Consumer Product Regulation and Safety: Overview (Brazil)

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A Practice Note providing an overview of Brazil's product regulation for foreign retailers, distributors, manufacturers, or suppliers of goods. This Note sets out information regarding product safety laws and regulations, industry-specific considerations, disclosure requirements, and enforcement in Brazil.

Consumer products are highly regulated in many jurisdictions, which makes product safety and compliance an essential consideration in the global product development, distribution, and retail process. Product safety regulation typically aims to balance consumer protection with innovation and competition. Generally, products 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.

This Note discusses:

- The legal and regulatory requirements governing product safety in Brazil, including industry-specific regulation.
- Key compliance considerations related to products imported into, manufactured, or sold in Brazil, including notification requirements and product recalls.
- Enforcement of product safety issues in Brazil, including sanctions and penalties.

Product Safety Legislation and Regulation

The Consumer Protection Code (*Código de Defesa do Consumidor*) (Law No. 8.078/1990) (CDC) is the main legislation governing product safety in Brazil. The CDC aims to ensure that products and services supplied to consumers comply with adequate quality, safety, durability, and performance standards. The CDC also aims to protect consumers' life, health, and safety against the risks caused by dangerous and harmful products and services.

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

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.

In addition, suppliers must duly inform consumers of:

- The risks that are inherent to the nature of the product.
- The adequate use and maintenance of the product.

(Articles 8 and 12, CDC.)

Under the CDC, suppliers also must not place defective products on the market. A product is considered defective if it does not provide the level of safety that could legitimately be expected of that product. A supplier must recall defective products from the market whenever they become aware that these products may be harmful to consumers' health or safety.

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).

Product Requirements, Approvals, Registrations, and Certifications

The CDC also states that products placed on the consumer market must comply with the standards, norms, and regulations issued by the competent official authorities, depending on the type of product, such as:

- The National Institute for Metrology, Standardization, and Industrial Quality (INMETRO), which is responsible for publishing a detailed list of products subject to mandatory technical standards and conformity assessment requirements to ensure the quality and safety of products and services supplied in Brazil (Law No. 5.966/1973).

  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, highchairs, televisions, washing machines,

household gas stoves and ovens, bicycle tires, and various household appliances). For example, INMETRO's Ordinance No. 333/2012 applies to products subject to compulsory conformity assessment and imposes requirements on suppliers that become aware that a product being sold poses a potential risk to the health and safety of consumers or to the environment.

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.

- The Brazilian Association of Technical Standards (*Associação Brasileira de Normas Técnicas*) (ABNT), which is responsible for issuing technical standards that establish minimum quality, utility, resistance, and safety requirements for different materials, products, installations, processes, and services (Law No. 4.150/1962). If these requirements are met, ABNT can grant labels, seals, and certificates demonstrating compliance with the technical standards called "marks of conformity," which provide credibility and security for the public.

A supplier must not place any product on the market that does not comply with the standards issued by:

- The competent industry regulator.
- The ABNT or any other entity accredited by the National Council of Metrology, Standardisation and Industrial Quality (CONMETRO). CONMETRO is the principal body responsible for shaping, co-ordinating, and overseeing the national policy on metrology, industrial standardization, and certification of products, services, and personnel quality, with INMETRO acting as its Executive Secretariat.

(Article 39, VIII, CDC.)

Products that are not subject to specific requirements must comply with the general rules in the CDC. There are no overarching, general requirements for placing products on the market, as no single authority regulates all products. Requirements are tailored to the specific industry or product type (see Industry-Specific Product Regulation).

Industry-Specific Product Regulation

In addition to the CDC, specific product regulations are issued by various regulatory agencies, such as:

- The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*) (ANVISA). ANVISA is an independent agency affiliated to the Ministry of Health that is responsible for the regulation, approval, and oversight of pharmaceuticals, cosmetics, medical devices, household products, foods, and other health-related products. It ensures that these products are safe for consumer use and have passed the required clinical and laboratory tests.
- The National Telecommunications Agency (Agência Nacional de Telecomunicações) (ANATEL), which is a body linked to the Ministry of Communications responsible for implementing, within its sphere of competence, the national telecommunications policy. ANATEL is also responsible for:
  - issuing and recognizing the certification of products related to the telecommunications sector;
  - prosecuting infringements of users' rights; and
  - exercising powers relating to the control, prevention, and prosecution of infringements of the economic order, in relation to telecommunications.

- The Ministry of Agriculture, Livestock and Food Supply (Ministério da Agricultura, Pecuária, e Abastecimento) (MAPA), which is responsible for:
    - managing public policies to stimulate agriculture;
    - regulating and standardizing services linked to the agriculture sector; and
    - inspecting the production of animal and plant products.

ANVISA has issued Collegiate Board Resolutions (*Resoluções da Diretoria Colegiada*) (RDC) imposing specific requirements applicable to:

- **Food** (such as RDC 724/2022 regarding microbiology standards).
- **Medical devices** (such as RDC 546/2021 regarding safety and effectiveness essential requirements and RDC 548/2021 regarding clinical trials).
- **Medicines** (such as RDC 753/2022 regarding the medicines market authorization process and RDC 09/2015 regarding clinical trials).
- **Cosmetic products** (such as RDC 752/2022, which sets out technical requirements, procedures for registration, labeling and packaging guidelines, and microbiological control parameters).

Suppliers that place products on the market that do not comply with ANVISA resolutions must conduct a recall that complies with ANVISA's resolutions (see Product Recall).

Generally, MAPA regulates all animal feed products (Decree 6296/2007) and products of animal or vegetable origin for human consumption. ANVISA regulates some categories of food products (Decree 986/1969) such as food supplements (RDC 239/2018) and also issues general rules governing labels and certain product specifications.

However, there are certain exceptions. For example, MAPA regulates milk and dairy products, meat, fish, beverages (Law No. 8.918/1994), and wines and grape products (Law No. 7.678/1988) (Decree 9.013/2017 and Regulation of the Industrial and Sanitary Inspection of Products of Animal Origin (RIISPOA) 2020). Products such as food supplements, tea, cakes, chocolate, candies, and mixtures for food complementation are regulated by ANVISA's RDC 23/2000, RDC 22/2000 (for imported products), and RDC 27/2010.

Cosmetics, personal hygiene products, and perfumes are categorized as:

- Grade 1: these products have basic or elementary properties that do not require evidence or detailed information regarding their mode of use and restrictions on use.
- Grade 2: these products have specific indications that require proof of safety or efficacy, and information on precautions, mode of use, and restrictions on use.

(RDC 752/2022.)

Article 34 of the RDC 752/2022 provides a list of products that must be registered with ANVISA before being placed on the market (such as suntan lotions, hair straightening, curling, and dyeing products, antiseptic hand sanitizing gels, sunscreens, and insect repellents). Products that are not listed in Article 34 must be notified to ANVISA before being placed on the market (Article 35, RDC 752/2022).

Similarly, medical devices are classified as follows:

- Risk 1 or 2: these are lower-risk medical devices that must be notified to ANVISA.
- Risk 3 or 4: these are higher-risk medical devices that must be registered with ANVISA.

(RDC 751/2022 and RDC 36/2015 (for in vitro diagnostic (IVD) medical devices).)

The rules applicable to medical products also depend on whether the product is an equipment, an implant, a material or an IVD.

Contract: Express and Implied Terms

Suppliers have a general obligation to supply products that meet the standards of safety that can legitimately be expected of these products according to currently accepted industry standards (Article 6, CDC). This obligation is implied by law and cannot be excluded by the supplier from contracts and other legal transactions.

Sellers and suppliers are responsible for defective products for a minimum period. Brazilian law implies certain terms into consumer contracts and provides remedies for breach of these terms.

The minimum standards for goods, services, and digital content imply that goods and services are free from defects that may diminish their quality, quantity, durability, and the level of safety that is normally expected from them (Article 8, CDC).

In the event of defective or misdescribed goods, the supplier must be given an opportunity to repair the defect within 30 days of the consumer notifying the supplier of the defect. If the goods are not repaired, the consumer can opt for any of the following:

- Replacement of the goods, at the supplier's cost.
- A full refund of any payment already made (increased as necessary to reflect inflation and other economic factors for the period from the date of the consumer's original payment to the date of refund).
- A proportional reduction of the price.

(Article 18, paragraph 1, CDC.)

Sellers and suppliers can offer an additional contractual guarantee extending the period for which they are responsible for defective products and the remedies offered. Any additional guarantee is legally binding and must be set out in writing (Article 50, CDC). Remedies for breach of this guarantee are those for breach of an express contract term.

A supplier cannot limit or exclude its liability to consumers for defective products (for example, by restricting the remedies available under the law) (Article 25, CDC). Contractual clauses that exclude or limit the supplier's liability for defective products or restrict consumers' rights are null and void, except when the consumer is a legal entity (Article 51, I, CDC). However, the courts generally interpret this exception restrictively.

Product Packaging and Labeling

Information on the packaging and labeling of a product must correspond exactly to its characteristics, quantity, and intended purpose. Suppliers are liable for defects that render products unfit or unsuitable for the purpose for which they are intended

or diminish their value, including those arising from disparity with the indications on the container, packaging, labeling, or advertising message. (Article 18, CDC.)

Product Packaging

Product packaging must comply with the same safety requirements as other products, in accordance with current accepted industry standards (Article 18, CDC).

Regulatory agencies (such as ANVISA, INMETRO, and ANATEL) can also impose special packaging rules for industry-specific products.

For example, ANVISA has issued special requirements governing:

- Food packaging, to avoid the chemical migration of harmful substances from packaging to the product (RDC 91/2001).
- Child-proof packaging of controlled medicines (Ordinance No. 344/1998).

INMETRO has issued specific regulations on:

- Individualized blister-type food packaging that have a net content of up to 20 grams (Ordinance No. 387/2021).
- Packaging used for the bottling of alcohol (Ordinance No. 460/2021).
- Packaging used in land transportation of dangerous goods (Ordinance No. 320/2021).

The above requirements impose mandatory technical regulations regarding the manufacture, import, distribution, and marketing of the relevant types of packaging to protect consumer safety.

Product Labeling

Consumers have the right to receive adequate and precise information on:

- Products, including essential characteristics of the goods (Article 6, III, CDC).
- Potential hazards of products (Article 8, §1, CDC).

As a general rule, all labels must provide clear, precise, and readable information in Portuguese on the product's:

- Quality and quantity.
- Composition.
- Expiration date.
- Origin.
- Risks to consumers' health and safety.

- Manufacturer and importer/distributor, such as registered company's name, physical and electronic address, contact information, and registration number with the National Registry of Legal Entities (*Cadastro Nacional de Pessoas Jurídicas*) (CNPJ).

(Articles 6, III, and 31, CDC.)

In addition, specific labeling requirements apply to industry-specific products. For example, labels of cosmetic products must include all information listed in Chapter IV of ANVISA RDC No 752/2022 (such as content, warnings, restrictions on use (if applicable), expiration date, and customer service contact details). In addition, specific warnings must be included on labels of certain cosmetic products, as set out in Section II of RDC No 752/2022 (for example, aerosol products, hair whitening products and dyes, tan activators, hypoallergenic products, and so on).

Medicines are generally subject to more stringent labeling requirements. For example, labels of medicines must not include:

- Images of people using the medicine.
- Stamps, logos, or brands of medical or patients' organizations.
- Images that may indicate the medicine's taste.
- Images or expressions implying that the person's health may be affected if they do not use the medicine.
- Any label that has a similar layout to that of another medicine with the same active ingredient registered by another company.

(RDC 71/2009.)

Labels of medicines must be in Portuguese and are subject to approval with ANVISA on registration of the medicine. They must also indicate the brand name and active ingredient in Braille (Article 24, RDC 71/2009). In addition, all medicines must be commercialized with an information pamphlet or leaflet that provide details on their use, side effects, and contraindications and comply with the content, formatting, and accessibility requirements of RDC 47/2009. Medical devices must also have instructions for use in Portuguese.

Labels of imported cosmetics, foods, and medical devices commercialized in Brazil can be in a foreign language. However, they must be accompanied by a label in Portuguese displayed outside of the product so that consumers can read it and make an informed purchasing decision.

Imported Products

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

Importers of Foreign Manufactured Products

Under the CDC, a supplier is 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).

Importers can be held liable for non-compliance with product safety regulations in Brazil. Therefore, they should ensure that imported products comply with all domestic safety and health regulations, such as labeling and information requirements (see Product Labeling).

A foreign supplier or distributor can serve as an importer of goods into Brazil. They must comply with all Brazilian product safety, import, and tax laws. In addition, any person that the consumer reasonably perceives as a supplier of the product is held to be part of the supply chain of that product. Therefore, manufacturers, importers, distributors, and retailers are jointly and severally liable for any damage caused to consumers by a defective product, regardless of fault (Articles 7, 12, and Article 25, paragraph 1, CDC).

If the importer cannot be identified, the retailer may instead be held liable for a defective product (Article 13, I, CDC).

Imported products subject to ANVISA's requirements cannot be commercialized in Brazil without previous authorization from ANVISA. Foreign manufacturers of these products must have a partner company incorporated in Brazil that will be legally responsible for the products imported into, and distributed in, Brazil. For example, medical devices must go through the INMETRO certification process and, in some cases, homologation by ANATEL, before being notified to, or registered by, ANVISA. After ANVISA import authorization is obtained, the importer is legally responsible for the product in Brazil.

Foreign Manufacturers

A foreign manufacturer is considered a supplier under the rules on product liability (Article 3, CDC). When a foreign manufacturer does not export products directly to Brazil, but uses an intermediary such as a local distributor, both the manufacturer and intermediary are liable for product defects and safety issues. The foreign manufacturer and all 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).

Brazilian consumers can file actions for damages in Brazil against a foreign manufacturer. Any resulting damages award 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)).

Manufacturers are jointly and severally liable with other persons in the product's supply chain, regardless of whether they are local or foreign (see Product Liability).

A foreign manufacturer may face penalties and be required to take corrective actions when dealing with a hazard or defect associated with their products (see Product Recall and Sanctions and Penalties).

Brazilian consumer authorities and regulators can also 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 recall and safety measures.

Also, foreign manufacturers of high-risk medical devices (risks 3 and 4) and medicines must have their manufacturing sites inspected and certified by ANVISA to obtain Good Manufacturing Practices (GMP) Certification. This is required for registration of the product with ANVISA. In practice, GMP Certification is issued to the Brazilian entity responsible for the product in Brazil, as only Brazilian entities can apply for international GMP certification. A certification request must include documents on the international manufacturing site. Typically, these include a manual of food practices, the site layout, and inspection reports from other authorities.

GMP Certification lasts one to three years, depending on the type of product. GMP Certification must be renewed between 270 and 180 days before its expiration. GMP Certification must be maintained throughout the product's registration in Brazil. If manufacturing defects are confirmed, the foreign manufacturer may have its GMP Certification canceled and be prevented from selling products in Brazil.

Product Safety Compliance and Risk

An effective product safety compliance program should involve a conformity assessment of the product using quality management techniques, to ensure that the products meet Brazilian product safety requirements set out in the CPC and industry-specific regulations.

A systematized conformity assessment process usually involves manufacturers (domestic or foreign), taking the following steps, among others:

- Selecting a standard or regulation.
- Collecting samples.
- Performing analyses.
- Selecting a laboratory responsible for testing.
- Carrying out tests.
- Conducting inspections.
- Interpreting the results of tests and inspections.
- Auditing suppliers' quality management systems.
- Conducting follow-up audits.
- Defining the systematic treatment of non-conformities that may be identified.
- Taking follow-up measures in the market.

The initial conformity assessment should be complemented by ongoing monitoring and control measures to ensure that the product is effectively put on the market in accordance with the applicable rules. Monitoring and control measures are more complex than the initial assessment and therefore, requires more resources (such as training of personnel) and a greater degree of systematization (including robust quality and traceability systems).

Generally, the above considerations apply equally to foreign and domestic manufacturers.

Risk Management

Risk management is a quality management tool involving the systematic application of management policies, procedures, and practices to analyze, assess, control, and monitor risks associated with a particular product or process. The goal is to mitigate risks as much as possible, reducing any damage that can be caused to consumers.

There is no law that guides manufacturers, importers, distributors, and sellers on how to assess risk and safety defects. However, some industry-specific instruments impose risk management requirements for certain products.

For example, ANVISA resolutions provide that risk management for health products and medicines must be carried out in accordance with GMP (Article 18, RDC 665/2022 (health products); Article 21, RDC 658/2022 (medicines)). GMP require manufacturers and suppliers of ANVISA-approved products to maintain an internal Risk Management (*Gerenciamento de Risco*) (GR) document to help make decisions regarding field actions, such as product recalls. For example, a company that receives a complaint indicating a new risk (not mapped on the GR document) must take appropriate measures. If the complaint relates to a risk that has already been mapped, the company may not need to take any action, as measures may have already been taken in accordance with the GR document. This obligation only applies to ANVISA-approved products.

In addition, ANVISA has issued specific rules on post-market risk assessment for:

- Medicines (RDC 406/2020).
- Medical devices (RDC 67/2009).
- Cosmetics (RDC 332/2005).

Manufacturers of products that are not subject to specific standards can rely on international standards, such as ISO 31000:2018, which covers risk management.

Communication to SENACON

SENACON and the DPDC are the main government bodies responsible for:

- Regulating and supervising product recalls.
- Monitoring suppliers' compliance with recall procedures.

SENACON's and DPDC's responsibilities are set out in Articles 105 and 106 of the CDC and Article 3 of Federal Decree No. 2.181/1997.

A supplier that becomes aware that a product placed on the consumer market is harmful or dangerous must immediately inform consumers, SENACON, and any competent regulatory authority (such as ANVISA or INMETRO). (Article 10, first paragraph, CDC).

SENACON must be informed within 24 hours of the supplier's 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 of the Ministry of Justice).

Any voluntary decision to recall products must be communicated to SENACON, preferably through the Electronic Information System (SEI) or any other system designated by SENACON, within two business days from the decision to conduct the recall campaign (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 communication with SENACON (Article 3(4)-(5), Ordinance No. 618/2019).

Communication to SENACON that a product is harmful or dangerous must be in writing and in Portuguese, and include the following information:

- Identification of the supplier.

- Detailed description of the product and defective component, with characteristics necessary for their identification.
- Detailed description of the defect and date of discovery of the hazard or harmfulness.
- Detailed, clear, and ostensible description of the risks and their implications for consumers.
- Quantity of defective products placed on the Brazilian market, including those still in stock, and number of consumers affected.
- Geographic distribution of defective products, per federate state, and countries where the products were exported.
- Measures already adopted and proposed measures to remedy the defect and mitigate risks.
- Description of accidents related to the defective product (if applicable).
- Media plan for informing affected consumers.
- Model of risk notice to consumers.
- Consumer support plan.

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

SENACON must issue a technical note on compliance with the above information requirements within five business days from receipt of the communication (Article 3(6), Ordinance No. 618/2019).

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

The competent authorities (such as SENACON, INMETRO, ANVISA, and so on) may also become aware of potential safety risks relating to products through consumer complaints, market monitoring, news of accidents, and recalls carried out in other countries. For example, INMETRO monitors cases of consumer accidents and when INMETRO or other competent authorities identify health and safety risks, INMETRO must inform SENACON that it will adopt the necessary measures for the conduct of a recall.

Product Recall

Product recall is the main form of corrective measure to remove harmful and dangerous products from the market (see Practice Note, Consumer Product Recalls: Overview (Brazil)). A supplier must take all appropriate measures to ensure that defective products are immediately collected and replaced, repaired, or reimbursed.

If the supplier does not voluntarily carry out a recall, certain competent authorities (mainly SENACON and the DPDC) can require suppliers to conduct a recall and determine the recall procedure. A recall can be imposed for products that are potentially harmful or dangerous to the health or safety of consumers (Article 6, paragraph 1, Ordinance No. 618/2019).

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

- Deadlines to notify public authorities about the supplier's investigation and decision to perform a recall.
- The contents of the recall communication to SENACON (see Communication to SENACON).
- The supplier's media plan for informing consumers.

- The contents of the risk 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 in Brazil:

- Ordinance No. 20/2020 of the Ministry of Justice.
- SENACON's Technical Notes No. 4/2020, No. 6/2020, and No. 28/2020.

A voluntary recall of the same product in another jurisdiction also triggers a communication obligation to SENACON if the product was introduced onto the Brazilian market. A recall must also then be conducted in Brazil. A foreign manufacturer that did not introduce the product onto the Brazilian market is not required to perform the recall in Brazil. In this case, the importer, distributor, 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.

Generally, the recall must be carried out in accordance with the manufacturer's instructions. However, as a foreign manufacturer is considered a supplier under the CDC, it must still comply with consumer protection rules (Article 3, CDC).

SENACON must inform state and municipal consumer protection agencies (*Procuradorias de Proteção e Defesa do Consumidor*) (PROCONs) of recall campaigns. When federal, state, or municipal authorities become aware that services or products may present a health or security risk to consumers, these authorities must also inform consumers about this (Articles 10(3), CDC).

Depending on the product, the supplier may also need to notify other government agencies of the recall (such as ANVISA, INMETRO, or MAPA). Certain industry regulators have issued rules governing the recall of certain products. For example:

- ANVISA impose requirements for the recall of medicines (RDC 625/2022), food products (RDC 665/2022), and medical devices (RDC 551/2021).
- Decree No. 9.013/2017 of the Presidency of the Republic regulates the mandatory recall program for products of animal origin.

Enforcement and Liability

Product safety legislation is enforced by the following bodies:

- Regulatory agencies (such as ANVISA, INMETRO, and ANATEL).
- The Judiciary and courts, which have jurisdiction over disputes related to consumer relations.
- The Public Attorney's Office, through its agents and specialized attorneys, which can investigate conduct affecting consumer protection.

- The DPDC, which co-ordinates the national consumer protection framework and has the power to investigate and impose sanctions for conduct affecting consumer protection.
- PROCONs, which deal with consumer complaints and have the power to investigate and impose sanctions for conduct affecting consumer protection in the relevant federal state.
- Private consumer protection associations, which promote actions to enforce consumers' rights.

Breach of product safety rules can lead to:

- **Civil liability.** Suppliers that do not meet safety requirements may be ordered to compensate consumers for damages (material and moral) resulting from defective products (Articles 12 and 14, CDC). Compensation can be awarded in the context of both collective and individual lawsuits (see Product Liability).
- **Administrative liability.** Generally, administrative sanctions for breach of product safety regulations include fines and administrative intervention (Article 56, CDC). SENACON and PROCONs can also impose specific sanctions for breach of Ordinance No. 618/2019, which governs product recalls (see Sanctions and Penalties).
- **Criminal liability.** a company's board of directors and anyone who contributed to that failure may be liable to a fine (Article 77, CDC) and a term of imprisonment of six months to two years (Articles 63, 64, 66, and 75, CDC) for:
  - failure to notify the competent authorities of harmful or hazardous products or failure to comply with the order to recall harmful or hazardous products from the market;
  - failure to include words or signs about the harmfulness or danger of products on packaging or advertisements; and
  - making false or misleading statements about the quality, quantity, price, characteristics, or safety of products.

Sanctions and Penalties

PROCONs and SENACON can impose administrative sanctions for violations of the CDC, including:

- Fines of up to BRL12 million.
- Seizure of the product.
- Destruction of the product.
- Revocation of product registration with the competent authorities.
- Prohibition on product manufacture.
- Suspension of the supply of products or services.
- Temporary suspension of activity.
- Revocation of concession or permission of use (for providers of public services that hold a public service concession or permission to use public assets).
- Revocation of the establishment's license.

- Total or partial interdiction of establishment, work, or activity.
- Administrative intervention (that is, restrictions on the manufacturer's activities to protect consumers).
- Counter-advertising measures.

(Article 56, CDC.)

The Public Attorney's Offices and consumer defense associations can file class actions against a supplier for violations of consumer legislation. They can request the court to order the supplier to take specific measures and provide compensation for individual damages and collective moral damages. Specific measures and compensation can be also granted by the judge in an injunction order.

Product Liability

Under the CDC, product liability arises for damages caused by a defective product. This is a form of strict liability, meaning that a supplier is liable regardless of fault.

Manufacturers, producers (domestic or foreign), suppliers, distributors, and importers of defective products are liable for:

- Damages caused to consumers by defects in a product's design, manufacture, construction, assembly, formulation, manipulation, presentation, or packaging conditions.
- Failure to provide information, or providing inadequate or insufficient information, on the use of and risks related to a product.

(Article 12, CDC).

Manufacturers, importers, distributors, suppliers, retailers, and all the parties involved in the supply chain are jointly and severally liable for consumers' damages arising from product safety issues. These parties can contractually allocate responsibility among themselves, but not their liability to consumers.

A manufacturer is only exempted from liability if it can show that:

- It did not place the product on the market.
- Although it placed the product on the market:
    - there was no defect; or
    - the damage was exclusively attributable to the consumer or third parties.

(Article 12(3), CDC.)

In exceptional circumstances, the retailer may be held liable if it sells products either:

- Without clear identification of the manufacturer, constructor, producer, or importer.
- In a poor state of preservation (for perishable products).

(Article 13, CDC.)

Compensation can be awarded for the following damages:

- Pecuniary.
- Non-pecuniary.
- Individual.
- Collective (regarding an identifiable category or class of persons).
- Diffuse (regarding an unknown group of individuals, for example, arising from misleading advertising).

(Article 6, CDC.)

Any person who suffers damage as a result of a defective product can bring a claim against the supplier, distributor, manufacturer, or any other person directly involved in the supply chain, regardless of whether they are party to a contract with the defendant (Article 931, Civil Code (Código Civil) (Law No. 10.406/2002); Article 17, CDC).

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