NRCS Act, recalling food and drink (the “Food Products”) is regulated by the Policy Guidelines: National Food Safety Alerts and Official Food Product Recalls in South Africa (the “Food Recall Guidelines”). The Food Recall Guidelines are not legally binding or enforceable.

The responsibility for enforcing the Food Recall Guidelines lies with the National Health Authority.

A Food Product recall can be initiated in the following ways if the Food Product presents a risk to health or gross deception, or is otherwise defective:

- (a) Voluntarily, at any time, by manufacturers, distributors, wholesalers and retailers (the “Food Suppliers”); bar exceptional circumstances, the Food Suppliers are solely responsible for the removal of the Food Products from the market.
- (b) Official Food Product Recall, initiated and implemented by the National Health Authority with the assistance of the Food Suppliers and relevant municipal authorities
- (c) Any other relevant food control authority, in the interest of public health, can request any Food Supplier to initiate and undertake a Food Product recall.

Recalls of Food Products are categorized into different classes, depending on the risk associated with the Food Product, and further as either a trade/industry recall or a consumer recall, which will affect the extent of the recall and notifications.



As an alternative to Food Product recalls, Food Suppliers may voluntarily issue a food safety alert (the “Voluntary Food Safety Alert”). A Voluntary Food Safety Alert will request consumers to return an implicated Food Product to retailers and/or to the business concerned or dispose of it. In this case, the consumers are usually refunded for the products they return or dispose of.

Alternatively, the National Health Authority may issue an official food safety alert, whereby provincial and municipal health authorities and, in some cases, the public are informed of a risk associated with a particular Food Product. Provincial and municipal authorities are informed in writing by the Department of Health, Directorate: Food Control, while a media release, by the Communications Unit of the Department of Health, is used to inform the public. In most cases, an official food safety alert is followed by an official food product recall as described above.

Motor vehicles and parts

There is no separate regime or regulator that specifically regulates the recall of motor vehicles or parts, so the jurisdiction of the CPA and the NRCS Act applies.

5. Legal consequences of noncompliance

A Supplier who fails to notify the NCC of its decision to proceed with a recall may be found guilty of an offense under section 110 (2) of the CPA. Any person convicted of such offense may be liable to a fine and/or to imprisonment for a period not exceeding 12 months.

The MRSA, Medical Recall Guidelines and the Food Recall Guidelines do not contain any consequences or penalties for noncompliance.

South Africa

Sources of information

Further information on best practice for product recalls is available at:

<http://www.nccsa.org.za>

<http://www.nrcs.org.za>

<http://www.mccza.com>

<http://www.health.gov.za>



South Korea

The primary Korean statutes specifically addressing products and product recalls are the Framework Act on Consumers (*Sobijakibon-bub*), which provides broad consumer protection and covers almost all consumer products, and the Framework Act on Product Safety (*Jaepumanjunkibon-bub*).

1. Definition of a “consumer product”

The Framework Act on Product Safety (FAPS) defines a product as “any article, or component part or accessory thereof, which is ultimately intended for use by a consumer.” This definition applies to almost all consumer products.

2. Agencies involved in regulating consumer products

The primary government authority that regulates product safety is the Korean Ministry of Trade, Industry and Energy (MTIE). The MTIE regulates compliance with the FAPS. The FAPS governs the activities of any “business entity,” which is defined as an entity that either manufactures or distributes products.

Pursuant to the FAPS, the MTIE must establish a product safety management plan every three years (Article 7.1 of the FAPS) and conduct safety investigations on certain products in the market to determine if the products pose any risks (Article 9 of the FAPS).

If a product in the market is defective and deemed to cause, or likely to cause, danger to consumers, the MTIE may make recommendations to the relevant business entity, such as a product recall or discontinuation of the product in the market (Article 10 of the FAPS). If the business entity fails to follow the MTIE’s recommendations without any justifiable reason, the MTIE may make an official announcement (Article 10 of the FAPS) and issue product recall orders or take other necessary measures (Articles 10 and 11 of the FAPS).

In addition to the MTIE, the Ministry of Health and Welfare (MHW), the Ministry of Land, Infrastructure and Transport (MLIT), the Ministry of Employment and Labor and the National Emergency Management Agency regulate products and determine whether they comply with the relevant legislation.

3. Reporting requirements and recall procedures

Under the Framework Act on Consumers (FAC), a business entity has an obligation to notify the relevant government authorities of any significant product defect that poses a risk of death, bodily harm or property damage (Article 47 of the FAC). There is no specific form for doing so. The FAC defines “business entity” as any entity that manufactures, imports or sells products. Further, the Enforcement Decree of the FAC (EDFAC) defines a “significant defect” as any defect that lacks safety and imposes or is likely to impose danger such as death, physical injury, disease that requires at least three weeks of medical treatment, or food poisoning of at least two persons. It further states that any product defect that violates specific safety standards under the relevant regulations shall also be considered a “significant defect.” Under this obligation, a business entity must, within five days after acknowledging a “serious defect,” report the relevant information to the government authorities and include a brief description of the significant defect and the danger imposed. However, the relevant government authority is restricted from disclosing the reported information until the defect is confirmed (Article 35 of the EDFAC).

A business entity is also required to report accidents that were caused by products to the relevant government authority. This reporting obligation applies regardless of whether there was a significant defect. The FAPS states that an “accident” that requires reporting is an accident involving death, injuries requiring at least four weeks of medical treatment, a fire or explosion, or involves repeated accidents (Article 13-2 of the FAPS). It is important to note that business



entities are also required to report repeated accidents that occurred overseas if the same product is being distributed in the Korean market.

Aside from the general reporting obligation under the FAC and the FAPS, the other product safety laws for specific categories of products (except the Pharmaceutical Affairs Act, Food Sanitation Act and Motor Vehicle Management Act, as discussed below) generally do not require reporting by companies, including manufacturers and importers, within a relatively short period of time, unless the relative government authorities issue a reporting order.

As discussed, a business entity has an obligation under the FAC to notify the relevant government authorities of any significant defect that poses a risk of death, bodily harm or property damage (Article 47 of the FAC). If the defective product potentially poses a risk of death, bodily harm or property damage to consumers, the business entity is required to voluntarily recall the defective product or take other necessary measures upon submitting the report to the government authorities (Article 48 of the FAC). The Korean government also has the authority to order the business entity to conduct a mandatory recall of the defective product or issue other corrective orders (Article 50 of the FAC).

4. Product-specific regimes

Other than the general reporting requirement and the general recall regime under the FAC and FAPS, other legislation, such as the Pharmaceutical Affairs Act (PAA), the Food Sanitation Act (FSA) and the Motor Vehicle Management Act (MVMA), establish their own reporting requirements and recall regimes for products regulated by those statutes.

Unlike the general recall regime under the FAC, the PAA, FSA and MVMA impose mandatory recall obligations and companies are required to immediately recall defective products as soon as a defect is acknowledged.

Pharmaceuticals / Medical devices

Under the PAA, approved sellers, manufacturers and distributors are required to report a recall plan to the Minister of Food and Drug Safety and recall the relevant pharmaceutical drug products as soon as it acknowledges that there is an issue in relation to safety or efficacy (Article 39 of the PAA). The form is available at:

<https://ezdrug.mfds.go.kr/#!/CCCAH01F010>

Food and drink

The FSA provides that manufacturers, processors, importers and sellers of products related to food and beverage products are under an obligation to report a recall plan to the relevant government authorities, including the Minister of Food and Drug Safety, and recall any defective product as soon as it acknowledges that the product is in breach of the FSA. However, the reporting and recall obligation does not apply if the breach does not cause any harm (Article 45 of the FSA).

Motor vehicles and parts

The MVMA provides that manufacturers of motor vehicles and the parts of motor vehicles are required to disclose any defects that do not comply with the applicable safety standards or pose any safety risks. Manufacturers are also required to disclose a recall plan to purchasers, report the defect to the Ministry of Land, Infrastructure and Transport, and recall the products as soon as it acknowledges any defect (Article 31 of the MVMA).

The MVMA was recently revised. Before the revision, manufacturers were required to disclose defects that resulted in an exaggerated indication of the vehicle's fuel consumption rate and an exaggerated indication of the rate of the power of the engine, but manufacturers were not required to recall the products with these types of defects. Under the revised MVMA, however, manufacturers will be required to recall products with these types of defects or provide monetary



compensation. The revised MVMA becomes effective on 18 January 2018.

5. Legal consequences of noncompliance

Korean government agencies have the authority to order the recall of defective products or order that product distribution be discontinued for products that pose risks to consumers. If a business entity does not follow any such orders, it can be penalized by imprisonment of up to three years or with fines of up to KRW 50 million (Article 84 of the FAC). If a business entity fails to report serious defects in its goods, or makes a false report, an administrative penalty of up to KRW 30 million may be imposed (Article 86 of the FAC).

With respect to pharmaceutical products, if a seller, manufacturer or distributor fails to recall defective products, fails to report its recall plan or makes a false report, the relevant government authority may prohibit the offending company from manufacturing or importing pharmaceutical drug products, or order suspension of business operations for up to one year (Article 76 of the PAA).

The FSA, which covers food and beverage products, states that if a manufacturer, processor, importer or seller of a defective product fails to recall a defective product, fails to report a recall plan or makes a false report, the appropriate government authority may cancel the company's business license or order suspension of its business operations for up to six months (Article 75 of the FSA). Further, if a company fails to recall a defective product, it can be punished by imprisonment of up to five years or be fined up to KRW 50 million (Article 95 of the FSA).

The MVMA, which regulates motor vehicle products, states that if a manufacturer fails to disclose a defect, discloses inaccurate information or fails to recall a defective product immediately after acknowledging the defect, it may be penalized by imprisonment for up to 10 years or fined up to KRW 100 million (Article 78 of the MVMA).

South Korea

Sources of information

MTIE

<http://www.motie.go.kr/www/main.do>

MHW

http://www.mohw.go.kr/front_new/index.jsp

MLIT

http://www.mohw.go.kr/front_new/index.jsp



Spain

Royal Decree 1801/2003 of 26 December 2003 on general product safety (“RD”) implements the EU’s General Product Safety Directive 2001/95/EC into Spanish law.

1. Definition of a “consumer product”

The RD does not contain a definition of a “consumer product.” However, Article 1.2 defines the scope of the application of the RD and states that it shall apply to:

“Any consumer product, including those offered or made available to consumers within the framework of a services arrangement so that they may directly consume, handle or use such products, or that, subject to reasonably foreseeable conditions, may be used by the consumer, even though such product is not intended for them, may be supplied to them or made available to them, at a charge or free of charge, within the context of a commercial activity, either new, used or reconditioned.”

Paragraph 3 of Article 1 excludes any used products that are supplied as antiques or in order to be repaired or reconditioned before being used, provided the supplier clearly informs the person to whom the product is being supplied that the product is of this type.

The definition includes all types of products for use or consumption, provided the item concerned is “intended for consumers or may be used by consumers under reasonably foreseeable conditions.”

The term “consumer product” in the RD also covers products that are not sold to consumers, but that are only “made available” for the purpose of rendering certain services.

In addition, Royal Legislative Decree 1/2007 dated 16 November 2007 (“RLD”), approving the revised text of the General Law for the protection of consumers and users and other supplementary laws when providing the general rules applicable to defective products, uses the

term “product” rather than “consumer product.” The term “product” is defined under the RLD as “any movable asset, even when this is combined or incorporated into another movable or immovable asset, as well as gas and electricity.”

2. Agencies involved in regulating consumer products

Article 13 of the RD states that the competent bodies for exercising the powers conferred in the RD are those of the autonomous communities and the cities of Ceuta and Melilla, and on a national government level, the Ministry of Health and Consumption (currently Ministry of Health, Social Services and Equality), through the National Institute of Consumption (*Instituto Nacional de Consumo*) (the Spanish Consumption, Food Safety and Nutrition Agency - *Agencia Española de Consumo, Seguridad Alimentaria y Nutrición*).

Notwithstanding the above, the RD provides that the Ministry of Health and Consumption (the Ministry of Health, Social Services and Equality), through the National Institute of Consumption (the Spanish Consumption, Food Safety and Nutrition Agency) may take some of the measures set forth in the RD for the autonomous communities, during a period deemed strictly necessary and proportional to the situation calling for such measures, in the following cases:

- When a serious risk to the health and safety of consumers may only be addressed by adopting measures on a national level, in particular, in the event of adopting one of the measures required by the European Commission under Article 13 of Directive 2001/95/EC80
- When the measures adopted or envisioned by the different autonomous communities to address a serious risk to the health and safety of consumers come into conflict and such conflict is an obstacle to guaranteeing product safety, and when all existing mechanisms for coordination and cooperation have been exhausted



3. Reporting requirements and recall procedures

When a manufacturer discovers or has sufficient indication to believe it has placed products on the market that pose risks to consumers and that are incompatible with the manufacturer's general obligation to ensure product safety, it must take the necessary measures to avoid such risks, without the need to receive any request from the competent administrative authorities. These include the following:

- Informing consumers through the publication of special warnings, where applicable
- Withdrawing the products from the market
- Retrieving such products from consumers

In addition, distributors must control the safety of products on the market through the following:

- Informing the competent authorities and the manufacturers regarding risks that have come to their attention
- Maintaining the necessary information for ascertaining the origin of products for a period of three years from the time when stocks run out
- Collaborating with the authorities and manufacturers to avoid any potential risks

Additionally, manufacturers and distributors that are aware or should be aware, on the basis of the information they possess and their experience, that a product which has already been made available or supplied to consumers in Spain poses risks conflicting with their general obligation to ensure product safety, shall report such events immediately to the competent administrative authorities of the autonomous community concerned. If the product is or has in any way been supplied to consumers in more than one autonomous community, notice shall be sent to the competent authority in the autonomous

community where their registered address is located, which will immediately forward such notice to the National Institute of Consumption so that it may then be sent to the other autonomous communities concerned.

This notice must contain at least the following:

- Details clearly identifying the product or batch of products
- A full description of the risk posed by such products
- Any available information useful for tracking the product
- A description of the action taken to prevent risks for consumers, which must include the withdrawal of the products from the markets or those measures deemed appropriate for preventing risks

Manufacturers and distributors must tightly control products subject to restrictions and refrain from making them available in any way until authorization from the competent administrative authorities is obtained.

There are no specific rules as to what kinds of measures have to be taken to correct or eliminate any specific product risk. It is therefore up to the manufacturer to assess the risks posed by the product concerned and decide upon an adequate course of action that ensures that such product risks are effectively corrected or eliminated.

The competent authority will assess whether the measures taken by the manufacturer or other responsible parties are sufficient to effectively protect consumer health and safety.

Manufacturers and distributors shall collaborate with the competent administrative authorities, at their request, in the actions taken to correct or eliminate the risks posed by the products that they supply or have supplied. In particular, they must furnish any relevant information requested from them, including any information that may



be protected by trade or industrial secret, within five days, unless a shorter period is indicated due to the urgency of the case. Information protected by trade or industrial secret may not be disclosed or used for any purpose other than that which justifies its receipt.

If the manufacturers and distributors fail to fulfill their obligations and a product is deemed unsafe, the competent administrative authorities may take any measures strictly necessary for restoring and guaranteeing health and safety, including the following:

- Temporarily prohibiting the supply or display of the product for the period necessary to conduct the various safety inspections, checks or evaluations, or until such time as it may be scientifically proven beyond doubt that the product is safe
- Prohibiting the marketing of the product and taking additional measures necessary for ensuring compliance with such prohibition (if the product risk may be corrected or eliminated by means of certain modifications, precautions or conditions prior to its placement on the market, these must be indicated in the administrative prohibition)

For any unsafe product that has already been placed on the market, the following measures may be taken:

- Withdrawal of the product from the market, and as a last resort, its retrieval from consumers
- Destruction of the product subject to suitable conditions

4. Product-specific regimes

Pharmaceuticals / Medical devices

Pharmaceuticals and medical devices have a specific defective product regime. This regime is governed by Royal Legislative Decree 1/2015, dated 24 July 2015, approving the revised version of the Law on Guarantees and Rational Use of Pharmaceuticals and Medical

Devices, Royal Decree 577/2013, dated 26 July 2013 on pharmacovigilance of pharmaceuticals; Royal Decree 1616/2009 dated 26 October 2009, on active medical devices; Royal Decree 1591/2009, dated 16 October 2009 on medical devices; and Royal Decree 1662/2000 on in vitro medical devices.

Spanish Royal Decrees related to medical devices have been replaced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (the regulations were published in the EU Official Gazette of 5 May 2017 and therefore came into force on 25 May 2017; however, most of their contents will not be applicable for another three years for medical devices and five years for in vitro medical devices).

For both pharmaceuticals and medical devices, the applicable regulator is the Ministry of Health, Social Services and Equality through the Spanish Pharmaceuticals and Medical Devices Agency (*Agencia Española de Medicamentos y Productos Sanitarios*).

With regard to reporting adverse reactions related to pharmaceuticals, both marketing authorization holders and healthcare professionals are obliged to promptly notify the competent pharmacovigilance bodies of each autonomous community of any suspected adverse reaction of which they are aware, using the form available at www.aemps.es. The autonomous communities will transfer the information received to the Spanish Pharmaceuticals and Medical Devices Agency. Such reporting must be made according to the European Good Pharmacovigilance Practices. The Spanish Pharmaceuticals and Medical Devices Agency shall immediately inform the European Pharmaceuticals and Medical Devices Agency.

With regard to medical devices, the manufacturer, the authorized representative, the importer, the distributor, and the healthcare professionals must send a notification (using the form available at www.aemps.es) to the Spanish Pharmaceuticals and Medical Devices



Agency about any malfunction or alteration of the performance of any medical device, as well as any inadequacy of the labeling or the instructions that may give rise to or could have resulted in death. Such notifications shall be made notwithstanding those which may be required by the health authorities of the relevant autonomous community.

Food and drink

Food has a specific defective product regime. Such regime is governed by Law 17/2011 dated 5 July 2011.

This regime is deeply inspired by Regulation (EC) No 17/2002 of the European Parliament and of the Council. In fact, as set out in article 19 of this regulation, the Spanish law provides that if a food business operator considers that a food is not in compliance with the food safety requirements: (i) it shall start procedures to withdraw the food from the market; or (ii) it shall inform the consumer and the authorities in the event that the food has reached the consumers.

Motor vehicles and parts

There is no specific defective product regime for vehicles and their parts under Spanish law. Notification should be made to the authorities listed in section 2 above.

5. Legal consequences of noncompliance

Noncompliance with the obligations contained in the RD may be penalized by the authorities in accordance with the provisions of the General Health Act 14/1986 of 25 April 1986 and the RLD. In particular, such infringements may result in a fine of up to EUR 600,000 or five times the price of the affected products. If the conduct of the manufacturer or distributor constitutes a criminal offense (eg, willful noncompliance with the obligation to withdraw products from the market, being fully aware of the existing risks), which results in bodily injuries to consumers, criminal penalties would be applicable rather than administrative penalties.

Spain

Breach of the legal obligations when the affected product is a pharmaceutical or a medical device may involve penalties up to EUR 1 million or five times the price of the affected pharmaceutical or medical device.

Noncompliance of the obligations imposed when the affected product is food or drinks may be fined up to EUR 600,000.

Sources of information

Andalucía

Departamento de Consumo
red-alerta.calri@juntadeandalucia.es

Aragón

Departamento de Consumo
controlmercado@aragon.es

Asturias

Departamento de Consumo
reddealertas@asturias.org

Islas Baleares

Departamento de Consumo
redalerta@dgconsum.caib.es

Islas Canarias

Departamento de Consumo
dgconstf.ceic@gobiernodecanarias.org

Cantabria

Departamento de Consumo
redalertaconsumo@gobcantabria.es



Castilla y León

Departamento de Consumo
redalertaconsumo@jcyl.es

Castilla La Mancha

Departamento de Consumo
seguridad.consumo@jccm.es

Cataluña

Departamento de Consumo
catalert.ctc@gencat.net

Ceuta

Departamento de Consumo
mptorroba@ceuta.info

Extremadura

Departamento de Consumo
alertas.consumo@gobex.es

Galicia

Departamento de Consumo
redes.alerta@xunta.es

La Rioja

Departamento de Consumo
consumo.control@larioja.org

Madrid

Departamento de Consumo
consumo.seguridad@madrid.org

Spain

Melilla

Departamento de Consumo
mangos01@melilla.es

Murcia

Departamento de Consumo
josefina.andreu2@carm.es

Navarra

Departamento de Consumo
seccion.consumo@cfnavarra.es

País Vasco

Departamento de Consumo
alertas-SOIVRE@kontsumobide.es

Comunidad Valenciana

Departamento de Consumo
consumo_gva@gva.es



Switzerland

The recall of consumer products in Switzerland is addressed in various statutes, with the general rules on product recalls being contained in the Act on Product Safety and related ordinances. However, it should be noted that certain specific product recalls are governed by product-specific laws. This overview addresses the general rules as set forth in the Act on Product Safety; some important product-specific laws are discussed in section 4 below.

1. Definition of a “consumer product”

The Act on Product Safety applies to “products” in general, not only to consumer products. However, certain provisions of this Act specifically concern consumer products, such as the provision on market surveillance and product recall.

A “product” under the Act on Product Safety is defined as a movable item that is ready for use, even if an item is part of another movable or immovable item. A consumer product is a product designed for consumers or is a product that could be used by consumers under reasonably predictable conditions.

2. Agencies involved in regulating consumer products

Several agencies of the federal government or of the cantons, as well as certain non-governmental expert organizations are in charge of product safety, due to the fact that there are various statutes applying to consumer products and due to the different nature of consumer products. These agencies and organizations decide what measures must be taken in the event of a product that does not meet the required safety standards (eg, ordering a recall). They are obliged to report the measures to the federal State Secretariat for Economic Affairs (SECO).

The SECO is responsible for the coordination of the implementation of the Act on Product Safety, in coordination with the agencies and organizations that are in charge of product safety. If it is not clear

which agency or organization is responsible for a product recall, it is recommended to contact the SECO for assistance (www.seco.admin.ch).

3. Reporting requirements and recall procedures

The Act on Product Safety establishes post-marketing obligations for consumer products. Manufacturers and importers are obliged to take appropriate measures to identify and prevent potential danger from the product during the declared or reasonably predictable service life of the product. In addition, the manufacturer and importer must take appropriate measures to enable traceability of the product.

Appropriate measures to protect users from the hazards of the product can be issuing warnings, suspending sales, withdrawing products from the market, or recalling the product. In line with the principle of proportionality, a full product recall is required if the potential risk is high. If the risk created is small, an appropriate warning to users may be considered to be sufficient.

If the manufacturer or the marketer of the product finds out, or has a reason to believe, that its product is endangering the health and safety of users and bystanders, it must immediately file a notification to that effect with the competent authority. The notification must contain all the information necessary for an exact identification of the product, a comprehensive description of the danger posed by the product, and all information available concerning the supplier of the product and to whom it was delivered as well as the measures taken to avert the danger (eg, a product recall). There are no specific formal requirements in the Act for the product recall itself. Many competent authorities provide forms for a notification; it is recommended to make use of these forms. Product recalls, which are to be notified directly to the SECO, should be reported by means of the form provided by the SECO (available at www.seco.admin.ch, tel. no. +41 58 462 3120).



According to the Act on Product Safety, the authorities in charge of the enforcement of the Act are competent to prevent products from being put in circulation if they do not meet the required safety standards. If the risk of exposure to the user is high, the authorities may issue a public warning and recall or confiscate the devices if the seriousness of the risk at stake justifies the application of such measures.

Switzerland does not participate in the Community Rapid Information System (RAPEX) of the European Union (although in practice the Swiss authorities may become aware of RAPEX notifications when these are published on the European Commission's website). Therefore, a notification to RAPEX does not release the manufacturer or marketer from the obligation to notify the Swiss authorities.

Even if not mandatory, recalls are usually published on the official website of the Federal Consumer Affairs Bureau, which cooperates with the SECO (www.konsum.admin.ch/dienstleistungen).

4. Product-specific regimes

The Act on Product Safety is not applicable if, in connection with a particular product, other more specific laws pursue the same goal with regard to product safety. However, insofar as the safety standard regulated in the specific laws does not reach the standard set by the Act on Product Safety (eg, no notification obligations are stipulated in the specific laws), the Act on Product Safety will be applied in addition to the specific laws. The following paragraphs pertain to certain important consumer products which are subject to specific legislation.

Pharmaceuticals / Medical devices

Pharmaceuticals and medical products are governed by the Federal Statute on Pharmaceuticals and Medical Products and the ordinances related thereto. Swissmedic, a federal agency, is responsible for the surveillance of quality, safety and efficacy of pharmaceuticals and medical products (www.swissmedic.ch).

Swissmedic is the regulatory authority to which undesired effects and events related to pharmaceuticals and medical products must be notified. Such a notification must be made by the manufacturer or by the marketer of the pharmaceutical / medical product. The duty of notification also applies to medical doctors and pharmacists and to the users of medical products. Swissmedic provides forms which should be used for notifications (available at www.swissmedic.ch, tabs “Market surveillance,” “Documents and Forms”). Swissmedic is authorized to take far-reaching measures to ensure the safety of consumers, such as eg, the issuance of warnings, the ordering of product recalls, the withdrawal of permits for the marketing of pharmaceuticals and medical products, the shutting down of factories, etc.

Food and drink

The Statute and the Ordinance on Foodstuffs and Utility Articles cover food and its packaging.

The cantonal authorities (which can be identified at www.kantonschemiker.ch) deal with product security of food. Any recall of such products must be notified to, and carried out in, cooperation with the cantonal authorities (some authorities provide forms which should be used), which are, in turn, supervised by the Federal Office for Foodstuffs Safety and Veterinary Matters (www.blv.admin.ch).

The Act on Foodstuffs and Utility Articles and various regulations related to it set safety standards for the specific products governed by the Act. A manufacturer must nominate a person to be responsible for products’ compliance with the Act (self-regulation). Products that endanger or have already endangered the health of users must be taken off the market. Should such products already be in the possession of users, they must be recalled.



Motor vehicles and parts

Vehicles and their parts are subject to the surveillance of the Federal Agency on Roads (ASTRA; www.astra.admin.ch). In case of a product recall, the ASTRA may ask for the addresses of the owners of the vehicles concerned. The ASTRA may order a recall if a vehicle does not meet the traffic safety standards required by the law or if it does not comply with the general permit granted for the admission for traffic for the type of vehicle concerned. The ASTRA provides guidelines for a product recall and a form for the notification of hazardous products (available at the ASTRA, www.astra.admin.ch, tel.no. +41 58 463 2128).

5. Legal consequences of noncompliance

A manufacturer or another responsible party which fails to meet the notification requirements of the Act on Product Safety may be fined up to CHF 40,000 and, in the case of negligence, up to CHF 20,000. The Product Safety Act does not penalize the failure to implement appropriate measures (eg, a recall) to rectify a potentially dangerous situation for users' health and safety. However, the failure to perform a recall, despite the manufacturer or another responsible party knowing or having enough indications to be aware of the hazardous situation created by the product, can lead to civil liability under the Code of Obligations or under the Act on Product Liability. It may also lead to criminal liability under the Swiss Penal Code if the hazardous product causes the injury or death of a person (eg, homicide through negligence). It should also be noted that the product-specific legislation (cf. section 4 above) may provide for additional or modified sanctions.

Sources of information

www.seco.admin.ch

www.konsum.admin.ch

www.astra.admin.ch

Switzerland

www.kantonschemiker.ch

www.blv.admin.ch

www.swissmedic.ch



Taiwan

Taiwan's regime on product safety is found in the Consumer Protection Act (CPA), which was enacted on 11 January 1994 and last amended on 17 June 2015. The CPA establishes the general principles for regulating product recalls in Taiwan. Although the CPA serves as the basis for regulating consumer product recalls in Taiwan, other laws overlap with the CPA in some circumstances (see further section 4 below). The Commodity Inspection Act (CIA) imposes additional recall requirements on the range of agricultural, industrial and mining products that are subject to inspection by the Bureau of Standards, Metrology and Inspection.

1. Definition of a “consumer product”

The CPA provides the following definitions:

- “Consumers” means persons who enter into transactions, use goods or accept services for the purpose of consumption
- “Business operators” means persons who are engaged in the business of designing, producing, manufacturing, importing or distributing goods, or who are engaged in providing services
- Under the CPA enforcement rules, “goods” refers to real or personal property that is the object of a transaction, including final products, semi-finished products, raw materials or parts and components

A consumer product is thus any commodity provided by business operators as an object of a transaction or usage for the purpose of consumption by consumers.

2. Agencies involved in regulating consumer products

Virtually every law in Taiwan designates a relevant government agency or agencies as the competent authority or authorities responsible for administering and enforcing the law. For consumer

product safety, Article 6 of the CPA designates competent authorities at both the central and municipal government levels. Competent authorities at the central level are those central government agencies or institutions with regulatory responsibility throughout Taiwan. Competent authorities at the municipal level are those responsible for an industry or sector at the county or city level.

3. Reporting requirements and recall procedures

The CPA authorizes the competent authorities to initiate recalls of products within their purview and also prescribes circumstances in which business operators must initiate product recalls.

Pursuant to the CPA, business operators engaged in the design, production or manufacture of goods or in the provision of services shall ensure that the goods and services they provide comply with all current technical and professional standards before the goods or services are circulated in the market. As applicable, such goods must include a clear and concise warning of any potential risks.

Business operators' initiative

Business operators are legally obligated to voluntarily recall defective products that are deemed to endanger the safety and health of consumers. Business operators must immediately recall a product when a sufficient fact establishes a suspicion that the product poses a risk to the safety and health of consumers, unless other actions taken by the manufacturer are sufficient to remove the risk. Business operators must also voluntarily recall goods that pose a risk of damage to the life, body, health or property of consumers when a warning notice that includes any applicable response methods for emergency is not conspicuously displayed on the product. Where a recall of a product has taken place in another jurisdiction, the competent authorities will generally opt to recall the same product circulated in Taiwan.



Competent authority's initiative

Where the competent authority believes that goods or services provided by a business operator may endanger the lives, bodies, health or property of consumers, it must immediately undertake an investigation and may publicly disclose the process and results of such investigation. If, after the investigation, the agency believes that the goods or services provided by the business operators have endangered or will endanger the lives, bodies, health or property of consumers, that agency shall order the business operator either to improve the products within a designated period or to recall them, depending on the level and severity of the risks involved. The business operator may also be ordered to cease the design, production and manufacturing, processing, importation or distribution of the defective goods or services, or to take other necessary measures.

Notification

For voluntary product recalls implemented at the initiative of a business operator, neither the CPA nor the CIA establish notification requirements or specify procedures. In some cases, however, notification requirements are stipulated by laws specific to particular industries.

4. Product-specific regimes

Separate regimes have been established for pharmaceutical and medical devices, food and beverages, and vehicles and parts. These regimes generally have a similar mechanism and regulations as the CPA, especially in terms of legal consequences. However, they specify special requirements for the recall mechanism, initiatives and notification.

Pharmaceutical and medical devices

The Pharmaceutical Affairs Act (PAA) governs drugs and medical devices (collectively “medicament”). The PAA designates the Ministry of Health and Welfare as the competent authority at the

central level and municipal/county/city government as the competent authority at the local level.

The PAA imposes certain requirements for product recalls on business operators. If any of the following circumstances apply to any medicament, its manufacturer or importer shall immediately notify medical care institutions, pharmacies and pharmaceutical firms, and, within a prescribed time limit, shall recall the medicament in question from the market and dispose of it together with its stock of the medicament:

- (1) Where the medicament has been granted a permit license, but is subsequently prohibited by public announcement from being manufactured or imported
- (2) Where the drug has been deemed counterfeit, substandard or prohibited
- (3) Where the medical device has been deemed defective or has been manufactured or imported without approval
- (4) Medicaments produced by a medicament manufacturing factory are found, after inspection, to be damaging, or to be likely to damage the life, body or health of users
- (5) Where an application for extension of a medicament manufacture or import permit license previously granted has not been filed or has been denied
- (6) Where an amended registration of the package, label or use instructions of the medicament in question has been approved
- (7) Other medicaments whose recall has been publicly announced by the central competent health authority

The Regulations for Medicament Recall provide further requirements for product recalls. The recall needs to be completed within one, two or six months, depending on the medicament's level of risk to health.



The business operator must inform its direct distributors, which bear the duty to assist the recalls process, and/or the competent authorities, which can publish information of the recalled product. There is no template notification form. Furthermore, business operators should establish a comprehensive distribution record as well as an operational procedure for medicament recall.

Food and beverages

The recall of food and beverage products (the “food product”) is governed by the Act Governing Food Safety and Sanitation (AGFSS). The central competent authority is the Ministry of Health and Welfare, while the local authorities are the municipal/county/city governments.

The business operator shall implement self-management and enact a food safety monitoring plan to ensure the sanitation and safety of its products. Upon discovery that a product may be unsanitized or unsafe, the business operator shall immediately cease manufacturing, processing and selling, and shall recall and report such products to the local competent authorities (again there is no template notification form).

The AGFSS emphasizes particular circumstances in which the government is to initiate recalls. First, the food products are harmful to human health, including those deteriorated, rotten, unripe, toxic, contaminated by pathogenic organisms, nuclear fallout or radioactivity, adulterated, counterfeited, passed their expiry date or those with pesticide or veterinary drug residue. Second, the food products do not comply with the governmental standard of sanitization and safety. Third, the labeling or instructions on the containers or packaging of the food product does not explicitly state the required content, such as the expiry date, nutrition label, genetically modified food ingredients, additives, etc.

In addition, the import of certain foods, genetically modified food ingredients, additives, utensils, containers, packaging and cleansers, as designated by the central competent authority, should apply for an

inspection and report its relevant information to the central competent authority. Otherwise, the competent authority could order the business operator to recall, destroy or return the products.

For a significant or an unexpected food safety incident, based on a risk assessment or epidemiological survey result, the central competent authority can restrict or suspend import, manufacturing or processing, order a recall within a specified period and take other necessary measures for specific products or products from specific areas.

The regulations of recall and destruction for food and related products further set forth notification requirements. The business operator with the duty of recall must submit a plan with the details required by law, such as the total number of the products, its distribution record, recall measures to be adopted, deadline of recall implementation, subsequent safety measures and the alert issued to consumers. The business operator must set up a panel responsible for this plan. During and after the recall implementation, the business operator should report the progress to the local competent authorities.

A violation of any of the above recall requirements will have similar legal consequences as stated in the CPA, but the AGFSS specifies higher fines, up to NTD 200 million, suspension for a certain period, revoking business registration, and a one-year prohibition from business registration after the revocation.

Vehicles and their parts

The Regulations for Motor Vehicle Safety Investigation (RMVSI) prescribe the Ministry of Transportation and Communications as the central competent authority, and the municipal/county/city governments as the local competent authorities.

For business operators, vehicle and vehicle body manufacturers, vehicle's import agents and importers should initiate a recall when a vehicle may pose a severe danger to driving safety.



For the competent authority, if the central authority finds that a vehicle may pose a severe danger to driving safety, it should conduct a safety investigation, which can be delegated to a professional technical institution. If the result of the investigation confirms the vehicle may pose a severe danger to driving safety, the central authority can also initiate a recall.

The RMVSI also details the notification mechanism, although there is no template notification form. Regardless of whether the recall is initiated by the central authority or the business operator, the business operator shall publish the information in public media and inform the vehicle owners in other effective ways. More importantly, for conducting the recall, the business operator must propose a recall and correction plan with details as required by the laws to a professional institution for review and then to the central competent authority for approval. Follow-up reports during and after the implementation are also required.

5. Legal consequences of noncompliance

A business operator's failure to comply with the obligations set forth in section 3 above or in the administrative recall order will be deemed a violation of the business operator's obligation to ensure the safety of its goods. Such failure will render the business operator liable for any resulting damages to injured consumers. For multiple business operators, those who fail to meet the obligations outlined in section 3 and thus cause injury to consumers or third parties will be jointly and severally liable. However, the court may reduce the liability for damages of any business operators who can prove they were not negligent. In a lawsuit brought in accordance with the CPA for the injuries caused by the operator's willful violation, the plaintiff may claim a punitive damage of up to five times the amount of the actual damages. If such injuries are caused by gross negligence, a punitive damage of up to three times the amount of the actual damages may be claimed. If such injuries are caused by negligence, a punitive damage of up to the amount of the actual damages may be claimed.

There are no criminal penalties associated with violations of a business operator's product recall obligations under Taiwanese law. However, business operators may be fined for failing to comply with recall orders or for otherwise failing to cooperate with the competent authorities during product recall procedures. In addition, the competent authorities can suspend an operator's business activities or even cancel its business licenses and permits when the violation may cause damage to the lives, bodies or health of consumers and is considered material.



Thailand

There are three main statutes concerning product recalls in Thailand. The first is the Consumer Protection Act B.E. 2522 (1979), which provides general consumer protection mainly in the areas of advertising, product labeling, contract and others. The second is the Product Liability Act BE 2551 (2008). The third is complementary legislation designed to facilitate and simplify court proceedings in consumer cases, including cases concerning the product liability law: the Act on Court Proceedings for Consumer Cases BE 2551 (2008).

1. Definition of a “consumer product”

Under the Product Liability Act, consumer “goods” are defined as all movable property manufactured or imported for sale, including agricultural products and including electric current, except goods prescribed in the Ministerial Regulations issued by virtue of the Act. Currently, only certain types of agricultural products and medical devices are exempted.

Under the Consumer Protection Act, “goods” are defined as things manufactured or possessed for sale.

2. Agencies involved in regulating consumer products

The governmental agencies that are most relevant with respect to consumer products in Thailand are the Office of Consumer Protection Board, Office of the Secretariat of the Prime Minister (the “Board”), the Industrial Standard Institute, Ministry of Industry, the Office of Food and Drug Administration, and Ministry of Public Health.

3. Reporting requirements and recall procedures

Thailand does not have specific legislation requiring business operators to report product recalls to the authorities. However, under the Consumer Protection Act, if the Board suspects that any product is harmful to consumers, the Board can investigate and test the product. If, in its view, the products are harmful, the Board may order the

business operators to recall the products, bring back exported products, prohibit the sale of such products or order the destruction of those products remaining on the market.

The Consumer Protection Act empowers the Board to order a product recall if the results of a test on suspected products by a business operator or by the Board show that the products may be harmful to the consumers and this cannot be prevented by the addition of a label. The Act on Court Proceedings for Consumer Cases also contains an express reference to product recalls. It confers a discretionary power upon the court to order a product recall. Such an order would require the recall to be performed within a stipulated period and at the expense of the supplier.

If a case goes to court, the court has the power to order the business operator to publish an announcement and recall the affected products for rectification or replacement. If the products cannot be rectified or replaced, the court may award damages in an amount it deems appropriate given the condition and nature of the products at the time of the recall and the perceived integrity of the business owner. Furthermore, the court has the power to prohibit the business operator from manufacturing or importing such products and to order the destruction of any remaining products.

Note that the court will have the power to order a product recall once the court renders a judgment or order to strike out the case. In other words, if there is no case before the court, the court has no power to recall products.

4. Product-specific regimes

Pharmaceuticals / Medical devices

Under the Drug Act BE 2510 (1967), if the competent officials (eg, the Food and Drug Administration) learn that a drug is not safe or might be harmful to drug users, they are authorized to order the recall of those drugs, either by the competent officials themselves or by the importer, seller or manufacturer of those drugs. In the latter case, the



recall must be conducted within a period specified by the competent officials, and the competent officials are also authorized to destroy such recalled drugs.

Under the Medical Devices Act BE 2551 (2008), if the competent officials learn that a medical device is not safe or might be harmful to drug users, they are authorized to order the recall of those medical devices, either by the competent officials themselves or by the manufacturer, importer, seller or possessors of those medical devices. In the latter case, the recall must be conducted within a period specified by the competent officials.

Food and drink

Currently, there is no specific product recall requirement for food and drink.

Motor vehicles and parts

Currently, there is no specific product recall requirement for vehicles.

5. Legal consequences of noncompliance

Failure to comply with a court-ordered recall for any type of product can result in criminal sanctions and penalties. The court is authorized to: (1) order not more than six months of arrestment or imprisonment of the business operators or authorized person until the recall is carried out; or (2) order an executive officer or other person to pay expenses. The person under arrestment or imprisonment who willfully failed to comply with the court-ordered recall will also be subject to a payment and/or security prescribed by the court.

Turkey

Turkey has a plethora of laws which regulate product recalls, but the main ones that apply to the recall of general consumer products are the Consumer Protection Law (CPL), the Technical Legislation Law (TLL) and the Ministry of Customs and Trade Market Surveillance Regulation (the “Regulation”).

1. Definition of a “consumer product”

The CPL defines a “consumer transaction” as “any transaction between a consumer and a seller or supplier with regard to a good or service.” The seller or supplier can be a real person or legal entity, including a public authority. “Consumer product” is defined under both Article 3 of the TLL and Article 4 of the Regulation as “any product to be placed in the market.”

2. Agencies involved in regulating consumer products

The general supervisory authority in Turkey is the Ministry of Customs and Trade. Pursuant to Article 66 of the CPL, the Ministry of Customs and Trade has established a Consumer Council and local arbitration committees for consumer problems. These agencies have different competences and responsibilities regarding problems arising from consumer transactions. Pursuant to Article 12 of the Regulation, the Market Oversight and Inspection Coordination Board is responsible for coordinating the competent public authorities. The nature of the product determines the relevant competent public authority, and producers, manufacturers and/or importers are subject to the regulations prepared by each authority. These authorities also investigate noncompliance with regulations.

3. Reporting requirements and recall procedures

The CPL and the Regulation do not impose a reporting requirement on companies. However, Article 7 of the Regulation states that a “...Producer, within the limits of its own activities, is responsible for providing the necessary information about minor risks which may not



be detected without sufficient warning, marking the product with its underlying characteristics, testing the product placed on the market by taking samples when necessary, investigating complaints and informing the distributors about their results, and preventing risks by withdrawing and disposing of defective products, within the expected useful life of the product.” Under the CPL and the Regulation, “producer” is defined as “any real or legal person who produces, manufactures or improves a product or introduces himself/herself as a producer by putting his/her name, trademark or distinguishing mark on the product, as well as any real and legal persons involved in the supply chain of the product whose activities affect the safety features of the product.” In addition, if the producer is not located in Turkey, the importer of the products will be deemed as the producer. Therefore, if a product has a defect that cannot be eliminated by providing warnings to customers, or it is possible to cure the defect by making corrections in the product, the producer is obliged to recall the product and make the necessary improvements or alterations. If the problem does not result from a design or manufacturing error, and use of the product poses a risk, customers must be notified to eliminate the risk.

The procedure for a product recall is not clearly regulated under Turkish law. In practice, products can be recalled by letter where it is possible to identify the purchasers of the products. However, if it is not possible to notify buyers by letter, then recall by public notification is required. Typically, a recall in this manner can be achieved by publishing notices in two national newspapers.

If a notified consumer ignores the recall and later suffers damage from the product, the producer may avoid liability by establishing that it complied with the recall requirements. The consumer’s failure to act will be considered as contributory (concurrent) negligence, to a degree that negates the prior negligence of the producer.

Furthermore, under Article 11 of the TLL, if there are “definite indications that a product is unsafe,” then the responsible public authority must temporarily prohibit the product from being placed on the market while necessary inspections are carried out, even if the product complies with applicable technical requirements. If the inspections show that the product is unsafe, the public authority must take the following measures at the producer’s expense:

- Prohibit the placing of the product onto the market
- Order the withdrawal of any products already on the market
- If it is possible to cure the product’s defect, instruct the producer to make the product safe within a period specified in the relevant technical regulation, or as determined by the public authority if no such period is stated
- Order the disposal of some or all of the products if it is impossible to render them safe
- Announce the necessary information on the first three measures above to the persons at risk in two daily newspapers and on two nationwide television channels (or local television and newspapers if this will be sufficient to inform the persons at risk)

If the persons at risk can be identified individually, the announcement may be made directly to these persons. If the risk exists in countries within the EU, and if deemed necessary, the competent public authorities will notify the EU Commission of the measures imposed.

To encourage prevention of possible risks related to a product, the relevant public authority is obligated to inform producers, distributors, and other related parties as necessary about the reasons for its concern and the measures it intends to take, and solicit their opinion on the measures to be imposed.



4. Product-specific regimes

Pharmaceuticals / Medical devices

The product recall process for pharmaceuticals is regulated under the Product Recall Regulation, published by the Ministry of Health. The main regulatory authority responsible for the recall process of pharmaceutical products is the Turkish Medicines and Medical Devices Agency (TİTCK), established within the Ministry of Health. The Product Recall Regulation imposes certain obligations regarding the recall of pharmaceutical products on accountable companies, which refer to the manufacturers and/or persons who hire the manufacturer, or who put the product on the market.

There are two different types of product recall for pharmaceuticals: voluntary product recall and withdrawal orders by the TİTCK (involuntary recalls). For both procedures, however, there are some common procedural aspects, including the determination of the class based on the level of risk to consumer health and level of the product recall, ie, the level of the distribution chain to which the recall applies.

In the case of a voluntary recall, upon the detection of any product that is confirmed or suspected to be defective, the accountable company must immediately inform the TİTCK, and complete and deliver the Notification Form provided under the Product Recall Regulation. In life-threatening situations, the accountable company will immediately inform the TİTCK, regardless of working days and hours.

For products that are detected to be defective through market surveillance and inspection conducted by the TİTCK, the TİTCK may decide to withdraw the products from the Turkish market and will notify the accountable company of the withdrawal order and request the accountable company to complete and deliver the Notification Form within five working days.

Recalls of medical devices are not regulated under a separate set of rules, and the procedures set forth under the TLL and the Ministry of Science, Industry and Technology Market Surveillance Regulation are applicable to medical devices. If a device's deficiency or malfunction presents risks to the public, and the potential hazard or risk to the patient or any other user associated with the continued use of the device is identified by the device manufacturer and/or importer, a Field Safety Notice must be filed with the Ministry of Health, providing details of the deficiencies, hazards and potential consequences of continued use. After the submission of the Field Safety Notice to the Ministry of Health, the manufacturer and/or importer can carry out a recall in line with the procedures set forth under the Ministry of Science, Industry and Technology Market Surveillance Regulation.

Food and drink

Product recalls of food products are regulated under Law No. 5996 on Veterinary Services, Herbal Health, Food and Feed (the "Food Products Law"), which requires food operators to immediately initiate the recall process for the food products that they have produced, processed, imported, sold or distributed and inform the Ministry of Food, Agriculture and Livestock if they consider or have reasonable doubts that such products do not comply with legislation or applicable standards on food safety.

A "food operator" is defined under the Food Products Law as "any real or legal person who is responsible for ensuring compliance of operations with the provisions of the relevant legislation at any stage, including production, import, processing and release into the market."

Motor vehicles and parts

The main piece of legislation regulating the product recall process for vehicles is the Regulation on the Type Approval of Motor Vehicles and Their Trailers (the "Motor Vehicles Regulation"), adopted based on EC Directive 2007/46/EC. The product recall process for vehicles



is conducted under the supervision of the Ministry of Science, Industry and Technology.

In parallel with the EU legislation, the Motor Vehicles Regulation requires any manufacturer who has been granted an EC vehicle type-approval to recall the vehicles already sold, registered or put into service in the event that one or more systems, components or separate technical units fitted to the vehicle presents a serious risk to road safety, public health or environmental protection, and immediately inform the Ministry of Science, Industry and Technology thereof.

The manufacturer will propose a set of appropriate remedies to the Ministry of Science, Industry and Technology to eliminate the risks and then the Ministry of Science, Industry and Technology will communicate the proposed measures to the authorities of the other Member States without delay. If the measures of the manufacturer are deemed insufficient, the Ministry of Science, Industry and Technology may take all protective measures required, including the withdrawal of the EC vehicle type-approval where the manufacturer does not propose and implement effective corrective measures.

A recall of any part of motor vehicles, however, is subject to the general recall procedures of industrial products in accordance with the Ministry of Science, Industry and Technology Market Surveillance Regulation under the supervision of the Ministry of Science, Industry and Technology.

5. Legal consequences of noncompliance

The public authorities are competent to take the following measures in accordance with the TLL and the Regulation: (i) prohibit placement of a product on the market; (ii) withdraw products already on the market; (iii) instruct the producer to make a product safe where it is possible to cure the defect within the period specified in the related technical regulation, or determined by the public authority if the period is not stated; (iv) dispose of some or all of the products where it is

impossible to render them safe; or (v) impose administrative fines as set forth under the relevant regulations.

In addition, pursuant to Article 24 of the Law, in the event that goods offered for sale are defective, the Ministry, consumers or consumer organizations may bring an action seeking an order that the production and sale of the defective goods be suspended and that such goods be recalled from those in possession of them for sale. In the event that goods offered for sale have been found to be defective by a court, the sale of that product must be temporarily suspended. A warning can be issued to the manufacturer, producer and/or importer to cure the defect of the good within three months from the date on which the court's decision has been served. In the event that it is impossible to cure the defect, the goods must be recalled by the producer, manufacturer and/or importer. The recalled goods must be partially or fully destroyed (depending on the risks involved).

The Regulation and the Ministry of Science, Industry and Technology Market Surveillance Regulation, as well as the Motor Vehicles Regulation, refer to the administrative fines stated in the TLL for violation of the provisions of the Market Surveillance Regulation. However, this provision is not clear as it does not state which fine is to be applied to which violation, or whether it will be per item or per violation. The fines specified in the schedule start at TRY 1,833 and rise to TRY 114,884.

The Product Recall Regulation for pharmaceutical products refers to the Pharmaceuticals Law and the Turkish Criminal Code No. 5337 in cases of noncompliance with the applicable procedure. The sanction, therefore, changes depending on the reason for the recall. For example, if the recall is carried out due to manufacturing without a marketing authorization, under Article 18 of the Pharmaceuticals Law, a fine ranging between TRY 10,000 and TRY 500,000 is imposed.

Noncompliance with the Food Products Law, on the other hand, may result in administrative fines from TRY 5,000 to TRY 10,000.



Lastly, criminal liability may also arise especially with regard to food products as well as pharmaceuticals and medical devices, as manufacturers and/or importers may be held liable for personal injury or threatening public health upon negligent behavior under the Turkish Criminal Code.

Ukraine

The oldest and least specific law regulating recall of goods is the Law On Protection Of Consumers' Rights dated 12 May 1991 (the "Consumer Rights Law"), which has subsequently been supplemented by a number of secondary regulations and specific statutes, as explained below.

1. Definition of a "consumer product"

There is no definition of a "consumer product" in Ukrainian law. The Consumer Rights Law defines a "product" as "... any product (goods), work or service that is produced, made or provided in order to satisfy the needs and interests of society." A "consumer" is defined as an "... individual who buys, orders, uses or has an intention to buy or order goods for personal purposes not directly related to the individual's entrepreneurial activity or employment duties."

2. Agencies involved in regulating consumer products

The State Inspectorate of Ukraine on Food Safety and Consumer Protection (the "Inspectorate") was formed in September 2015 and is subordinated to the Cabinet of Ministers of Ukraine. The Inspectorate is responsible for the implementation of state policy in the areas of the state control of foodstuffs safety, veterinary, sanitary and phytosanitary safety, state control of metrology, consumer rights protection, related advertisement, and state control of compliance with applicable regulations and technical standards.

In general, the Inspectorate has regulatory and controlling functions. Its headquarters are in Kyiv, and there is a local branch in each of the 26 administrative regions of Ukraine. Its officers are authorized to carry out planned and ad hoc inspections of the quality of products or services (including in response to customer complaints), to impose fines and to issue mandatory orders, or to suspend operations of the production or trading facility if any violations of consumer rights (eg, poor quality products or services) are detected.



The Inspectorate is also empowered to impose administrative sanctions for violations in the field of consumer products; to examine the warehouses and other premises of manufacturers, providers of services and merchants; to select samples of products and goods for safety and quality testing; to prohibit production, transportation and/or sales of goods that are not in compliance with the applicable rules and regulations; to suspend operations of companies and of individual entrepreneurs who repeatedly sell defective products or violate the rules for sales or provision of services; and to issue waivers for products with minor deviations from the rules and regulations.

3. Reporting requirements and recall procedures

Under the Consumer Rights Law, the producer, seller or distributor of a product is obligated to stop production or sales and to recall the product if the product has been determined to be potentially dangerous to consumers' life, health or property. The same requirement is reiterated in several other related pieces of Ukrainian legislation.

Ukrainian legislation provides that the following products are deemed dangerous:

- Products that are not in compliance with the laws of Ukraine regulating their quality
- Products that are not in compliance with laws of Ukraine as to the safety of life, health or property of individuals
- Adulterated products
- Products with labels that are not in line with the rules for labeling
- Products after their “best before” date
- Products not accompanied by documents required for their manufacture, storage or sale

The Law On General Safety of Nonfoodstuffs dated 2 December 2010 (the “General Safety Law”) provides the framework for release to the market and for ensuring the safety of any product that is not a foodstuff, whether imported or manufactured domestically. The safety of products is presumed, as long as they conform to the state technical standards, which have been harmonized with the relevant EU regulations. If a national standard does not exist, certain other documents, including foreign standards, will be taken into account. The General Safety Law also establishes labeling requirements and user manual/safety instructions for non-foodstuff products and requires the recall of products if other safety measures have failed.

The General Safety Law was the first to regulate recall notices. Under this law, the producer and/or the distributor must notify state authorities of a product’s noncompliance with the applicable safety requirements immediately after it comes to their attention. The form of the notice and procedure for its submission is specified by the Cabinet of Ministers of Ukraine. Notifications in respect of products that pose significant danger or have dangerous defects must include greater detail, indicating, among other things, what steps have already been taken in order to minimize the risks.

Under the Law On Withdrawal From Circulation, Recycling, Utilization, Destruction Or Further Using of Defective And Dangerous Production dated 14 January 2000, the owner of dangerous products (the producer, distributor, wholesaler, etc.) must recall dangerous products and ensure that they be either recycled or destroyed at the owner’s cost. The recalled products must be stored in sealed premises until disposed of in an appropriate manner. Alternatively, if the recalled product can be processed to remove its dangerous features or elements, it can be released back to the market once it is safe for consumers.



The General Safety Law also provides that where the Inspectorate deems products to be dangerous to consumers, it should immediately carry out the following:

- Bar such products from entering the Ukrainian market (including a prohibition on delivering them into Ukraine, advertising them or displaying them to consumers) and take measures in order to enforce such prohibition
- Take measures in order to ensure that the products are recalled from the market and consumers are warned of the risks that the products entail
- In cooperation with the producer and/or distributor, take measures to ensure that any products already sold to consumers are recalled and destroyed

Product recalls ordered by the authorities are to be employed only in exceptional circumstances, where measures taken by the producer and distributor are insufficient to prevent the risks associated with the products from materializing.

There are a number of secondary regulations on the procedure for involuntary recall of dangerous goods. In particular, such procedures are set out in the Resolution of the Ukrainian Parliament On Approval Of Provisions On Protection Of Consumers' Rights dated 25 January 1995. The most significant requirement of this resolution is that, if the withdrawal of the dangerous product from the market is ordered by the authorities, the owner is obligated to announce the withdrawal through (i) a major printed newspaper, (ii) a major radio station and (iii) a major TV channel. This requirement does not automatically apply to a voluntary recall of a product. Thus, a voluntary recall may be a more attractive option (although the authorities may demand that such an announcement is made even in connection with a voluntary recall).

4. Product-specific regimes

Pharmaceuticals / Medical devices

The procedure for recalling pharmaceuticals is contained in the Ministry of Health Order No. 809, dated 22 November 2011 for Recall or for Temporary Suspension of Circulation of Pharmaceuticals. There is no separate procedure for recalling medical devices.

The decision on recall (or temporary suspension) is to be made by the State Service on Pharmaceuticals (which is an entity supervised by the Ukrainian Ministry of Health). Whether a recall or temporary suspension is instituted, the market authorization holder is notified with 1-2 days (depending on the seriousness of the violation) by email and the decision on recall/suspension is publicized promptly (eg, on the website of the Ministry of Health). If the defect is serious, the European Pharmaceutical Agency and the relevant authorities in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) countries will also be notified.

Food and drink

Under the Law On the Basics of Requirements of Safety and Quality of Foodstuffs of 1997, as amended, the products are deemed non-compliant if they are dangerous, unusable, wrongly marked, not registered (if required) or smuggled. Under Art. 20 of the Law, the operator (ie, the producer, the wholesaler or the importer of the products that are not compliant) should immediately withdraw a non-compliant product from the market and notify the relevant authority within two working days using the relevant notification form. If the product has already gone to consumers, the product should be immediately recalled (unless other measures for ensuring safety of consumers may be implemented) and the consumers notified of the reason.



If there are reasons to believe that a product may be dangerous to the health of consumers (as opposed to just non-compliant), the operator that introduced the product into the market must notify the authorities in writing within one day and describe the measures that have been implemented by the operator to prevent risks for consumers.

The decision about a recall can be made by the Chief State Inspector or by the Chief Veterinary State Inspector, in accordance with Part 4 of Art. 11 of the Law on the State Control for Compliance with the Legislation on Foodstuffs, Feeds, Derivative Products of Animal Origin, Health and Welfare of Animals.

Vehicles and their parts

If the manufacturer recalls a type of vehicle due to discovered defects that could create a danger to consumers, it must immediately notify the authorized body, according to Art. 13 of Order of the Ministry of Infrastructure No. 521, dated 17 August 2012.

There is no specific procedure or form of notice for such a recall and no specific state body has been named as the authorized body to launch an involuntary recall. Therefore, the most appropriate authority to be notified in case of a voluntary recall would be the Ministry of Infrastructure.

5. Legal consequences of noncompliance

Administrative liability

Although there is no specific liability for a failure to recall products, there are sanctions under the Consumer Rights Law for the manufacture or sale of defective or dangerous products and for failure to abide by the order of the authorities to cease and desist from infringing upon consumers' rights, either of which can be applied to both producers and sellers. The penalties range from 1% to 1000% of the cost of the noncompliant goods or the services rendered.

Meanwhile, the Code of Ukraine on Administrative Offenses provides for a fine ranging between UAH 17 and UAH 3,400 (USD 0.7 to USD 136) for the sale of any defective or dangerous goods. Both the General Safety Law and the Law On State Market Surveillance and Control of Nonfoodstuffs also provide for a system of administrative liability for noncompliance, the punishment for which is graded depending on the type, severity and character of the offense. Generally, such liability consists of a fine ranging between UAH 4,250 and UAH 85,000 (USD 170 to USD 3,400).

In addition, an importer of dangerous goods may be subject to a fine of 100% of the value of the dangerous goods sold in the Ukrainian market, in accordance with the Law On Securing Sanitary and Epidemiological Welfare of the Population dated 24 December 1994, as amended. It is not entirely clear from the wording of the relevant article whether this fine can be applied to the importer in the case of a voluntary recall of products.

In theory, it is therefore possible for multiple fines to be imposed under different statutes for the same violation, although this would be extremely unusual in practice.

Criminal liability

In addition, under the Criminal Code of Ukraine, the maximum penalty for the large-scale willful sale of defective products is a fine from UAH 8,500 to UAH 17,000 (USD 340 to USD 680), with deprivation of the right to occupy certain positions or to engage in certain activities for up to three years. Large-scale sale is defined as sales exceeding UAH 268,250 (USD 10,730).

Failure to recall the non-compliant products may result in a criminal fine between 30 and 38 times the Minimal Monthly Salary Amount (ie, between EUR 3,200 and EUR 4,050) on the operator.



United Arab Emirates

Federal Law No. 24 of 2006 Concerning Consumer Protection (the “Law”), supplemented by the Cabinet of Ministers’ Resolution (12) of 2007 in respect of Executive Regulation to the Law (the “Regulations”), are federal laws that govern the protection of consumers in the United Arab Emirates.

1. Definition of a “consumer product”

The Law defines a consumer product as “goods,” which means an industrial, agricultural, animal or converted product, including the primary components of the materials and ingredients that form the product.

The Regulations define a consumer product as “goods,” which include any industrial, agricultural, farm or recycled product, including raw materials and components or ingredients of the product. Further, the Regulations also contain a definition of “durable goods,” which are “goods that can be used or utilized for many years.”

2. Agencies involved in regulating consumer products

The UAE Ministry of Economy oversees the implementation of the Law. It has established a Consumer Protection Department (the “Department”) in charge of coordinating with the concerned authorities in the UAE in combating illegal commercial practices that harm consumers.

The Higher Committee for Consumer Protection (the “Committee”), established by the cabinet of ministers, consists of representatives of consumer protection societies in the UAE. The role of the Committee is to advise the minister of the UAE’s Ministry of Economy in relation to the protection of consumers in the UAE.

3. Reporting requirements and recall procedures

The Regulations provide certain rights to consumers, including the right of protection against products, production operations, or services causing harm to health or safety and the right of compensation for “inferior or unsatisfactory goods, or any practices harming consumers.”

Any concerned bodies, consumers or parties having an interest may apply to the Department for the recall of any defective products and may provide supporting evidence. The Department is required to investigate the content of the application and take any necessary action in this regard.

If the Department receives a complaint about a defect in products, it must open an investigation. Where it is established that such a defect exists, the Department must notify the provider to recall the products within the timeline specified by the Department, depending on the nature of the product.

Under the Regulations, a “provider” is defined as any natural or corporate person providing a service or information, or manufacturing, distributing, trading, selling, supplying or exporting any goods, or is involved in the production or the trading thereof.

A provider must recall products from the local markets in the UAE or consumers in the following events:

- A defect is found by the provider
- Reports or studies prove the presence of a defect in the products
- Complaints are received from consumers reporting defects in the products
- An official memorandum is issued by the UAE Ministry of Economy for the recall of the products



- Recall procedures are initiated anywhere outside the UAE for the same products
- It is established that the products are not in conformity with the specifications approved by the Emirates Authority for Standards & Specifications

The recall must be initiated within 24 hours if there is a “threat to consumers” (ie, a safety risk), or within 30 days in other cases. In practice, it is always advisable to initiate the recall as soon as possible.

The provider must notify the Department in writing no later than 14 days following any such recall. However, in practice, it is advisable to contact the Department as soon as possible and to adhere to any timelines that may be advised by the Department following the notification (which may be stricter or more generous than the deadlines specified in the Regulations, as the Department has a wide discretion). There is no specific format for the recall notice. However, it must include the following information:

- The name of the products and the provider and the country of origin
- A colored presentation (photo) of the products and the defective parts
- A detailed description of the defect and its causes
- The quantity sold and the quantity to be recalled
- The type and nature of the likely damage caused to consumers (if any)
- The procedures adopted by the provider to recall the products
- The manner of announcing the recall, together with the duration and timing of such announcements

- The procedures to be adopted by the provider in relation to the defective products
- The expected timeframe to remedy the defect, provided that the circumstances and interests of consumers are taken into consideration

The Department will then open a “recall file,” which must include the above information together with any other information or procedures it deems necessary in relation to the recall of the defective products, according to the type and nature of the products.

Under the Regulations, a provider is required to announce the recall of any defective products in accordance with the following conditions:

- (i) The provider must advertise the recall on the UAE Ministry of Economy’s website, and at least twice in two local daily newspapers, one of which must be issued in Arabic. In the case of a recall initiated by the Department, this must be done no later than 24 hours from being notified of the recall by the Department.
- (ii) The advertisement must not be less than 15 cm x 15 cm and must include the following:
 - The name and address of the provider
 - The trademark of the products in question
 - The name of the products and country of origin
 - A description of the defect
 - The instructions that consumers should follow to avoid any likely harm as a result of using the products
 - The instructions that consumers should follow to have the products repaired, replaced or their price refunded



The Department may also specify another medium, duration or timing for the recall of the defective products.

In the case of a recall of products, a provider is required under the Regulations to replace or repair the products, refund the price, or replace or repair the defective parts free of charge, regardless of the warranty period, according to the type and nature of the products and the defects. The provider must bear the costs of transporting the defective products, dispatching technicians to replace or repair the defective parts and all associated costs in respect of recalling the products.

Consumers are granted the right to select the manner of remedying any defective products, that is, replacement, repair or refund, provided that the type and nature of defective products together with the time to be taken in remedying the defect shall be taken into consideration. The consumer shall, according to the type and nature of the defective products together with the time to be taken in remedying the defect, be entitled to obtain substitute products free of charge until the remedial procedures are completed.

Prior to carrying out any repair or modification works to the defective products, the provider is required to notify customers in writing, and at no charge, of the estimated cost of repair and the validity period for the offer of repair. Following completion of the repair, the provider must issue an invoice and specify the replaced parts, the associated cost and whether such parts are new, used or overhauled. The provider must bear the cost of any labor charges and provide a warranty for the replaced parts. The warranty for electric and electronic products must not be less than three months, and not less than six months from the date of delivery following repair for durable products. In the case of the latter, the warranty is not required to cover any improper use of the products.

Within 30 days of recalling the product, a provider must provide a report to the Department on the products that have been repaired or replaced in whole or in part and/or those products for which the price

has been refunded. This report must include the following information: (i) the quantity sold; (ii) the quantity recalled; (iii) the quantity of products repaired, replaced or whose prices are refunded; and (iv) the procedures to be adopted to avoid such defect, if applicable.

The Department must, pursuant to authorization from the UAE's Minister of the Economy, carry out the procedures for recalling the defective products at the expense of the provider in the following events:

- Failure to take the recall procedures by the provider
- Reluctance or delay by the provider in carrying out the recall procedures in cases where it is believed that the defective products pose a likely risk of harm to consumers
- Difficulty in identifying or reaching the provider

The Department must also follow up on products being recalled within the UAE or abroad and regularly advise the Committee of the recall process taking place.

4. Product-specific regimes

Pharmaceuticals and medical devices

The UAE Ministry of Health is the federal body responsible for regulating pharmaceutical products and medical devices, with a key aim to ensure these products are not harmful.

Although the UAE Ministry of Health does not prescribe a specific recall process for defective pharmaceutical products and medical devices at the federal level, local health authorities in each Emirate have jurisdiction to legislate their own Emirate-specific product recall processes in the healthcare sector.

By way of example, the Health Authority Abu Dhabi (HAAD) has an established system for the recall of defective pharmaceutical products,



as set out in its ‘Policy for Recall of Drugs and Healthcare Products.’ The HAAD recall procedure categorizes dangerous/defective products into different classes. Depending on the relative risk that a given defect in a medical product presents to patients, this may result in bypassing all or parts of the recall process in order to expedite the recall.

Food and beverage

The UAE has a federal food safety law. In addition, each Emirate has a local regime for food standards. For example, in the Emirate of Dubai, the Food Safety Department is responsible for implementing the standards and has issued the ‘Food Code,’ which provides that food shall be recalled if it is found to be unacceptable, unsafe or non-conforming with the Islamic law and/or the norms and the traditions in the UAE. The Food Code also provides that food shall be recalled if any concerned health authority in the UAE issues a recall order for a specific product.

Similarly, the Food Control Authority in Abu Dhabi is responsible for monitoring the health and safety of food and has its own system of guidance and control.

Vehicles and their parts

There is no industry-specific body or authority entrusted with the recall of vehicles. The UAE’s Ministry of Economy is also entrusted with supervising the recall of vehicles and their parts. However, the UAE’s Ministry of Economy has been working with the key players in the vehicle industry to create a protocol for handling mechanical defects and recalls.

The UAE’s Ministry of Economy requires any safety defects to be reported within 24 hours of discovering the defect; any other less serious defects must be reported within 14 days of their discovery. The reporting requirement primarily applies to dealerships but may apply to manufacturers or other suppliers involved in the process.

5. Legal consequences of noncompliance

Without prejudice to any other penalties stipulated by any other UAE laws, any person who violates the provisions of the Law and the Regulations shall be fined at least AED 5,000.

In the event that the supplier of the product does not clearly warn against the risk of using the product, which then results in causing damage to the consumer, the fine imposed on the consumer shall be at least AED 10,000 and up to AED 200,000. In addition to such fines, the courts in the UAE may confiscate or destroy the product, or the materials and equipment used to produce the relevant product. The same penalties and consequences would apply to any defects found in vehicles and any of their spare parts.

Fines prescribed in the Law are doubled if the same violation is repeated within one year of committing the previous violation, provided that the penalty is not less than half of the limit specified according to the Law after doubling the fines.

The Department has a certain level of discretion as to whether these fines are to be calculated per incident or per non-compliant product sold. However, the usual practice is to calculate the fine per incident.

In the event of noncompliance with the relevant remedial and rectification periods specified in the Regulations, the minister may suspend the supplier from carrying out its activities for a period of up to one week and report the matter to the courts in the UAE with a view to closing down the supplier and disposing of the products that are the subject of the violation.



United Kingdom

The EU's General Product Safety Directive 2001/95/EC has been implemented into UK law by the General Product Safety Regulations 2005 (GPSR).

1. Definition of a “consumer product”

The GPSR does not specifically define “consumer product.” The GPSR demonstrates, however, that protection is intended to be given in relation to a wide range of products.

The GPSR applies to all new, used or reconditioned products which are intended for consumers or are likely, under reasonably foreseeable conditions, to be used by consumers (even if not intended for them), and which are supplied or made available in the course of a commercial activity, whether for payment or not. In addition, they apply to products that are supplied or made available to consumers for their own use in the context of providing a service.

The GPSR only applies, however, to the extent that the product in question is not subject to product or sector-specific legislation regarding safety. Examples of consumer products subject to specific safety legislation include the following:

- Toys (the Toys (Safety) Regulations 2011)
- Cosmetics (the Cosmetic Products Enforcement Regulations 2013)
- Low voltage electrical equipment (the Electrical Equipment (Safety) Regulations 2016)
- Fireworks (the Fireworks Regulations 2004, as amended)

Note though that if the product or sector-specific product safety legislation does not impose product recall-related obligations, the GPSR regime will apply if the product is a consumer product (as defined in the GPSR).

2. Agencies involved in regulating consumer products

Responsibility for enforcement of the GPSR and other related regulations in respect of most consumer products lies with local government authorities, primarily local Trading Standards in England, Wales and Scotland, and District Council Environmental Health Officers in Northern Ireland. Other agencies are responsible for enforcing the GPSR and certain other related legislation in respect of specific categories of consumer products, such as medical devices and food (see Section 4 below). Some businesses have the option to enter into a partnership with a local authority under the Primary Authority Scheme, giving them access to tailored advice, guidance and assistance from the local authority, including on product safety.

3. Reporting requirements and recall procedures

If a producer or distributor realizes it has placed an unsafe consumer product on the EU market or has supplied such a product in the EU, it must notify the competent authorities in the country or countries affected of the safety concern, together with the action it has taken to remove the risk to consumers. Strictly speaking, the notification must be sent to the relevant authorities of all EU Member States where the product has been marketed or supplied. In most cases involving consumer products placed on the market in the UK and/or by a company based in the UK, the competent authority will be the company's local Trading Standards Authority (however, see Section 4 below).

Notifications should usually be made using the European Commission's online procedure called the "Business Application" (see <https://webgate.ec.europa.eu/gpsd-ba/index.do>). A key element of the notification is a risk assessment. This can be prepared using the



European Commission's online tool at <https://ec.europa.eu/consumers/consumer-safety/rag/>, supported by the European Commission's guidance on risk assessments. The other main information that is required to be provided concerns the product, the hazard posed by the product and the corrective action being undertaken.

Where multiple EU Member States are involved, it is possible to ask a local competent authority to accept the notification as a single, EU-wide notification. In the case of the UK, if the local Trading Standards Authority Office and the Department for Business, Energy & Industrial Strategy (BEIS) agree to do so, the notification will be passed to BEIS for dissemination to all the relevant authorities across the EU, often via RAPEX.

In 2017, the UK government launched a new website with links to information about recent recalls (<https://productrecall.campaign.gov.uk/#check>), including a link to the following:

- The summaries of all notifications transmitted via RAPEX, which are published on a weekly basis and can be seen at http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/
- Details of recalls which are published on the Chartered Trading Standards Institute website at <https://www.tradingstandards.uk/consumers/product-recalls>

Notification is not required where the risk relates to a limited number of specifically identifiable products or isolated circumstances. However, in this case, the producer or distributor must have solid evidence to prove the risk is controlled and that its cause has been corrected.

Further information about when and how to make a notification can be found on the European Commission's website at http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf. BEIS is working with the British Standards Institution and industry participants and experts, including Baker McKenzie, to prepare a Code of Practice for Consumer product safety related recalls and other corrective actions, which is expected to be published in early 2018.

After notification is made, producers and distributors are required to cooperate fully with the relevant enforcement authority, including providing information about a product and the nature of the risk. Despite notification, they remain under an obligation to inform customers of any potential risks posed by their products that are not obvious and, if necessary, to provide instructions on the safe use of the product.

4. Product-specific regimes

Medicinal products and medical devices

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the regulatory authority for medicinal products and medical devices in the UK.

- **Medicinal products**

The Human Medicines Regulations 2012 (Regulations 37 and 38) sets out requirements for manufacturing license holders to comply with the requirements for good manufacturing practice in Directive 2003/94. Those requirements include implementing “*an effective system for recalling, promptly and at any time, medicinal products in the distribution network*” (further guidance is available on the European Commission website — https://ec.europa.eu/health/documents/eudralex/vol-4_en).



Similarly, a wholesale dealer license holder must comply with the requirements on good distribution practice (Regulation 43 of the Human Medicines Regulations 2012). The European Commission published a guideline on good distribution practice (2013/C 343/01), which provides, for example, that the effectiveness of recall arrangements should be evaluated regularly and should be capable of being initiated promptly and at any time.

There is a dedicated unit within the MHRA which deals with recalls of medicinal products, the Defective Medicines Report Centre (DMRC). The DMRC should be notified immediately once investigations have identified a defect that could result in recall or other restrictions on supply. The DMRC has a dedicated email address and hotline. Contact can also be made with the DMRC out of office hours via the MHRA duty officer.

The MHRA categorizes risks associated with medicinal products into three main categories and the risk classification affects how the recall may be carried out. Depending on the circumstances, for example, the nature of the risk and the likely number of customers affected, the DRMC may issue a drug alert to support recall action. Drug alerts are generally circulated to a number of contacts to be forwarded to healthcare professionals and are usually published on the MHRA website shortly afterwards.

Further guidance is available at the following link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403210/A_guide_to_defective_medicines.pdf.

- **Medical devices**

The MHRA adopts the EU term “Field Safety Corrective Action” (FSCA) to encompass recalls and related warnings for medical devices, and encourages manufacturers to comply with the FSCA reporting guidance contained in the European Commission’s MEDDEV 2.12. Guidance

(<https://www.gov.uk/government/collections/medical-devices->

[guidance-for-manufacturers-on-vigilance](#)). The MHRA operates a Manufacturers' Online Reporting Environment called MORE for medical device manufacturers and suppliers to electronically submit vigilance reports and respond to MHRA incident investigations (<https://aic.mhra.gov.uk/>).

The MHRA also operates a Yellow Card Scheme for reporting by healthcare professionals and patients of possible adverse effects of medicines and medical device adverse incidents (<https://yellowcard.mhra.gov.uk/>).

Food

The GPSR does not apply to food products, which are separately regulated. The Food Standards Agency (FSA), working in conjunction with local authorities, is responsible for food safety and food hygiene in the UK.

Article 19 of Regulation (EC) 178/2002 on General Food Law provides that where a food business operator considers or has reason to believe they have placed food on the market that is or may be injurious to human health, it must immediately notify the relevant competent authorities (eg, the FSA in England). Article 19 also sets out obligations in relation to the withdrawal and recall of food products. Food business operators are required to withdraw food from the market where it does not comply with food safety requirements. Further, they must recall products already supplied to consumers where other measures are not sufficient to achieve a high degree of health protection.

The FSA's Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall (2007) provide further guidance (<https://www.food.gov.uk/sites/default/files/multimedia/pdfs/fsa1782002guidance.pdf>). The FSA also operates an online system for notification of food incidents (<https://www.food.gov.uk/business-industry/food-incidents#toc-2>).



Motor vehicles and their components

The Driver and Vehicle Standards Agency (DVSA) is the authority in the UK that deals with product safety issues in the automotive sector.

The DVSA has published two codes of practice and separate guidance in relation to product safety.

- One Code of Practice sets out what should happen when manufacturers become aware of potential safety defects in vehicles available for supply (<https://www.gov.uk/government/publications/code-of-practice-on-vehicle-safety-defects-and-recalls>)
- A second Code of Practice sets out what should happen when manufacturers become aware of potential safety defects in aftermarket parts available for supply in the UK (ie, parts to be fitted to a vehicle after it has left the manufacturer's production line) (<https://www.gov.uk/government/publications/code-of-practice-on-safety-defects-and-recalls-vehicle-aftermarket>)

Both Codes of Practice provide guidance on notifying and engaging with the DVSA in relation to “safety defects” (ie, a failure due to design and/or construction that is likely to affect the safe operation of the product without prior warning to the user and may pose a significant risk to the driver, occupants and others).

Further, the DVSA Manufacturers' Guide to Recalls in the Automotive Sector (2014) provides a best practice guide to assist producers and distributors in the construction and execution of a recall (<https://www.gov.uk/government/publications/manufacturers-guide-to-recalls-in-the-uk-automotive-sector>).

5. Legal consequences of noncompliance

Breach of the various duties and obligations imposed on producers and distributors by the GPSR constitutes a criminal offense. For breach of the general safety duty (which includes the duty of a

producer not to place an unsafe product on the market), the maximum penalty is GBP 20,000 and/or 12 months' imprisonment.

For lesser offenses under the GPSR, the maximum penalty is an unlimited fine and/or three months' imprisonment. In addition, a producer or distributor who fails to make a notification to an enforcement authority when required to do so, or who breaches any of his/her specific duties, may face a maximum penalty of three months' imprisonment and/or an unlimited fine.

If the offense is committed by a company or corporate body, that body will be liable. However, if the offense is committed with the consent or connivance of any director, manager, secretary or other similar officer of the corporate body or is attributable to the neglect of a person in such a position, that individual is also guilty of the offense, along with the corporate body.

The consequences for failing to comply with product or sector-specific requirements vary. However, failure to comply with the relevant legislative requirements for many products is a criminal offense. For example, placing an unsafe food product on the market can result in a fine and/or a prison sentence of up to two years.

Sources of information

The UK government set up a Working Group to review the product recall and product safety regime in the UK. The Working Group is made up of experts in the fire service, trading standards, consumer groups and industry. Kate Corby and John Leadley (both Partners at Baker McKenzie) are members of the Working Group. One of the Working Group's recommendations was to work with the British Standards Institution to create a Code of Practice for businesses and regulators on best practice for corrective action (<https://www.gov.uk/government/publications/report-to-margot-james>). At the time of writing, preparation of the Code of Practice is underway (see further Section 3 above).



The UK government and the UK Chartered Trading Standards Institute have produced high-level guidance for producers and distributors about product safety (<https://www.businesscompanion.info/en/quick-guides/product-safety/general-product-safety-producers> and <https://www.businesscompanion.info/en/quick-guides/product-safety/general-product-safety-distributors>).

More detailed guidance is available from the European Commission — see the European Union chapter.

United States

The safety of general consumer products is governed at the federal level by the Consumer Product Safety Act (CPSA), which is enforced by the Consumer Product Safety Commission (CPSC). The CPSC has also issued regulations pursuant to the CPSA that provide more guidance as to the general rules related to product safety and when and how to engage in a consumer product recall. In August 2008, the CPSA was amended by the Consumer Product Safety Improvement Act (CPSIA), which imposed new regulations, empowered the CPSC with enhanced resources, increased civil penalties and created new enforcement tools. Years later, the CPSC continues to clarify these new regulations as it continues to implement the requirements mandated by the United States Congress.

Other federal and state laws coexist with the CPSA, but can affect whether a consumer product must be recalled or withdrawn or a corrective action taken.

Additionally, other federal agencies have product safety or recall regulations applicable to specific categories of consumer products, over which the CPSC does not have jurisdiction.

The US Food and Drug Administration (FDA) regulates food, cosmetics, consumer medical devices (such as toothbrushes), over-the-counter health products (such as sunscreens), and components or accessories of these products pursuant to the Food, Drug, and Cosmetics Act (FDCA). While the FDA technically has limited direct recall authority, products with defects are considered “adulterated” or “misbranded” and are subject to FDA’s seizure authority; and, in some cases, failure to voluntarily recall can result in civil or criminal penalties.

The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture regulates the safety and recall of farmed animal products except shell eggs. FSIS oversees voluntary recalls of these products, and has a variety of enforcement options available to it.



The National Highway Traffic Safety Administration (NHTSA) has statutory enforcement authority over motor vehicle and motor vehicle equipment defects and noncompliance pursuant to the Federal Motor Vehicle Safety Act (FMVSS). This authority also includes a variety of enforcement options, ranging from civil enforcement actions to mandatory recalls.

1. Definition of a “consumer product”

The CPSA defines a consumer product as any article or component part thereof produced or distributed: (1) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; or (2) for the personal use, consumption or enjoyment of a consumer in and around a permanent or temporary household or residence, a school, in recreation, or otherwise. The CPSA excludes from this definition “any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer.” The CPSC has explained that in determining whether the product is a consumer product, the manufacturer of the product has the responsibility to determine distribution and use patterns, and any doubts should be resolved in favor of considering the product to be a consumer product.

Excluded from this definition are certain products under the jurisdiction of other federal agencies, including automobiles, food and pharmaceuticals or medical devices. As explained in section 4 herein, the safety of such products and any recall procedures to correct unsafe products in the market are governed by other federal statutes and overseen by other federal agencies.

The CPSC broadly interprets the term “consumer product.” The CPSC has overseen recalls involving consumer products ranging from drywall to baby cribs, power tools to fire suppression systems, and software used to operate such products.

The CPSA, as amended by the CPSIA, devotes special attention to the category of children’s products. The CPSIA defines a children’s

product as “a consumer product designed or intended primarily for children 12 years of age or younger.” In determining whether a consumer product is primarily intended for a child 12 years of age or younger, the following factors may be considered:

- Whether the manufacturer provides a statement about the intended use of the product, and an age label or age grading, if it is reasonable
- Whether the product and its packing designs are primarily intended to appeal to a child 12 years of age and younger
- Whether the product is represented in its packaging, display, promotion or marketing/advertising as appropriate for use by children 12 years of age or younger
- Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger
- The Age Determination Guidelines issued by the CPSC in September 2002 and any successor guidelines

The CPSIA amended the CPSA to subject consumer products, particularly children’s products, to increased product safety regulations. The amendments include: lead and phthalate limits; mandatory third-party testing by a CPSC-accepted laboratory of children’s products to ensure compliance with all applicable product safety regulations; mandatory tracking information on both the product and packaging for children’s products; and mandatory toy safety standards, addressing such risks as accidentally ingestible parts and sharp edges.

2. Agencies involved in regulating consumer products

The CPSC has jurisdiction over general consumer product safety and consumer product recalls. As detailed further in section 4, other agencies have jurisdiction over specific categories of products, such as the NHTSA for motor vehicles, the FDA for food, drugs, medical



devices, cosmetics and components or accessories of these products, and the Department of Agriculture for farmed meat and poultry food products other than shell eggs.

3. Reporting requirements and recall procedures

Section 15(b) reports

The CPSA establishes reporting requirements for manufacturers, importers, distributors and retailers of consumer products, or other products over which the CPSC has jurisdiction under any Act, distributed in commerce. Each such entity must give notice to the CPSC if that party obtains information that reasonably supports the conclusion that the product:

- Fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the CPSC has relied under the CPSA
- Fails to comply with any other rule, regulation, standard or ban under the CPSA or any other Act enforced by the CPSC
- Contains a defect that could create a substantial product hazard to consumers
- Creates an unreasonable risk of serious injury or death

While the specific language for consumer products not within the jurisdiction of the CPSC may vary, the principle of evaluation of defects in design, labeling, or manufacture for health hazards is universal. Factors to consider when determining if a product is defective include: (1) the utility of the product involved; (2) the nature of the risk of injury that the defect presents; (3) the importance of the product; (4) the population exposed to the product and its risk of injury; (5) the obviousness of the risk; (6) the adequacy of warnings and instructions to mitigate such risk; (7) the role of consumer misuse of the product and the foreseeability of such misuse; (8) known experience and expertise with the product; (9) case law in the area of

product liability; and (10) other factors relevant in the determination, including information about patterns of consumer use of the product.

A “substantial product hazard” is defined in the CPSA as “a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.” The term also includes a failure to comply with any Act administered by the CPSC, which includes the CPSA, the Federal Hazardous Substances Act, the Poison Prevention Packaging Act, the Flammable Fabrics Act and the Refrigerator Safety Act, if such failure creates a substantial risk of injury to the public.

Pursuant to federal regulations, a manufacturer should report to the CPSC “immediately” or within 24 hours of receiving information that reasonably supports the conclusion that it has a reporting obligation. Information giving rise to a reporting obligation may include complaints, claims for damage, injury or incident reports, quality control, production and engineering data, safety-related production or design changes, and requests for returns, replacements or credit. The timing of reports for other consumer goods to other agencies is comparable permitting many companies that have multiple lines of consumer products to institute corporate wide policies.

A company must consider information from US and ex-US marketing and post-marketing experience if the ex-US product is the same. The CPSC considers manufacturers to have knowledge of product safety information when such information is received by an employee or official of the company who may reasonably be expected to be capable of appreciating the significance of that information. Many companies have developed employee training on internal reporting systems to ensure that relevant information about product safety is assessed appropriately. According to the CPSC, under ordinary circumstances, five days is the maximum reasonable time for that information to reach the individual or individuals responsible for complying with CPSC reporting requirements.



Information on consumer complaints may also come from the CPSC or other federal regulatory agencies that receive consumer complaints. Consumers have the ability to report an unsafe or potentially unsafe product to the CPSC through [SaferProducts.gov](https://www.saferproducts.gov). Companies will be notified of any complaint about their product, and have the ability to publicly respond on the database. Companies should consider any reports published on the database when assessing whether a substantial product safety issue exists and whether notification under section 15(b) is required.

If information received by a manufacturer regarding the product is not deemed reportable based on the initial assessment, the manufacturer is permitted to conduct a “reasonably expeditious” investigation to evaluate the reportability of the information received. This investigation and evaluation should not exceed 10 days unless the manufacturer can demonstrate that a longer period is reasonable. The CPSC will deem that, at the end of the 10 days, the manufacturer has received and considered all information that would have been available to it had a reasonable, expeditious and diligent investigation been undertaken. If the manufacturer elects to conduct an investigation, the 24-hour period begins when the company has information that reasonably supports reportability. In evaluating whether or when a company should have reported, the manufacturer will be deemed to know what it would have known if it had exercised due care to ascertain the truth of complaints or other representations.

The purpose of the drafters in enacting the reporting requirements under section 15(b) of the CPSA was to encourage the reporting of potential product hazards. The CPSC often uses sources other than company reports to identify potentially hazardous products, but reporting by companies under section 15(b) remains the most timely and effective source of information about such products. The rationale is that the reporting company often learns of potential product safety problems at an early stage. For this reason, companies involved in the manufacture, importation, distribution or sale of consumer products should develop a system for maintaining and reviewing information

about their products that might suggest a product defect or an unreasonable risk of serious injury or death. Such information includes consumer complaints, warranty returns, insurance claims or payments, lawsuits, reports of production problems, product testing or other critical analyses of products and the like.

The CPSC encourages companies to report even if in doubt about whether a defect exists, or if in doubt about whether a defect could create a substantial product hazard. A firm's reporting requirement is triggered by a product's potential harm, and reporting should be made when a company believes that the potential exists, even if there has not been any actual injury.

Reporting a product to the CPSC under section 15(b) does not automatically mean that the CPSC will conclude that the product creates a substantial product hazard or that corrective action is necessary. Rather, following a section 15(b) report, the CPSC staff will evaluate the report and work with the reporting company to determine if corrective action is necessary.

To make this determination, the CPSC staff undertake a product hazard analysis similar to that requested of the reporting companies. Once the staff identify a defect, they then apply the criteria set forth in section 15(b) to assess the substantiality of the risk presented to the public. The staff apply hazard priority standards to classify the severity of the problem and can then make a preliminary determination that the product contains a defect that creates a substantial product hazard.

If corrective action to correct a hazard is deemed to be necessary, the company must develop a comprehensive plan that reaches throughout the entire distribution chain to consumers who have the product. The resulting plan will need be approved by the CPSC. The goals of a corrective action plan (CAP) are:

- Stop production and further distribution of affected products



- Locate all affected products as quickly as possible
- Remove the affected products from the distribution chain and the possession of the consumers
- Communicate accurate and understandable information in a timely manner to the public about the product defect, the hazard and the corrective action

Notice is a critical aspect of recalls. Notice should be made as soon as practicable to the distribution chain, including retailers, to stop further distribution of affected products. Notice to consumers must be made in a way designed to reach those with affected products and motivate people to respond to the recall by taking the action requested by the company. Companies are encouraged to use multiple notification approaches to optimize the effectiveness of the recall. Common notification methods include press releases, postings on company websites, direct mailings and email, point-of-sale notices, blog posts and social media. It is common for the CPSC to expect companies to post recall information on the company website and/or online application, and on all forms of social media utilized by the company, including Facebook, Google, Twitter, YouTube, Instagram, and Pinterest, among others. The CPSC expects companies to maintain a toll-free telephone line for consumers to contact the company about the recall.

The CPSC will issue a press release about a product recall, which it seeks to do jointly with the company. The CPSC will negotiate with the company about the language of the press release, but if no agreement can be reached, it will issue its own press release. The CPSC also utilizes its own social media to notify the public about product recalls.

The CPSC monitors the efficacy of all recalls by requiring that the reporting company provide a monthly progress report for the CAP, in which the company identifies the products corrected and captured by the company during the reporting period, the notification measures

used during the reporting period, the consumers' feedback as to how they learned of the recall, and a listing of the number of consumer contacts made to the company via toll-free numbers, email, social media, written requests and website visits. The CPSC reviews these reports to assess the effectiveness of the CAP and to identify additional measures to be taken by the company if the CAP is not meeting the goals of a recall — to retrieve, repair or replace affected products.

Fast track recall program

A company that files a section 15(b) report may opt to follow an alternative procedure known as a Fast Track Recall, which the CPSC established primarily to expedite recalls. Under the Fast Track Product Recall program, if the company reports a potential product defect and, within 20 working days of the filing of the report, implements with the CPSC a consumer-level voluntary recall that is satisfactory to the staff, the CPSC staff will not make a preliminary determination that the product contains a defect that creates a substantial product hazard. The purpose of the program is to allow the staff and the company to work together on an immediate CAP rather than spending the time and other resources necessary to investigate a reported defect further to determine whether it rises to the level of a substantial product hazard.

In order to participate in the program, the reporting company must:

- Provide all of the information required for a full report
- Request to participate in the program
- Submit a proposed CAP with sufficient time for the CPSC staff to analyze any proposed repair, replacement or refund offer and to evaluate all notice materials before the implementation and announcement of the CAP, which is to occur within 20 working days of the report

Once the CPSC staff and the company agree on the CAP and approve all notice materials, they work together to compose an effective plan



for public notification and implementation of the recall. The plan includes the company's agreement that the CPSC may publicize the terms of the plan to the extent necessary to inform the public of the nature of the alleged substantial product hazard and the actions being undertaken to correct the hazard.

For companies that conclude early that a recall is necessary, a Fast Track Recall is likely to be the recommended procedure. This procedure allows the company to implement the recall quickly, by getting CPSC approval on the recall logistics and CAP as soon as possible.

Section 37 reports

In addition to reporting potential defects, a manufacturer is also obligated to report to the CPSC under section 37 of the CPSA if: (1) a particular model of a consumer product is the subject of at least three civil actions in federal or state court; (2) each suit alleges the involvement of that model in death or grievous bodily injury; and (3) at least three of the actions resulted in a final settlement involving the manufacturer or in a judgment for the plaintiff within specified two-year periods. A manufacturer must file a report within 30 days after the settlement or judgment in the third civil action to which the section 37 reporting requirement applies.

4. Product specific regimes

Prescription drugs, over-the-counter personal health care products, foods and related food items, beverages, and consumer and prescription medical devices

The US Food and Drug Administration (FDA) has standard guidelines that apply to recalls of all products within its jurisdiction (21 C.F.R. Part 7 Subpart C). The FDA has regulatory authority over cosmetics, food other than from farm animals, over-the-counter healthcare products (such as sunscreens), medical devices, which include consumer goods such as toothbrushes, radiation-emitting devices (eg, cell phones or microwaves), biologics, human cellular and tissue-

based products (HCT/P), and e-cigarettes and traditional tobacco products. There are also product specific standards for mandatory recall of certain FDA-regulated articles. For instance, the FDA has no statutory authority to order a cosmetic recall, although it does have such statutory authority over other products in certain limited settings. For example, for many products, including food, drugs, and medical devices, the FDA also has the authority to order a recall to protect the public health from products that present a reasonable probability of causing a serious adverse health consequence or death.

FDA-regulated products and labeling that have defects are considered adulterated or misbranded, and are subject to recall. As an example, food is adulterated when it is impure, unsafe or unwholesome; contains a pathogen, a foreign material, an unapproved food additive, a chemical or physical hazard, an undeclared allergen or is simply not manufactured to required standards, such as sanitation, even when a pathogen is not detected. Food may also be misbranded if it is mislabeled or adulterated if it has a packaging defect.

The FDA has the authority to seize adulterated or misbranded products in lieu of a company conducting a voluntary recall on its own initiative or upon agency request. In practice, however, almost all recalls of FDA products are conducted voluntarily by the manufacturer in cooperation with the FDA after notification of the agency. Discussions with the FDA most often result in an FDA request for a voluntary recall in lieu of the FDA's direct notification of the public of a product-related defect or a threatened court action.

The FDA can also impose an import alert on reasonable suspicion of a health hazard, among other violations. It can also criminally prosecute companies or individuals for failing to remove or otherwise cease distribution of adulterated or misbranded products. The FDA can and does issue warnings requesting recalls of products that contain false, misleading or unbalanced claims to beneficial health effects, or for other reasons, such as failing to meet manufacturing standards.



Medical device manufacturers and importers are required to report a correction or removal of a medical device if it involves a “risk to health” as defined by FDA regulation. The report must be submitted to the FDA within 10 working days from when the company “initiates” (as interpreted by the FDA) the correction or removal of the medical device. If there is not a “risk to health” involved in the correction or removal, a report to the FDA is not required, but the manufacturer or importer must keep certain records of the recall (correction or removal).

Where a risk to health is involved, manufacturers and importers must notify the FDA’s relevant district office of the medical device correction or removal. Foreign manufacturers should contact the FDA District Office that covers the geographic location where its US agent resides. The content of notifications is similar to those required by the CPSC.

All companies conducting recalls of FDA-regulated articles should develop a recall strategy with specified components. The FDA will conduct and/or request the submission of a health hazard evaluation (HHE), which is used to determine the recall classification. Recalls overseen by the FDA are put into one of three classes:

- Class I (in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death)
- Class II (in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote)
- Class III (in which use of or exposure to a violative product is not likely to cause adverse health consequences)

The HHE examines a number of different risk factors, which results in a classification that reflects the severity and likelihood of the risk to

the public. The recall strategy also includes an assessment of the depth to which the recall applies, ie, to the distributor, retailer or consumer. A communication and effectiveness strategy should be developed and submitted to the FDA for approval. Recall effectiveness check plans should also be established. The FDA posts all recalls on its website. The FDA maintains a publicly searchable database of recalls. Direct notification of consignees and consumers is the norm for FDA recalls but, where it is not possible because the consignee or consumer identities are not known, a press release and additional notification efforts via the internet or social media may be requested or required. The FDA also uses the news media to publicly share information about Class I recalls, if it deems it necessary.

The FDA has piloted a program whereby consumers may be notified of a drug recall before the recall is classified, as the evaluation can take time to complete.

Companies should have a standard operating procedure that sets forth its recall strategy, including its assessment of the effectiveness of the recall. For most of the regulated industry, manufacturers must have unique product identifiers or lot identification to facilitate the effective recall of all affected lots. Maintaining sufficient product distribution records makes tracing the location of products easier as well. Recent statutory enactments related to prescription drugs require monitoring of all lots from when they depart the manufacturing site to when they are received by consumers to prevent entry of substandard products into the distribution chain, and to facilitate initiation of a national recall of all affected lots to the consumer within 48 hours. Under recent food safety legislation, recall procedures must be tested in advance of an actual recall.

Farmed animal products (except shell eggs)

The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture is responsible for overseeing recall of farmed animal products except shell eggs. While such meat recalls are generally voluntary, initiated by a food manufacturer to remove food from the



market that pose a risk to public health, notification of FSIS is also required.

As with the FDA, meat that is adulterated or mislabeled is subject to recall. Moreover, as with the FDA, meat that is not produced in compliance with manufacturing standards is considered adulterated even if no specific hazard has been identified in the meat. FSIS expects companies to identify these hazards by establishing a hazard analysis and critical control point system under which all potential chemical, physical and micro-biological hazards are identified, and controlled through standard operating procedures which are evaluated for effectiveness in the control of the potential hazard. For instance, microbiological testing that detects non-pathogenic microorganisms that derive from fecal contamination or the detection of uncontrolled coprophilic insects or rodentiae automatically make all products manufactured in the plant adulterated and subject to recall.

FSIS has adopted the same process to classify the severity of a meat or poultry recall following a health hazard evaluation, as well as the depth and level of required effectiveness evaluation. FSIS oversees the recall process to assist the company in ensuring that appropriate actions are taken to protect public health.

FSIS is authorized to take administration actions that can require a recall. Such actions are rare, but may be necessary if, for example, a company refuses to recall a food that may pose a significant health hazard.

Vehicles and their parts

Recalls of motor vehicles and their parts are governed by the NHTSA. NHTSA oversees and implements the National Traffic and Motor Vehicle Safety Act (MVSA) and has the authority to issue vehicle safety standards. NHTSA can also require manufacturers to recall vehicles for safety-related defects or noncompliance with federal safety standards.

NHTSA has promulgated the Federal Motor Vehicle Safety Standards (FMVSS). These standards set minimum performance requirements for parts that most affect safe operation (brakes, tires, lighting) and for parts that protect from death and serious injury in the event of a crash (air bags, safety belts, child restraints, energy absorbing steering columns, motorcycle helmets).

A recall is required when:

- A motor vehicle or item of motor vehicle equipment (including tires) does not comply with the FMVSS
- There is a safety-related defect in the vehicle or equipment
- A defect is “any defect in performance, construction, a component, or material of a motor vehicle or motor vehicle equipment”
- A defect is safety-related if it:
 - poses a risk to motor vehicle safety; and
 - exists in a group of vehicles or equipment of the same design/type and manufacture

Notice is almost always provided by the vehicle manufacturer. The OEM or replacement equipment manufacturer may have an independent duty to report if the vehicle manufacturer fails to do so. The reporting typically occurs electronically through a “Defect and Noncompliance Information Report” filed electronically. This report is to be filed within five days after deciding a safety defect/noncompliance exists. Notification is not to be delayed if the cause of the defect is not yet identified or a remedy for the issue is not yet determined.

In addition to NHTSA notification requirements, notification of the defect or noncompliance also must be given to owners, purchasers and dealers. Notifications are to be mailed within a reasonable time, but no



later than 60 days after initial report is made to the NHTSA. NHTSA approves all notifications, and expects to identify the defect, describe the risk to motor vehicle safety and outline the remedy available and when it is available. A remedy is typically a repair, replacement or refund (less a reasonable amount of depreciation). The remedy must be free of charge to the consumer. It also may not be immediately available, but that delay should not impact the company's report to NHTSA or its notification efforts.

NHTSA generally oversees implementation and effectiveness of a recall. It may also investigate the root cause and/or adequacy of the remedy proposed. Safety recall information is public through NHTSA's website and its automobile safety hotline.

5. Legal consequences of noncompliance

CPSC

The CPSC can impose civil penalties on manufacturers for failing to report in a timely fashion as required by the CPSA. In addition to untimely reporting, the CPSIA expanded the prohibited acts that may result in the imposition of a civil penalty, from failing to comply with certification requirements to exporting a product that is subject to a voluntary or court-ordered recall in the United States. The CPSIA also increases the maximum civil penalty to USD 10,000 (from USD 8,000) for each violation, and increases the maximum total civil penalty to USD 15,150,000 (from USD 1,825,000). A violation of any prohibition under the CPSA, including selling banned hazardous substances or selling products not in conformity with any applicable consumer product safety rule under the CPSA, is considered a separate offense with respect to each consumer product involved, except that the maximum civil penalty shall not exceed USD 1,250,000 for any repeated series of violations.

The CPSC has issued guidance on the factors that the CPSC may consider in evaluating the appropriateness and amount of civil penalty. Those factors include: (1) the nature, circumstances, extent

and gravity of the violation, including the nature of the product defect or the substance; (2) the appropriateness of the penalty in relation to the size of the business or of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and (3) other factors as appropriate. These factors are in addition to the factors already required to be considered: the severity of the risk of injury; the occurrence or absence of injury; and the number of defective products or the amount of substance distributed. Since the CPSIA's enactment, the CPSC has imposed significant civil penalties — including one civil penalty totaling the maximum amount possible — against companies. The CPSC cited a variety of factors in each instance, from repeated failures to timely report, to the severity of the risks associated with the product defect.

In addition to civil penalties, the CPSA grants the CPSC relatively broad powers to enforce the mandate to ensure that consumer products are made safe for the public. For instance, whenever the CPSC finds that a consumer product presents an unreasonable risk of injury and that no feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with the product, the CPSC may promulgate a rule declaring such product a banned hazardous product. The CPSC has used this power to ban products, such as a backyard game called “lawn jarts” involving sharp, pointed dart-like objects that could cause puncture wounds. The CPSC has also promulgated safety standards for lawnmowers, bicycle helmets, automatic garage door openers and, recently, bunk beds and identified drawstrings in children's apparel as a substantial product safety hazard.

Following a requirement to consider safety standards for durable infant and nursery products, the CPSC has implemented safety standards for baby cribs, bed rails, bath seats, infant walkers, play yards, portable hook-on chairs, infant sling carriers and infant bath tubs, and is considering other safety standards for children's products.



The CPSC also has the authority under the CPSA to embargo and prevent the distribution of consumer products within the United States if the CPSC determines that a product has and creates a substantial risk of injury to the consuming public. The CPSC works closely with US Customs and Border Protection (CBP) to support activities at the border aimed at preventing unsafe products from entering the US market. CPSC inspectors work at major ports alongside CBP inspectors and actively test and quarantine products found to be non-compliant with applicable regulations.

If a manufacturer continues to market a product that the CPSC has determined is hazardous to the consuming public, the CPSC has the authority to obtain federal court orders to prohibit the continued sale of the product and to impose both civil and criminal penalties upon those individuals and corporations who defy the CPSC's orders and reporting requirements. If the CPSC determines that a product is "imminently hazardous," the CPSC is no longer required to hold a trial-type hearing to order a stop sale or recall. After filing a court action, the CPSC can also stop distribution of the product and order all parties in the distribution chain to stop distribution and sale.

Criminal penalties, whistle-blower protections and state attorney-general actions are also available. The CPSIA lowers the threshold requirements the government must meet in seeking to impose criminal penalties. Significantly, the CPSIA removes the requirement that directors, officers and agents be aware of violations before being criminally charged; the statute also authorizes the forfeiture of assets associated with a violation. In addition, the CPSIA created whistle-blower protection for employees who report violations, testify or otherwise provide assistance in consumer product safety enforcement proceedings, or who refuse to participate in illegal conduct. The CPSIA also expressly empowers state attorneys general with the authority to seek injunctive relief, including court orders stopping sales of banned hazardous substances and children's products that lack tracking labels. However, the state attorneys general are not authorized to enforce reporting requirements.

Finally, it is unlawful to sell a recalled product, which includes recalls based on a defect, substantial product hazard or banned product. Criminal enforcement against violators has occurred in the past.

FDA

The FDA has a number of enforcement options available. It frequently issues Warning Letters that identify the noncompliance and request a change in the company's behavior. Requests for recalls often accompany a Warning Letter. The FDA can also take steps to seize a product because it is adulterated and/or misbranded, viewing voluntary recall as an alternative to seizure. The purpose of such an action is to remove the specific violative goods from commerce. Similarly, the FDA can seek an injunction from a court that requires an individual or corporation to do or refrain from doing a specific act. The FDA may seek injunctions against individuals and/or corporations to prevent them from violating or causing violations of the federal laws overseen by the FDA, or to conduct a recall.

The FDA may also seek civil monetary or criminal penalties under certain circumstances related to the failure to recall a product or the failure to comply with FDA requirements, which leads to product adulteration or misbranding.

USDA/FSIS

FSIS uses what are known as Product Control Actions to gain physical control over products when there is reason to believe that they are adulterated, misbranded or otherwise in violation of federal food safety laws. These actions are designed to ensure that those products do not enter commerce or, if they are already in commerce, that they do not reach consumers.

Product Control Actions include retentions and condemnations of products that may be misbranded or adulterated, or livestock that may be harmful to human food. FSIS also detains or seizes products that may be adulterated, misbranded or otherwise in violation of the law when found in commerce. Most detentions result in voluntary action,



such as voluntary disposal of the product by the product owner or custodian. If a detained product cannot be disposed of within 20 days, then the FSIS may request through a court action that an order be entered to seize the product. Similarly, if a company refuses to voluntarily recall its products, then the FSIS has the legal authority to detain and seize those products in commerce.

NHTSA

NHTSA has broad statutory enforcement authority over motor vehicle and motor vehicle equipment defects and noncompliance with the FMVSS. This authority includes investigations, administrative proceedings, civil penalties and civil enforcement actions. NHTSA can also order a mandatory recall if it determines that a defect that poses an unreasonable risk to motor vehicle safety exists. It may also seek a recall when a vehicle or its equipment does not comply with an applicable motor vehicle safety standard. Although exercised for the first time recently, NHTSA also has the authority to seek accelerated recall repairs if it deems that a manufacturer's remedy plans are likely to put Americans at risk.

As is the case with the CPSC, the bulk of NHTSA's enforcement activity is through the issuance of civil penalties. The civil penalty amounts available to NHTSA increased in 2016. The penalty for a single violation of the Motor Vehicle Safety Act was increased from USD 7,000 to USD 21,000, with the civil penalty cap for a series of similar events increasing from USD 35 million to USD 105 million. Civil penalty amounts in the tens of millions have been issued for failing to timely report defects, continuing to sell unrepaired defective vehicles, failing to notify NHTSA of motor vehicle incidents involving death and/or serious bodily injury and/or foreign safety recalls, and failing to adequately remedy defective vehicles.

Sources of information

The CPSC, FDA, USDA/FSIS and NHTSA all have publications and guidance documents available on their respective websites addressing

recall reporting obligations, and providing guidance on how to perform a recall. For example, the CPSC has published the Recall Handbook, which is a guide for manufacturers, importers, distributors and retailers on reporting under sections 15 and 37 of the CPSA and in preparing for, initiating and implementing product safety recalls. In addition, the Recall Handbook and CPSC website include recall checklists, website notification guidelines, sample safety recall posters, sample recall letters and press releases, and guidance on monthly progress reporting for corrective action plans.

Consumer Product Safety Commission

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Bethesda, MD 20814

Tel: +1 301 504 7923

Website: www.cpsc.gov

US Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Tel: +1 888 463 6332

Website: www.fda.gov

Food Safety and Inspection Service

US Department of Agriculture

1400 Independence Ave., S.W.

Washington, DC 20250-3700

Tel: +1 202 720 2791

Website: www.fsis.usda.gov/wps/portal/fsis/home

National Highway Traffic Safety Administration

1200 New Jersey Avenue, SE

Washington, DC 20590

Tel: +1 888 327 4236

Website: www.nhtsa.gov



Venezuela

The main law applicable to consumer product recalls is the Organic Law on Fair Prices (OLFP), published in Official Gazette No. 40.787 dated 12 November 2015, and the administrative practice derived from the repealed 2010 Law for the Defense of People’s Access to Goods and Services (the “2010 Consumer Protection Law”).

1. Definition of a “consumer product”

There is no definition of a “consumer product” under Venezuelan law. Under the Venezuelan Quality System Law (the “Quality Law”) published in Official Gazette No. 37.555 dated 23 October 2002, “product” is defined as the result of a process. A process is a set of mutually related or interacting activities that transform inputs into results. The 2010 Consumer Protection Law defines a person (consumer or user) as an individual or legal entity, whether public or private, organized or not, that acquires, uses or enjoys goods of any nature as the final user. Taking these regulations together, any product may be deemed a consumer product.

2. Agencies involved in regulating consumer products

The National Superintendence for the Defense of Socioeconomic Rights (SUNDDE) is the primary governmental agency that has jurisdiction over consumer product recalls. Depending on the nature of the products, other governmental authorities, such as the Venezuelan Tax Administration, the Ministry of People’s Power for Health and even the military, may get involved.

3. Reporting requirements and recall procedures

Currently, there are no express provisions mandating recalls or regulating the recall process in Venezuela. There were such provisions in the 2010 Consumer Protection Law, which has been repealed.

Notwithstanding the above, a recall obligation arises from: (i) the OLFP; (ii) the Quality Law; and (iii) the Law on Metrology, published

in Official Gazette No. 38.819 dated 27 November 2007. Broadly, the aforementioned laws establish the rights of consumers to (a) receive good quality products that do not endanger their life, health and security, (b) have guarantees from the supplier in cases of manufacturing or functioning deficiencies and (c) receive replacements and be entitled to repair and compensation in the case of damages suffered through receipt of defective and poor quality products.

Despite the repeal of the 2010 Consumer Protection Law, governmental authorities continue to apply the recall process regulations established therein. Article 11 of the 2010 Consumer Protection Law expounds on the procedure for the recall of products or services. When those involved in the “distribution, manufacturing and consumption chain” notice that a product or service, even if used correctly, poses a danger or risk to health, they must recall, substitute or replace the products or services and must bear the costs of this procedure.

Accordingly, once a product is received by consumers and an unexpected risk or danger to health is identified by the producer, manufacturer, importer, transporter, distributor or seller (the “Subjects”), such Subjects must carry out the following measures:

- Immediately notify the competent authorities, which includes SUNDDE and the competent authority that regulates the specific product
- Inform the public in general through adequate media and other alternative information methods
- Recall the defective products

Notifications to the competent authorities and the public must specify the products with the detected issue that is the subject of the recall, inform concerned parties of how the recall will be carried out and



acknowledge the issues that the product has and give recommendations on how to avoid damages.

Currently, the notification practice approved by the competent authorities has been to publish press releases in newspapers with nationwide circulation. The contents of these press releases must be prepared by the party carrying out the recall, which will also bear the associated costs. However, there is no mandatory rule as to the terms and conditions of the recall. As such, a broad array of alternatives is conceivably available as to the substance and method of the communication to the general public.

4. Product-specific regimes

Pharmaceuticals and medical devices

Pharmaceuticals and medical devices are specifically regulated in the Organic Health Law, published in Official Gazette No. 36.579 dated 11 November 1998, and in the Rules of the Pharmaceutical Product Review Board of 1998 (the “Rules”).

According to the Rules, the representative or sponsoring laboratories must inform the National Institute of Hygiene “Rafael Rangel” of any effect not described during the processing of the product that is derived from the pharmacological activity of the same or of some of its ingredients, and which is known after the product has been approved, as well as any adverse drug reactions known.

The competent authorities in charge of health control may then, in the event of actual health damage or in the event of an imminent risk of health damage, impose precautionary measures, such as requisition, inspection and examination, suspension of promotion and sales, withdrawal from the market, and confiscation and destruction of any goods for human use and consumption. The Good Manufacturing Pharmaceuticals Practice Guidelines set out general principles for the recall process. There are no specific regulations addressing the process for recalling medical devices.

Food and drink

There are no specific provisions regulating the recall process of food and drink. Instead, the recall process established in the 2010 Consumer Protection Law, even though it has been repealed, will continue to apply. Additionally, according to the General Food Regulations, published in Official Gazette No. 25.864 dated 16 January 1959, when deficiencies that constitute a danger to food health are observed, the relevant establishments, stores and vehicles may be closed or prohibited from conducting business by the health authorities.

Vehicles and their parts

There are no specific provisions regulating the recall process of vehicles and their parts. As with food and drink, the recall process established in the 2010 Consumer Protection Law will continue to apply.

The Joint Resolutions of the Ministry of the Popular Power for Finances, Light Industries and Commerce and for Energy and Oil No. DM/1951, DM/310 DM/SN, published in the Official Gazette No. 38.800 dated 31 October 2007 (“Resolution 310”), establishes that the consumer protection agency, SUNDDE, is responsible for ensuring compliance with Resolution 310’s provisions, which are aimed at protecting citizens who acquire vehicles.

Accordingly, if a company detects an issue with a vehicle for which it does not have a solution or method of repair, the company will have to recall the product, even if the product has only been distributed to dealers. If the product has been placed on the market, the company should then release a risk warning, following the procedure set forth in 2010 Consumer Protection Law, which includes notifying SUNDDE and the competent authorities, and informing the public in general.

The company responsible for the recall will be responsible for the replacement of the product or the granting of any compensation.



5. Legal consequences of noncompliance

Venezuelan legislation provides for sanctions, such as monetary fines and the temporary or permanent closing of establishments. Persons who are accountable for noncompliance may also be subject to civil, administrative or criminal penalties. These sanctions will also apply for failing to initiate a recall.

Sources of information

SUNDDE: Avenida Libertador, Centro Comercial Los Cedros, P.B.
Caracas, Bolivarian Republic of Venezuela

Tel. No.: (58-212) 705-3000

<http://www.superintendenciadepreciosjustos.gob.ve/>

Vietnam

The main laws in Vietnam governing product recalls are the Law on Products and Goods Quality (LPGQ) and the Law on Protection of Consumer Rights (LPCR).

1. Definition of a “consumer product”

An official definition of “consumer product” does not currently exist under Vietnamese law. However, in practice, Vietnamese authorities interpret “consumer product” to mean the output of a production or service provision process for purposes other than doing business. The definition of “product” under the LPGQ, in conjunction with the definition of “consumer” under the LPCR, supports this practical interpretation. The LPGQ defines a “product” as “the output of a production or service provision process for a commercial or consumption purpose.” The LPCR defines a “consumer” as “a person purchasing or using goods and services with the aim of consumption for personal use by an individual, family or organization.”

2. Agencies involved in regulating consumer products

Vietnam’s Ministry of Science and Technology is the authority responsible for the unified control of product quality.⁹ The Ministry of Industry and Trade is tasked with protecting consumer rights at the central level, with assistance from the Consumer Protection Division under the Vietnam Competition Authority.

Various ministries are also responsible for state control of the quality of particular products (see section 4 below).¹⁰

Different ministries have agencies under them that are tasked with examining product quality under their respective scope. The ministries

⁹ Article 9.2, Decree No. 20/2013/ND-CP dated 26 February 2013 regulating the functions, tasks, powers and organizational structure of the Ministry of Science and Technology.

¹⁰ Article 70.2, LPGQ.



also have specialized inspectorates to examine whether organizations and individuals involved in the production and trade of products are adhering to the law in terms of product quality.

In addition, municipal and provincial People's Committees have agencies that perform the same function within their respective localities, in accordance with the regulations of the different ministries. The products and goods quality examination agencies of the concerned ministries are required to coordinate with the product and goods quality examination agencies of the provincial and municipal People's Committees.

3. Reporting requirements and recall procedures

Product recall requirements and procedures are provided for in the LPGQ, LPCR and other regulations of specialized areas.

Under these regulations, there are two forms of product recall:

(i) voluntary recall by manufacturers or goods/service traders of defective products (eg, importers or resellers) and (ii) compulsory recall by the competent authorities.

Defective goods are goods that do not ensure safety to consumers, likely causing damage to the life, health and property of consumers, even if such goods are manufactured in accordance with current technical standards or norms, with no defects being detected at the time the goods are supplied to consumers.¹¹

Upon detecting the defective goods, manufacturers and traders are required to make a public announcement in the media about the defective goods and conduct a recall of such goods. When the recall is finished, they have a responsibility to report the result of the product recall to the relevant state management agencies. Neither the LPGQ nor the LPCR prescribes the required information, and there is no template for the post-recall report. As a matter of practice, the main information Vietnamese authorities would expect to receive is about

¹¹ Article 3.3, LPCR.

the number of affected products and how many of the affected products were successfully recalled by the reporter.

4. Product-specific regimes

In Vietnam, recall regimes for specific products are provided in regulations of specialized areas.

Pharmaceuticals / Medical devices

The recall of pharmaceutical products and medicinal ingredients is provided under the 2016 Pharmacy Law¹² and Decree No. 54.¹³

Under the 2016 Pharmacy Law, there are two methods of product recall: (i) compulsory recall by the authorities; and (ii) voluntary recall by traders, manufacturers or importers.¹⁴

For a compulsory recall, the Ministry of Health (MOH) is the competent authority to examine, supervise and decide on a recall nationwide. Subject to a decision from the competent authority, the trader, manufacturer or importer must suspend the production and sales of such products, conduct the recall and report to the MOH after the recall is completed.

In case of a voluntary recall, when detecting any defective products, manufacturers, traders or importers must stop producing and selling defective products and submit a recall proposal to the MOH before proceeding with the recall. The recall has to be conducted in accordance with the approved proposal.

¹² Law on Pharmacy No. 105/2016/QH13 was adopted by the National Assembly on 6 April 2016 and became effective on 1 January 2017 (the “2016 Pharmacy Law”).

¹³ Decree No. 54/2017/ND-CP dated 8 May 2017 guiding the implementation of the 2016 Pharmacy Law.

¹⁴ Article 63, the 2016 Pharmacy Law.



Regarding the recall of medical devices, Decree No. 36¹⁵ provides that recall is one method of handling defective equipment. The recall may be conducted on a voluntary basis by the registrant of the defective medical equipment or on a compulsory basis following a decision by the MOH.¹⁶

The compulsory recall of a defective medical device is undertaken as a consequence of the revocation of the free-sale registration number of such product due to a regulatory or noncompliance issue.¹⁷

Food and drink

Recall of food and drink products is generally governed by the Law on Food Safety.¹⁸ There are additional legislations, such as Circular No. 17/2016/TT-BYT dated 30 June 2016 regulating the recall and disposal of unsafe foods under the management of the MOH, Circular No. 58/2014/TT-BCT dated 22 December 2014 on issuance and revocation of certificates of food safety under the management of the MOIT and Circular No. 59/2012/TT-BNNPTNT dated 9 November 2012 regulating the production management of safe vegetables, fruits and tea.

Under these regulations, the MOH is generally responsible for performing the state management of food safety.

When detecting unsafe products, food producers or traders must trace the origin of unsafe foods.¹⁹ Within 24 hours after identifying products that need to be recalled, the product owners shall promptly notify responsible persons in their production and trading systems, including the production factory, distribution channels, agents and

¹⁵ Decree No. 36/2016/ND-CP dated 15 May 2016 on Medical Equipment Management (“Decree No. 36”).

¹⁶ Articles 31 and 35, Decree No. 36.

¹⁷ Article 36.1, Decree No. 36.

¹⁸ Law No. 55/2010/QH12 on Food Safety dated 17 June 2010 (the “Law on Food Safety”).

¹⁹ Article 54, Law on Food Safety.

stores, of the cessation of producing and trading these products, as well as the recall of these products. Upon recalling the products, product owners shall send a report on recall of unsafe products to the state agency in charge of food safety.²⁰

Moreover, food producers and traders are responsible for suspending production and trading, and sealing unsafe products right after receiving a decision on product recall from the authorities. Then, within three working days of receiving the recall decision, the food producers and traders shall submit a plan on recall of unsafe products to the agency that issued the decision on product recall and the state agency in charge of food safety. The decision-issuing agency shall take the responsibility for, and coordinate with state agencies in charge of food safety and other related agencies in supervising, the product recall.²¹

Motor vehicles and parts

The recall procedures for defective vehicles and their parts are regulated in Circular No. 45.²² According to Circular No. 45, the Vietnam Register affiliated to the Ministry of Transport (the “Vietnam Register”) is the state agency in charge of recalling defective products within the transport sector.²³

When discovering a technical defect in vehicles and their parts that have been sold on the market, manufacturers must undertake the following:²⁴

- Suspend production of the same type of defective products

²⁰ Article 3, Circular No. 17.

²¹ Article 4, Circular No. 17.

²² Circular No. 45/2012/TT-BGTVT dated 23 October 2012 on the inspection of the technical quality, safety and environment protection in the production and assembly of motorbikes (“Circular No. 45”).

²³ Article 3.8, Circular No. 45.

²⁴ Article 12.1, Circular No. 45.



- Send written requests to their agents asking them to stop selling such defective products or their same types within five working days from discovering the technical defects
- Send written reports to the quality control agency containing detailed information about the reasons for the technical defects, the remedial measures, the quantity of products to be recalled and the specific plan for product recall within 10 working days from discovering the technical defects
- Announce the product recall on their official website or the mass media
- Carry out the product recall in accordance with the requirements as prescribed by the quality control agency
- Report the product recall according to the plan to the quality control agency at least every three months
- Send written reports to the quality control agency on result of the recall within 30 working days from finishing the recall

If the Vietnam Register detects defective products and requires manufacturers to recall such defective products, it may revoke the defective products' Certificate of Type Approval until the manufacturers finish their product recall. If the manufacturers fail to report the result of the recall within three months of the last day of the recall, the Certificate of Type Approval shall be permanently revoked.²⁵

5. Legal consequences of noncompliance

Individuals or organizations that violate the LPGQ may face administrative sanctions and, if they have caused damage for users or their properties, pay compensation in accordance with the Civil Code. In such cases, liability extends to all levels of the supply chain,

²⁵ Article 12.2 (dd), Circular No. 45.

including manufacturers, importers, distributors, wholesalers and retailers. Individuals may also face criminal liability if their act falls under any of the crimes defined under the Vietnam Penal Code. For example, from 1 January 2018, an individual violating regulations on food safety and hygiene may be held criminally liable and face up to 20 years' imprisonment, plus monetary fines or a ban from holding certain positions, practicing certain occupations or doing certain jobs for 1-5 years.²⁶

Sources of information

Ministry websites

Ministry of Science and Technology:

<http://www.most.gov.vn/>

Ministry of Health:

<http://www.moh.gov.vn/homebyt/vn/portal/index.jsp>

Ministry of Agriculture and Rural Development:

http://www.agroviet.gov.vn/portal/page?_pageid=35.1&_dad=portal&_schema=PORTAL

Ministry of Transport:

<http://www.mt.gov.vn/default.aspx>

Ministry of Information and Communication:

<http://www.mic.gov.vn/>

Ministry of Industry and Trade:

<http://www.moit.gov.vn/vn/Pages/Trangchu.aspx>

Vietnam Authority Competition:

<http://www.vca.gov.vn/>

²⁶ Article 317, Penal Code.



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