

Product regulation, safety and recall Q&A: Brazil

by Julia Klarmann and Roberta Feiten, Souto Correa Advogados (based on an original provided by Rafael de Freitas Valle Dresch, Carvalho, Machado, Timm e Luz Advogados)

Country Q&A | Law stated as at 31-Jul-2019 | Brazil

Brazil-specific information concerning product regulation, safety and recall issues.

This Q&A provides country-specific commentary on *Product regulation, safety and recall: Cross-border overview*, and forms part of *Cross-border commercial transactions*.

Industry-specific regulation

1. Is there any industry-specific regulation as regards product safety?

The general regulation of product safety under Brazilian law is set out in the Brazilian Consumer Code (Consumer Code). The Consumer Code defines the liability of suppliers and producers for damage resulting from accidents involving defective products (*Articles 8 to 17, Consumer Code*).

Products and services made available to consumers must not create risks to consumers' health or safety, except those considered normal and predictable as a result of the type of product or service in question (*Article 8, Consumer Code*). Suppliers must provide adequate information about such products and services. The lack of information or the presentation of incomplete or inadequate information regarding the product's usage and risks is considered a defect and, therefore, justifies the supplier's and producer's liability.

If a supplier gains knowledge that a product or service previously placed on the market poses a risk to consumers' health or safety, it must immediately communicate this fact to the proper authorities and to consumers (*Article 10, paragraph 1^o, Consumer Code*) (see [Question 8](#)).

In relation to industrial products, the manufacturer must supply such information in the printed material that accompanies the product (*Article 8, paragraph 1, Consumer Code*).

In addition to the general law, there are specific regulatory acts issued by agencies in each sector of the economy such as those imposed by the National Sanitary Authority (ANVISA), who regulates all products and services that may affect public health (*Law No. 9.782/1999*) and by the National Telecommunications Agency (ANATEL), responsible for the national telecommunications policy and for ensuring the enforcement of consumer rights by telecoms companies (*Law No. 9.472/1997*). Moreover, the National Institute for Metrology, Standardization and

Industrial Quality (INMETRO) is responsible for the adoption of standards to ensure the quality and the safety of products and services provided in Brazil (*Law No. 5.966/1973*).

Consumer product legislation

2. How is general product safety regulated in the national jurisdiction? Does national law impose any product safety obligations over and above those contained in the 2001 General Product Safety Directive?

General regulation of product safety is set out in Articles 8 to 17 of the Consumer Code (see [Question 1](#)). The Consumer Code, influenced by the 2001 General Product Safety Directive and the US Consumer Code, establishes that products will be considered defective when they do not provide consumers with the levels of safety that could legitimately be expected of such products.

In addition, in accordance with Article 10, paragraph 1, of the Consumer Code, the National Department of Consumer Defense (DPDC), which is linked to the Ministry of Justice, also regulates the procedures to be adopted in recall campaigns. The procedures are set out in Ordinance No. 618/2019 (see [Question 8](#)). Recall is mandatory in Brazil whenever suppliers become aware that products or services provided in Brazil present a defect which may create damages to consumers' health or safety. In this case, suppliers must recall the products, communicate to consumers and present solutions.

3. How is product safety legislation enforced in the national jurisdiction? What powers do the enforcement authorities have?

Product safety legislation is applied by state powers.

The judiciary enforces such legislation when adjudicating individual and collective claims relating to product safety.

The executive power enforces the legislation mainly through regulatory agencies (such as ANVISA, INMETRO and ANATEL), PROCONS (Consumer Protection Offices) and DPDC, which regulate and supervise compliance with product safety regulations. DPDC may also challenge suppliers regarding the execution of recall campaigns where defective products or services have been placed on the market (see [Question 8](#) and [Question 9](#)). The Public Attorney's Offices may also supervise compliance with the regulations and enforce the legislation. In case of non-compliance, it may file a class action against the supplier.

Both PROCONS and DPDC have the power to impose administrative sanctions set out in Article 56 of the Consumer Code (which includes fines).

4. What sanctions are imposed under national law for breach of product safety legislation?

National law imposes civil, administrative and criminal sanctions for breach of product safety obligations.

In terms of civil liability, product manufacturers that do not meet safety requirements must compensate consumers for damages (material and pain and suffering) resulting from accidents with defective products (*Articles 12 and 14, Consumer Code*). Such compensation may arise from collective or individual lawsuits.

In relation to administrative liability, sanctions for breach of product safety regulations include fines and administrative intervention (that is, restricting the manufacturer's activities in order to protect consumers) (*Article 56, Consumer Code*). In case of non-compliance with Ordinance No. 618/2019 (see [Question 2](#) and [Question 9](#)) and/or if the supplier refrains from proceeding with the recall campaign, DPDC may impose a fine of up to approximately BRL9 million.

Finally, in relation to criminal liability, a term of imprisonment may be imposed (*Articles 63-80, Consumer Code*).

5. Does national law imply any terms into a contract in relation to product safety? Can they be excluded?

There is a general obligation regarding product safety which requires the product to meet the standards of safety that may legitimately be expected of the product according to the "state of the art" (that is, the speed at which knowledge is produced, transformed and propagated) (*Article 6, Consumer Code*). This obligation cannot be excluded from contracts or other legal transactions.

In addition, suppliers must duly inform consumers about the risks that are inherent to the nature of the product, as well as the adequate usage and maintenance of the product (*Articles 8 and 12, CDC*). In case of lack of information, the supplier may be deemed liable for accidents causing damages to consumers.

6. Do product safety regulations apply equally to imported products?

Yes, the same regulation is applied to imported products and the importer is liable.

Packaging

7. Does national law regulate the safety of packaging?

The safety of packaging is regulated in the same manner as that of products (*Article 18, Consumer Code*). Regulatory agencies (such as ANVISA, INMETRO, ANATEL, among others) may impose special rules about packaging in certain industries, such as the pharmaceutical sector and the electronics sector.

Product recall

8. What provision does national law make for product recall? Is it mandatory or voluntary?

Suppliers of products and services that present potential health or safety risks or that are dangerous must clearly and extensively inform consumers and the competent authorities of this risk or danger and take any other measures that may be necessary, on a case-by-case basis (*Articles 9 and 10, paragraph 1^o, Consumer Code*).

Suppliers may not make available to the market any product or service that is known to present a high level of harm or danger to health or safety. A supplier who learns that a product or service previously placed on the consumer market is harmful or dangerous must immediately notify the proper authorities (*Article 10, paragraph 1^o, Consumer Code*). The supplier must also notify consumers through a recall campaign, via advertisements placed in the media, radio and television at the supplier's expense. In addition, when federal state or municipal authorities learn that services or products may present a health or security risk to consumers, these authorities must also inform consumers about it (*Articles 10, paragraph 3^o, Consumer Code*).

In addition, Ordinance No. 618/2019 of the Ministry of Justice regulates the recall procedure. Some industry standards set out specific recall procedures, such as Resolution No. 55 of ANVISA which establishes those to be observed by the pharmaceutical sector.

9. Are there any sanctions for failure to initiate a product recall exercise?

There are no specific sanctions for failure to initiate a product recall, but those applicable to breaches of product safety obligations will apply in this scenario (see [Question 4](#)). Therefore, in case of non-compliance with the recall provisions, DPDC may impose a fine to suppliers of up to approximately BRL10 million.

END OF DOCUMENT