Consumer Product Recalls: Overview (Brazil)

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A Practice Note providing an overview of the consumer product recall process for foreign retailers, distributors, manufacturers, and suppliers of goods in Brazil. It discusses government regulation of recalls, voluntary recalls, required recall steps, consumer notices, and sanctions.

Consumer products are highly regulated in many jurisdictions, but regulation cannot mitigate all potential product hazards affecting consumers. In many countries, domestic authorities are authorized by law to take action to protect consumers from defective or harmful products. In Brazil, product recalls are regulated by the government and must be carried out whenever a supplier becomes aware that a product placed on the consumer market is harmful or dangerous.

All members of a consumer product supply chain, including manufacturers, distributors, and retailers, play a role in getting products to consumers. In turn, they may also play a role in removing hazardous products from the marketplace. Typically, the manufacturer has primary responsibility for product recalls. Manufacturers, importers, distributors, and retailers must be aware of Brazil's product safety recall requirements and enforcement procedures.

This Note discusses:

- The legal and regulatory requirements governing product recalls in Brazil, including industry-specific recall requirements.
- Recall process requirements in Brazil.
- Enforcement and liability related to recalls in Brazil.
- Recall compliance tips.

See also Practice Note, Consumer Product Regulation and Safety: Overview (Brazil).

Product Recall Regulation

The Consumer Protection Code (*Código de Defesa do Consumidor*) (CDC) is the main legislation governing consumer product safety in Brazil. The CDC provides the general rules applicable to product recalls.

Products placed on the consumer market must not pose risks to consumers' health and safety, except for risks that are considered normal and predictable due to the nature and use of the products. Suppliers must provide necessary and adequate information to consumers about these inherent risks. (Article 8, CDC.)

Suppliers must not place products on the consumer market that they know or should know to present a high degree of harmfulness or danger to consumers' health or safety (Article 10, CDC).

Suppliers of products that present potential health or safety risks must:

- Provide clear and comprehensive information about these risks.
- Take any other measures that may be necessary, on a case-by-case basis.

(Articles 9 and 10(1), CDC.)

A supplier who becomes aware that a product placed on the consumer market is harmful or dangerous must immediately notify the competent authorities and consumers through advertisements (Article 10(1), CDC). This obligation is the main legal basis for the supplier's duty to recall products on detection of a risk of harm or danger.

A product recall is a corrective measure to remove harmful or dangerous products from the market. The supplier must take all appropriate measures to ensure that the defective products are recalled (whether they are to be replaced, repaired, or collected). The supplier must bear the costs of the recall measures (Article 6(1), Ordinance 618/2019 of the Ministry of Justice).

Defective products are those that present a danger or risk to consumers. A product is deemed defective if it does not offer the safety legitimately expected of such product by the consumer. A defect can arise from the product's design, manufacture, construction, assembly, formulation, manipulation, presentation, or packaging. In addition, a product is deemed defective if the supplier fails to provide sufficient information on the use and risks of the product.

The factors to consider whether a product is defective are:

- Its presentation.
- The use and risks reasonably expected from the product.
- The time the product was put on the market (for example, a product cannot be considered defective simply because another product of better quality was subsequently placed on the market).

(Article 12, CDC.)

Dangerous products with risks that are inherent to their characteristics and functions are not considered defective, unless those risks are not communicated to consumers.

According to the Superior Court of Justice (*Superior Tribunal de Justiça*) (STJ), a supplier has a legal duty to recall defective (that is, harmful and dangerous) products. If a supplier does not voluntarily carry out a recall, the competent authorities can order the supplier to do so (STJ, Special Appeal 1838184/RS, 2021).

The main government bodies responsible for regulating and supervising product recalls are the Ministry of Justice's National Consumer Secretariat (*Secretaria Nacional do Consumidor*) (SENACON) and its Department of Consumer Protection and Defence (*Departamento de Proteção e Defesa do Consumidor*) (DPDC) (Articles 105 and 106, CDC; Article, 3 Federal Decree No. 2.181/1997).

Ordinance No. 618/2019 of the Ministry of Justice regulates the general product recall procedure in Brazil, including:

- Deadlines to notify public authorities about a supplier's investigation and decision to perform a recall.
- The contents of the recall communication to SENACON.
- The supplier's media plan for informing consumers.
- The contents of the risk warning notice to consumers.
- The consumer service plan.
- Other information, including follow-up reports, that the supplier must provide to SENACON.
- The supplier's obligations during the recall campaign.

The following instruments also regulate product recalls:

- Ordinance No. 20/2020 of the Ministry of Justice, which regulates reporting requirements during recall campaigns.
- SENACON's Technical Notes:
    - No. 4/2020, which regulates SENACON's power to make suggestions on recall media plans;
    - No. 6/2020, which governs the deadlines for communications to SENACON about potential risks to consumers; and
    - No. 28/2020, which regulates the termination of recall campaigns.

SENACON must inform state and municipal consumer protection agencies (*Procuradorias de Proteção e Defesa do Consumidor*) (PROCONs) of recall campaigns. For example, SENACON must inform PROCONs of recalls through physical or electronic media (Article 12, Ordinance No. 618/2019). When federal, state, or municipal authorities become aware that products may present a health or safety risk to consumers, they must also inform consumers of this risk (Article 10(3), CDC).

Industry-Specific Product Recalls

Certain types of products are subject to different product recall requirements.

In addition to SENACON, the DPDC, and PROCONs, other government agencies have powers to regulate and monitor the safety of specific products, such as:

- The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária) (ANVISA).
- The National Institute for Metrology, Standardization, and Industrial Quality (INMETRO).
- The National Transport Department (*Departamento Estadual de Trânsito*) (DENATRAN).
- The Ministry of Agriculture, Livestock and Food Supply (Ministério da Agricultura, Pecuária, e Abastecimento) (MAPA).

According to SENACON's Recall Practical Guide, all the agencies mentioned above have concurrent powers to monitor the safety of products in the market. Their respective regulations are not exclusive but complementary to the CDC and Ordinance No. 618/2019. Compliance with one agency's regulations does not exclude the obligation to comply with any other specific regulation applicable to the product.

Vehicles

Law No. 14.071/2020 and Joint Ordinance No. 3/2019 of the Ministry of Justice and Ministry of Infrastructure regulate recall campaigns of vehicles.

Suppliers of automotive vehicles, electric vehicles, trailers, and semi-trailers must immediately inform DENATRAN on becoming aware of the danger or harmfulness of such products on the market.

In addition to the general obligation to notify consumers, the supplier must send individual communications to owners through the notification service of vehicle recall (that is, an online system created by DENATRAN to send individual communications to current owners on the start of a recall, accompanied by a risk warning) or by post. The supplier must also submit monthly reports to DENATRAN, which must include a list of notifications sent to, and confirmations of receipt by, current vehicle owners.

Food, Medicines, Medical Products, and Cosmetics

ANVISA, an independent agency affiliated to the Ministry of Health, promotes the protection of the population's health. ANVISA controls the production, marketing, and use of products and services subject to health regulation (such as cosmetics, medicines, food, medical devices, pesticides, pharmaceutical ingredients, sanitizing products, and tobacco products), which includes controls at ports, airports, and borders.

ANVISA has issued Collegiate Board Resolutions (*Resolução da Diretoria Colegiada*) (RDC) that impose specific product recall requirements, for example:

- RDC 67/2009 regulates the technovigilance system, that is:
    - provides measures to ensure the protection and promotion of the population's health;
    - the monitoring of adverse events and technical complaints relating to health products in the post-market phase; and
    - the compulsory notification of incidents involving health products.

- RDC 551/2021 applies to medical products and devices (other than medicines) and imposes obligations on manufacturers and registration holders to reduce the risk of occurrence of adverse effects related to the use of these products on the market.
- RDC 625/2022 requires suppliers of medicines to communicate to sanitary authorities and consumers details of any potential health risk arising from their products.
- RDC 655/2022 regulates the recall of food products and the packaging or any other materials in contact with food, among other things.

All ANVISA's resolutions provide that suppliers must have a written product collection plan available to their employees and sanitary authorities on request. This plan must specify:

- The procedures for the quick and effective collection of recalled products.
- The procedures for communicating product recalls to ANVISA, the production chain, and consumers.

ANVISA also regulates product traceability.

INMETRO

INMETRO has powers to regulate, monitor, and order the recall of products subject to compulsory conformity assessment under the Brazilian Conformity Assessment System. INMETRO publishes a detailed list of products subject to mandatory technical standards and conformity assessment requirements. As of mid-October 2022, about 163 different products and product classes were subject to such standards and requirements (including party articles, school supplies, jewelry, toys, high chairs, televisions, washing machines, household gas stoves and ovens, bicycle tires, and various household appliances).

INMETRO monitors the safety of products subject to its regulations and has a co-operation agreement with SENACON to promote product safety for users. When INMETRO identifies health and safety risks, it must inform SENACON that it will adopt the necessary measures for the conduct of a recall.

Recall Process

Ordinance No. 618/2019 regulates the recall process in Brazil as follows:

- **Start of investigations.** When a supplier becomes aware of the possibility that harmful or dangerous products have been placed on the market, they must inform SENACON within 24 hours of their decision to start an investigation.

    Investigations must not last more than ten business days, unless the supplier shows that an extension is necessary to complete the investigations (Article 10(1), CDC; Article 2, Ordinance No. 618/2019).

The supplier must notify SENACON if the issue affects a series of products, that is, if the supplier has ruled out the possibility of an isolated incident (SENACON's Technical Note No. 06/2022).

On completion of the investigations, the supplier must submit a communication to SENACON or explain the reasons why a recall is not necessary (Article 2(2), Ordinance No. 618/2019).

- **Communication to SENACON.** The supplier has two business days from the decision to perform a recall to inform SENACON (preferably through the Electronic Information System (SEI)) or any other system designated by SENACON) and any other competent government agency (such ANVISA, INMETRO, and so on) (Article 3(1), Ordinance No. 618/2019). The communication must include certain information (see Communication to SENACON).
- **Media plan.** The supplier must notify consumers through a recall advertising campaign, at its own expense. The supplier must submit its media plan to SENACON. The supplier must also justify its choice of communication media, in light of the need to reach as many interested people as possible. For further details, see Media Plan.
- **Risk warning notice.** The supplier must publish a notice on its website informing consumers about the defective product. For further details, see Risk Warning Notice.
- **Progress reports.** The supplier must submit progress reports to SENACON at least every four months. The reports must include details of consumer services related to the recall, including the numbers of products collected, repaired, or replaced. SENACON can request the supplier to submit more frequent progress reports. After the end of the fifth year of the recall campaign, the supplier can request a waiver of its obligation to submit reports or an extension of the deadline for submission. If SENACON accepts to waive the supplier's obligation, based on the campaign results and the circumstances of the case, the supplier must present a final recall report. For further details, see Reporting to Authorities.
- **Final recall report.** The supplier must submit a final recall report to SENACON on completion of the recall campaign or if SENACON considers that the recall campaign is no longer required. For further details, see Reporting to Authorities.

Recall Triggers

A recall is mandatory once the supplier identifies that a product placed on the market poses a harm or safety risk (Article 3, Ordinance No. 618/2019).

A supplier may become aware of potential harm or danger through:

- Voluntary internal investigations.
- Quality and safety inspections.
- Analyses of incidents.
- Consumer complaints.

SENACON and the DPDC can receive, analyze, and deal with complaints of possible violations of consumers' right to life, health, and safety. Complaints can be filed by, among others:

- The Public Prosecutor's Office.

- Federal, state, and municipal public administration bodies.
- Members of the National Consumer Protection System.
- Non-governmental organizations.
- Consumers.

SENACON and the DPDC can also launch investigations *ex officio*.

The competent authorities (such as SENACON, INMETRO, ANVISA, and so on) may also become aware of potential safety risks of products through market monitoring, news of accidents, and recalls carried out in other countries. For example, INMETRO monitors cases of consumer accidents to:

- Enable focused and directed actions in the market.
- Reduce the incidence of accidents.
- Alert the public of the existence of risks associated with products and services on the Brazilian market.

INMETRO's Consumer Accident Monitoring System (*Sistema Inmetro de Monitoramento de Acidentes de Consumo*) (SINMAC) is an open system that allows all citizens to report consumer accidents. These reports help INMETRO identify products and services that pose risk to consumer health and safety.

According to Recommendation 01/2012 of DPDC's Group for Permanent Studies on Consumer Accidents (*Grupo de Estudos Permanentes de Acidentes de Consumo*) (GEPAC), in the event of a recall in another jurisdiction, the foreign manufacturer's Brazilian subsidiary or importer should inform SENACON on whether a recall will be required in Brazil or whether the same products were not commercialized in Brazil. If the same products are on the Brazilian market, a recall must also be conducted in Brazil.

SENACON monitors the safety of consumer products and consults information made available by international and state consumer bodies, such as:

- The Inter-American Rapid Alerts System (SIAR) of the Consumer Safety and Health Network (CSHN).
- The EU's Rapid Alert System for Dangerous Non-Food Consumer Products (RAPEX).
- The National Highway Traffic Safety Administration (NHTSA) (US).
- The Australian Competition and Consumer Commission (ACCC).

Communication to SENACON

As stated above, the supplier has two business days from the decision to perform a recall to inform SENACON.

The recall communication to SENACON must be in writing and in Portuguese, and include the following information:

- Identification of the supplier, including:

    - corporate and trade name;
    - economic activities;
    - registration number on the National Register of Legal Entities (*Cadastro Nacional de Pessoas Jurídicas*) (CNPJ) or Individual Taxpayers' Register (*Cadastro de Pessoas Físicas*) (CPF);
    - headquarters' address;
    - telephone and email address for receipt of communications;
    - names of the attorneys that can represent the supplier in administrative or judicial proceedings relating to the recall;
    - details of any representatives in member countries of the Mercado Común del Sur (MERCOSUR or Southern Common Market) (including contact details).

- A detailed description of the product, with the characteristics necessary to identify them, in particular:
    - trademark/brand;
    - model;
    - batch/lot, if applicable;
    - serial number, if applicable;
    - chassis, if applicable;
    - start and end date of manufacture; and
    - photographs.

- A detailed description of the defect and date when the hazardousness or harmfulness was discovered.
- A detailed, clear, and comprehensive description of the risks and their implications for consumers.
- Number of defective products placed on the Brazilian market, including those still in stock, and number of consumers affected.
- Geographic distribution of defective products, per federated state, and countries where the products were exported.
- Measures already adopted and proposed measures to remedy the defect and mitigate the risks.
- Description of accidents related to the defective product, when applicable, with the following information:
    - place and date of the accident;
    - identification of the victims;
    - property and physical damage caused;
    - details of judicial proceedings related to the accident, specifying the lawsuits filed, the names of plaintiffs and defendants, the judicial districts and circuit courts in which they are being heard, and docket numbers for each proceeding; and

    - measures taken in relation to the victims.

- Media plan to inform affected consumers (see Media Plan).
- Model of risk warning notice to consumers (see Risk Warning Notice).
- Consumer service plan (see Consumer Service Plan).

(Article 3(1), Ordinance No. 618/2019.)

The supplier can request an extension of the deadline of up to 15 business days to file the above information (Article 3(4)-(5), Ordinance No. 618/2019).

SENACON must issue a Technical Note on the regularity of the information provided by the supplier within five business days from receipt of the communication (Article 3(6), Ordinance No. 618/2019).

SENACON and the competent regulatory body can, at any time, issue a notice requesting additional or supplementary information to assess the effectiveness of the recall (Article 3(2), Ordinance No. 618/2019).

Communications with Consumers

The recalling entity must communicate various information to product purchasers and consumers. The format and form of communication are regulated and some requirements apply in relation to making information about the recall public.

Media Plan

SENACON and DPDC consider that a supplier cannot recall products through direct contact with consumers affected by the defective products (referred to as a "white recall") without conducting a campaign in public media.

Recall campaigns must be advertised through suitable means to reach as many interested parties as possible. The supplier must submit a media plan to SENACON which includes the following information (Article 4, Ordinance No. 618/2019):

- Start and end date of the advertising campaign.
- Advertising media to be used and time and frequency of advertisements, considering the need to reach as many interested parties as possible.
- Model of risk warning to be used for the campaign, taking into account the need to allow all consumers (including lay people) to understand the extent of the risk.
- Detailed advertising costs (in a way that protects the confidentiality of this information, if required).
- Justification for the choice of advertising media.

(Article 4, Ordinance No. 618/2019.)

The supplier must select at least one written, one audio, and one audiovisual form of communication. The selected media must be the most effective to communicate the recall message to the target audience. The supplier determines the advertising media

and frequency of messages together with SENACON. (Article 4(1), Ordinance No. 618/2019.) The following combinations are allowed:

- Printed written media and messages on the company's website.
- Sound and audiovisual broadcasting.
- Digital written media and messages on the company's website.
- Sound and audiovisual online communications.

(Article 4(1), Ordinance No. 618/2019).

SENACON's Technical Note No. 4/2020 provides that the supplier can reduce the scope of its media campaign in certain cases, including when the consumers can be identified and tracked and the supplier complies with various requirements. This must be agreed between the supplier and SENACON.

Risk Warning Notice

In addition to notifying SENACON, the supplier must immediately inform consumers of the harmfulness or dangerousness of a product placed on the market through a risk warning notice on its website. The risk warning notice is intended to provide sufficient information to consumers to mitigate the product's risk. To this end, the risk warning notice must provide clear and accurate information on:

- The affected product and the defective component (including brand, model, lot, serial number, initial and final date of manufacturing, and photo).
- The product's defect, risks, and their implications for consumers, in a way that allows any consumer to understand the extent of the risk, including a "risk of death" warning when applicable.
- Preventive and corrective measures that the consumer must take, when applicable.
- Measures to be adopted by the supplier.
- The supplier's contact information.
- Location, start date, and duration of the consumer assistance services.
- The fact that the recall does not involve any cost for consumers.
- Any other matters that aim to protect the safety of consumers.

The risk warning notice must be sized in such a way as to ensure that all consumers can access and understand the information about the harmfulness or dangerousness of the recalled product. Direct individual communications sent to consumers do not relieve the supplier from its obligation to publish a risk warning notice addressed to all consumers (Article 6(2) and (3), Ordinance No. 618/2019).

The risk warning notice must be available on the supplier's website in up to two clicks, for five years (although SENACON can extend this term) (Article 4(4), Ordinance No. 618/2019).

Consumer Service Plan

The consumer service plan provides details on the measures to be taken by the supplier to ensure that the defective products are immediately recalled (whether they are to be repaired, replaced, or collected) and information regarding customer services. The consumer service plan must consider the best national and international practices and include the following information:

- Types of customer services available to consumers, preferably with use of the Consumidor platform for the resolution of potential disputes (this is a public service that allows direct dialogue between consumers and companies for the online resolution of consumer disputes).
- Places and times of assistance services.
- Average duration of the services.
- Start date of the assistance services.
- Contingency plan and estimated timeline to reach all affected products.

(Article 5, Ordinance No. 618/2019.)

Repair, Replacement, and Refunds

There are no specific laws governing how recalled products are quarantined, collected, and transported. The supplier typically bears the expense of the collection and transport process.

The supplier must implement a consumer service plan, which can involve the repair or replacement of the recalled products (see Consumer Service Plan). The number of products collected, repaired, and replaced must be included in the supplier's progress reports filed with SENACON (see Reporting to Authorities).

The supplier must repair or replace the products free of charge, without passing on any costs to consumers (Articles 6(1) and 10, Ordinance No. 618/2019). The supplier's obligation continues even after the end of the recall campaign.

If repair or replacement of the product is not possible, the supplier must refund the amounts paid by the consumer (adjusted for inflation). In any case, the supplier may also be liable to compensate the consumer for any damage suffered as a result of the product's defect (Articles 12 and 14, CDC) (see Product Liability).

The supplier must provide the consumer with a certificate attesting of the service provided (repair, replacement, or refund), in physical or electronic form, indicating the place, date, time, and duration of the service and the measure taken (that is, repair, replacement, or refund). The supplier must keep a record of this certificate.

Reporting to Authorities

A supplier must provide the following reports to SENACON and other competent regulatory authorities, if any (see Industry-Specific Product Recalls):

- **Progress reports.** At least every four months, the supplier must submit progress reports including the following information (together with any documents):
  - total number of products affected by the recall;
  - number of products collected or repaired, including those in stock;

- total number of assistance services supplied to consumers during the reference period and throughout the campaign;
- campaign attendance rate;
- a spreadsheet with the number of assistance services performed nationally; and
- number of assistance services per federal state, in alphabetical order.

(Article 8, Ordinance No. 618/2019.)

SENACON can request that reports be submitted on a more frequent basis (Article 8(2), Ordinance No. 618/2019).

SENACON can discharge the supplier from its obligation to file progress reports and close the recall process if certain requirements are met, including the following:

- for non-durable goods: after one year following the product expiration date; and
- for durable goods: after the end of the fifth year of the recall campaign if the collection/repair rate exceeds 70% (for motor vehicles) or 50% (for other products).

  (Technical Note No. 28/2022 of SENACON.)

- **Final recall report.** If SENACON accepts to close the recall process, based on the campaign results and the circumstances of the case, the supplier must present a final recall report. In this case, the supplier remains responsible for repairing or replacing affected products, or reimbursing affected consumers, at any time.

  This report must include information on:

  - how consumers were informed of the risk;
  - the number and percentage of consumers reached, overall and per federal state; and
  - the reasons for not collecting or repairing any remaining products, and the measures to be adopted for such products.

  The supplier must also submit a final recall report when the campaign reaches 100% of attendance or is no longer necessary.

  (Articles 8, II, Ordinance No. 618/2019.)

SENACON can decide to extend the recall campaign at the supplier's expense if the results are unsatisfactory (Article 9, Ordinance No. 618/2019).

Disposal of Recalled Products

The recalling entity is responsible for the disposal of collected recalled products if disposal is necessary. It must comply with current regulations governing the appropriate final disposal and destination of products (for example, RDC 551/2021, RDC 625/2022, and RDC 655/2022).

The recalling company must keep records showing the final destination of the collected products (according to the good manufacturing practices and RDC 551/2021, RDC 625/2022, and RDC 655/2022). Government authorities do not typically witness the destruction of recalled products.

There are no specific restrictions on the export of recalled products, but export requirements may apply to specific types of products (regardless of whether they were recalled). The possibility to export recalled products should also be assessed in light of the country of destination, especially where there are differences in the concept of defective products.

Imported Products

Product safety regulations apply equally to imported and domestic products. Therefore, an importer may be liable for breach.

Manufacturers, importers, distributors, and retailers should be aware of Brazil's product safety and recall requirements. Typically, the manufacturer has primary responsibility for product recalls.

Any supplier who becomes aware that unsafe products have been placed on the Brazilian consumer market must recall the products. A supplier is defined as any public or private, Brazilian or foreign, individual or legal entity that carries out activities for the production, assembly, creation, construction, transformation, import, export, distribution, or marketing of products (Article 3, CDC). Therefore, importers and foreign manufacturers can be held liable for non-compliance with product safety rules (see Product Liability).

GEPAC recommends that Brazilian subsidiaries and importers of suppliers or manufacturers who carry out a recall abroad inform SENACON that the recall does not affect the Brazilian market. If the product was introduced on the Brazilian market, a recall must also be conducted in Brazil. Generally, the recall should be carried out in accordance with the manufacturer's instructions.

While there is no legal obligation to recall products that were not placed on the Brazilian consumer market, importers and local subsidiaries of foreign companies could be held liable for the repair, exchange, or refund of products purchased abroad by Brazilian consumers.

Foreign Manufacturers

A foreign manufacturer is considered a supplier under the rules on product liability (Article 3, CDC). The foreign manufacturer and all the parties directly involved in the supply chain can be held liable for compensation of consumers' damages arising from product safety issues (Articles 12 and 13, CDC) (see Product Liability).

Brazilian consumers can file lawsuits for damages in Brazil against a foreign manufacturer and a damages award against such supplier can be enforced in accordance with international rules on judicial co-operation. A foreign legal entity can be represented in court by the manager, representative, or administrator of its subsidiary, agency, or branch in Brazil (Article 75, X, Code of Civil Procedure (*Código de Processo Civil*) (Law No. 13.105/2015)).

The Brazilian consumer authorities and regulators may also seek to start proceedings against a foreign manufacturer for violations of product safety requirements. Brazilian authorities maintain communication and co-operation channels with international consumer authorities, which can facilitate the adoption of measures related to recall and safety issues.

A foreign manufacturer that did not place the product in the Brazilian consumer market is not required to perform a recall in Brazil (but remains jointly and severally liable). However, the importer, the distributor, the subsidiary, or the representative of the foreign manufacturer, or any party involved in the supply chain that introduced the product in Brazil, must perform the recall.

In this case, the recall is likely to be carried out in accordance with the foreign manufacturer's instructions. The foreign manufacturer therefore plays an important role as they should provide the supplier in Brazil with the necessary information for submission to Brazilian public authorities and indicate the measures to remedy the safety issue.

Enforcement and Liability

The main risks that may arise from non-compliance with product recall laws are as follows:

- **Civil liability.** Suppliers may be ordered to compensate consumers for damages (material, moral, and aesthetic) resulting from defective products (Articles 12 and 14, CDC). Compensation can be awarded in the context of both collective and individual lawsuits. While liability can arise regardless of whether the recalling entity complied with product recall laws, compliance may mitigate exposure to product liability claims (see Product Liability).
- **Administrative liability.** Generally, administrative sanctions for breach of product safety regulations and non-compliance with Ordinance No. 618/2019 include fines and administrative intervention (Article 56, CDC) (see Sanctions and Penalties).
- **Criminal liability.** In the event of failure to notify the competent authorities and consumers of harmful or hazardous products on the market (Article 64, CDC), a company's board of directors and any person who contributed to that failure may be liable to a fine and a term of imprisonment (Articles 75 to 80, CDC).

Sanctions and Penalties

Consumer authorities (SENACON, DPDC, and PROCONs) can impose administrative penalties on the supplier if it does not immediately start a recall process on becoming aware of a safety issue that may cause harm to consumers' health or safety. The DPDC and SENACON consider that delay in starting the recall is sufficient to impose a penalty.

SENACON, the DPDC, and PROCONs can impose one or more of the following penalties for non-compliance with rules on product recalls:

- Fine of up to BRL12 million.
- Product seizure.
- Destruction of the product.
- Cancellation of product registration with the competent authorities (such as SENACON, INMETRO, and ANVISA).
- Prohibition on product manufacture.
- Suspension of product or service supply.
- Temporary suspension of activity.
- Revocation of concession or permission for use (for providers of public services that hold a public service concession or permission to use public assets).
- Cancellation of license for the establishment or activity.
- Total or partial closure of the establishment, work, or activity.

- Administrative intervention (that is, restrictions on the manufacturer's activities in order to protect consumers).
- Counter-advertising.

(Article 56, CDC.)

SENACON, the DPDC, and PROCONs can apply the above penalties on a provisional basis in urgent cases to prevent harm (through an administrative injunction) or on a definitive basis.

A fine is the most common type of penalty imposed. To determine the amount of the fine, SENACON, the DPDC, and PROCONs must take into account the following factors:

- Seriousness of the violation.
- Extent of damages caused to consumers.
- Advantages obtained by the supplier from non-compliance.
- Financial condition of the supplier (total sales revenue can be considered).

(Federal Law No. 2.181/97.)

Product Liability

Product liability is mainly governed by CDC and subsidiarily by the Civil Code (*Código Civil*) (Law No. 10.406/2002) and the Code of Civil Procedure.

The Brazilian courts commonly interpret the concepts of "consumer" and "supplier" very broadly. Therefore, importers and local subsidiaries of foreign companies could be considered "suppliers" and held liable under the product liability regime.

According to the rules on product liability, the manufacturer, producer, builder (national or foreign), and importer are liable, regardless of fault, for:

- Damages caused to consumers by defects arising from the design, manufacture, construction, assembly, formula, handling, presentation, or packaging of their products.
- Failure to provide sufficient or adequate information about their product's use and risks.

(Article 12, CDC.)

Sellers can be held liable in any of the following circumstances:

- The manufacturer, builder, producer, or importer cannot be identified.
- The product is sold without a clear identification of the manufacturer, builder, producer, or importer.
- Perishable products were not properly stored.

(Article 13, CDC.)

Under the strict product liability regime, consumers do not need to prove the supplier's fault. To avoid liability, a supplier must prove any of the following:

- They did not introduce the product into the market.
- The product is not defective.
- The damages are exclusively attributable to the fault of the consumer or a third party.

(Article 14(3), CDC.)

The manufacturer, producer, constructor, and importer, and all persons involved in the supply chain, whether domestic or non-Brazilian, are jointly and severally liable for injuries and damages caused by defective products (Article 12, CDC). The person or entity ordered to compensate the injured party has a right of recourse against other parties who are jointly liable (Article 13, CDC).

Compliance with product recall laws does not exempt the supplier from liability for consumers' damages under product liability rules (Articles 12 and 14, CDC). The STJ has held that the fact that a consumer does not take recalled products for repair, despite a recall campaign, does not exempt the manufacturer from liability if an accident occurs (Special Appeal, 1.010.392/RJ).

Product Recall Compliance

The effectiveness of a recall and the reduction of enforcement risks for suppliers depend on:

- Strict compliance with all statutory deadlines and requirements.
- Full disclosure of information to the competent authorities about the defective product, its risks, and their implications for consumers.

If the defective product is marketed in more than one country, global alignment in the decision to recall and inform authorities and consumers can mitigate enforcement risks.

The traceability of products placed on the market can also contribute to higher rates of consumer servicing (repair or replacement) as it allows consumers to be notified directly (although this does not waive the requirement for public notice).

SENACON also recommends suppliers to use diverse measures and media to communicate with consumers, including through using behavioral inducements (nudges) in their consumer service plan. SENACON also encourages suppliers to use the Consumidor platform to resolve potential disputes with consumers (see Consumer Service Plan).

Information on Recall Campaigns

The DPDC publishes public information on recall campaigns carried out in Brazil (see Gov.br: Portal Defesa do Consumidor). SENACON also publish an annual Bulletin with data on product recalls and other topics related to consumer health and safety in Brazil (data can be accessed at Ministry of Justice: Recall – Campanhas de Chamamento (in Portuguese)).

In addition, SENACON has set up a National System of Recall Alerts (*Sistema Nacional de Alertas de Recall*) (SNAR), which provides access to information on ongoing recalls and reports on past recall campaigns. Registered users can receive alerts any time a recall starts. Users can choose the category of products for which they wish to receive alerts and information. SNAR also provides a database of defective products and can be used by the public to analyze, monitor, and manage product recalls.

SNAR can be accessed from third countries. SNAR is currently the object of a development plan through a partnership between SENACON and the National University of Brasilia.

Brazilian citizens can request to access information on product recalls at the DPDC. Registration with the website of the Ministry of Justice is required. After registration, users have access to the recall records in the SEI (including recall communication, media plans, and progress reports).

Product Recall Trends

The STJ has held that product recalls are beneficial to suppliers and society generally, given their role in preventing damage, rejecting any interpretation that a recall could be discrediting or negative for a supplier. Therefore, the STJ considered that performing a recall does not in itself lead to awards of collective or individual moral damages (Special Appeal, 1.838.184/RS, 5 October 2021).

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