

Shipboard sanitary inspections in Brazil



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Practical Guidance

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This publication is not a legal advice nor is not intended to be any comprehensive or to replace any other guidelines issued by the flag State, relevant health authorities and liability insurers.

1. Foreword

Based on our practical experience in dealing with Brazilian port health authorities, we prepared this handbook with information and practical guidance on the sanitary inspection conducted by these authorities and control measures the shipmasters and operators should take to reduce exposing the seafarers and passengers to health risk and avoid problems with authorities regarding the enforcement of the relevant health regulations.

Due to the regulatory complexities involved and lack of a centralised database on sanitary and health regulations and controls at national and international levels, there will inevitably be information gaps and we shall, therefore, perform regular reviews and update this publication as and when new information becomes available to us.

While this guidance is not aimed at being comprehensive or replace any provisions under relevant regulations and directives, we hope it is useful as a source of practical reference to the shipmasters, operators and insurers.

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2. International health regulations

The purpose of the International Health Regulations of 2005 (IHR 2005), which was adopted by the World Health Organization (WHO) and came into force in 2007, is to “*prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade*”¹.

Brazil is a Member of both WHO and the Pan American Health Organization (PAHO) and upholds the purpose and principles of the IHR 2005, which was introduced into its legal system in 2009² to form the basic framework of the domestic sanitary and health regulations pertaining to surveillance and control of airports, ports, ground crossings, aircrafts, ships and other conveyances.

The Agência Nacional de Vigilância Sanitária – ANVISA (National Health Surveillance Agency) is the regulatory body under the purview of the Ministério da Saúde (Ministry of Health) that plays the institutional role of port health authority and is responsible, amongst various other regulatory duties, to enforce compliance with the international health regulations and issue ship sanitation certificates, also functioning as the National IHR Focal Point (NFP) of the IHR 2005.

¹ Art. 2 of the World Health Organisation (WHO)'s “*International Health Regulations*”, 2005 (IHR 2005)

² IHR 2005 was approved by the Legislative Decree no. 395 of 2009, “*Regulamento Sanitário Internacional (RSI 2005)*”

3. Brazilian port health regulations

3.1. Legal principle

Health is a fundamental right under the Federal Constitution of Brazil and the government at all levels of the federation is responsible for the regulation and control of health activities and services, sanitary and epidemiologic surveillance and implementation of preventive measures to control spread of diseases.

These duties are exercised through the national healthcare system *Sistema Único de Saúde – SUS* (Unified Health System) that involves public organs and institutions at federal, state and municipal levels. SUS is composed of the *Secretaria de Vigilância em Saúde* (Secretariat of Health Surveillance), the *Departamento de Vigilâncias das Doenças Transmissíveis* (Department of Surveillance of Transmissible Diseases) and the *Agência Nacional de Vigilância Sanitária – ANVISA* (National Health Surveillance Agency).

The surveillance of ports, airports and ground crossings in Brazil falls within the jurisdiction of the federal government, through the *Ministério da Saúde* (Ministry of Health) and is conducted under the *Sistema Nacional de Vigilância Sanitária* (National System of Health Surveillance) by ANVISA.

3.2. Port health authority

ANVISA is the federal agency linked with the Ministry of Health that is in charge of the health surveillance, as mandated by the Federal Constitution. Created in 1999³, ANVISA is ruled by a Collegiate Board of Directors composed of five members and operates under a special regime of independent administration and financial autonomy.

Within its wide scope of jurisdiction, ANVISA has the duty of assuring the sanitary and epidemiologic surveillance, vector and health control strategies in Brazilian ports and vessels, including control of importation and exportation of goods subject to sanitary and epidemiologic surveillance.

3.3. Port health regulations

At federal level, port health matters are regulated by a vast array of laws, resolutions, ordinances and service orders, some of which have significant influence on the health and sanitary control of vessels trading in Brazil.

The core technical regulation in respect of health and sanitary control of vessels in Brazilian ports is mainly set forth in ANVISA's resolution RDC 72/2009⁴ and its subsequent amendments that regulates the entry and permanence of vessels in the country and enforces the health measures and documentary requirements provided for under the IHR 2005 and related regulations.

³ ANVISA was created through Law no. 9782 of 1999, as amended by Provisional Measure (*Medida Provisória*) no. 2190, 2001, that defined the National System of Health Surveillance (*Sistema Nacional de Vigilância Sanitária*), its institutional mission being "To protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance. This mission must be carried out in coordination with states, municipalities and the Federal District, according to the Brazilian Unified Health System principles, in order to improve the quality of life of the population."

⁴ Collegiate Directorate Resolution (*Resolução da Diretoria Colegiada*) – RDC no. 72, 2009, as amended by RDC no. 10, 2012, by ANVISA

There are numerous national laws and regulations with direct significance in the port health controls. The list below features the most relevant national health legislation and regulation:

Regulation	Subject
▪ Law-Decree No. 2,848, dated 07/12/1940 (Penal Code)	Crimes against Public Health
▪ International Health Regulations 2005 (IHR 2005)	Seeks to prevent, protect against, control and provide a public health response against the international spread of diseases, proportionate and limited to the risks to public health ways, and that avoid unnecessary interference with international traffic and trade, as approved by Decree 395/2009
▪ Law No. 6,259, dated 30/10/1975	Provides for the organization of the actions of Epidemiological Surveillance on the National Immunization Program, establishes rules for the compulsory notification of diseases, and other measures
▪ Law No. 6,437, dated 20/08/1977	Sets violations of federal health legislation establishes their sanctions, and other measures
▪ Law No. 8,080, dated 19/09/1990	Provides for the conditions for the promotion, protection and recovery of health, the organization and functioning of relevant services and other matters
▪ Law No. 12,305, dated 02/08/2010	Establishes the National Policy on Solid Waste; amends Law No. 9,605 dated 12/02/1988, and other measures
▪ Decree No. 87, dated 15/04/1991	Simplifies the health requirements for entry and stay of foreigners in the country, amending Decree No. 86,715, dated 10/12/1981, and other provisions
▪ Law No. 9,782, dated 26/01/1999	Defines the National Sanitary Surveillance System, created the National Health Surveillance Agency, and other measures
▪ Decree No. 7,616, dated 17/11/2011	Provides for the declaration of Emergency Public Health of National Importance – ESPIN and establishing the National Strength Unified Health System – SUS-FN
▪ ANVISA – RDC No. 21, dated 28/03/2008	Provides for the Guidance and Control Travellers Health in Ports, Airports, Flights Border and Customs
▪ ANVISA – RDC No. 56, dated 06/08/2008	Provides for the Technical Regulation of Good Sanitary Practices in Solid Waste Management in the areas of Ports, Airports, Flights Border and Customs.
▪ ANVISA – RDC No. 72, dated 29/12/2009	Provides for the Technical Regulation which aims to promote health in ports installed sanitary control in the country, and vessels transiting through them, as amended by ANVISA RDC No. 125, dated 30/11/2016
▪ ANVISA – RDC No. 33, dated 08/07/2011	Provides for Sanitary Control and Inspection of the Transfer of Human Remains
▪ ANVISA – RDC No. 345, dated 16/12/2002	Provides for the approval of the Technical Regulations for Operating Permit from companies interested in providing the interest of public health services in land vehicles that operate international public transport of passengers, vessels, aircraft, terminals waterway, organized ports, airports, border crossings and customs areas
▪ ANVISA – RDC No. 346, dated 16/12/2002	Approves as Annex I, the Technical Regulation for Special Operating Permit and Operating Permit for companies interested in operating the activity of storing goods under sanitary surveillance in Waterway Terminals, Ports Organized, airports, Frontier and Customs
▪ ANVISA – Resolution RE 09, dated 16/01/2003	Technical Guidance on reference standards of indoor air quality in artificially air conditioned environments
▪ ANVISA Sanitary Guide for Cruise Ships, 2011	<i>Guia Sanitário de Navios de Cruzeiro</i> (Brazilian Sanitary Guide for Cruise Ships), updated in 2014

4. International health documents

Under the IHR 2005, vessels, crew and passengers engaged in international traffic are required to possess a set of mandatory health documents when trading in States Parties, such as Brazil.

4.1. Certificate of vaccination or prophylaxis

All crewmembers and passengers must be in possession of an International Certificate of Vaccination or Prophylaxis⁵, with evidence that they have been vaccinated as per entry requirements, if any.

The vaccination certificate must be issued strictly:

- In the WHO format, written any language, in addition to English or French
- Signed in the hand of the medical practitioner
- With the official stamp of the authorised vaccination centre
- With the name of the manufacturer and the batch number of the vaccine
- Free from any erasures, amendments and with all fields completed

The vaccination certificate remains valid until the expiry date indicated for the vaccination or prophylaxis. Failure to possess the certificate with evidence of vaccination, where it is required, may result in the need of vaccination and a fine.

At present, yellow fever vaccination is a condition of entry into the country for persons who have been in Angola or D. R. Congo in the last seven days before arrival in Brazil⁶. Persons arriving from these two countries who do not possess evidence of vaccination, or who have been vaccination in less than 10 (ten) days, which is the time it takes for the inoculation to produce effect, may be denied entry or subject to vaccination and eventual quarantine at the discretion of ANVISA.

Otherwise, yellow fever vaccination is only recommended to specific regions of the country⁷.

It should be noted that with effect from July 2016, the period of validity of the yellow fever vaccination was changed from 10 (ten) years to the duration of the life of the person vaccinated⁸.

4.2. Maritime declaration of health

Before vessel's arrival, the Master must ascertain the state of health of the crew and passengers on board during the voyage and upon arrival at the port and faithfully complete the Maritime Declaration of Health⁹, strictly in the WHO format.

⁵ Article 36 of IHR 2005

⁶ ANVISA Resolution RE No. 1,822 of July 2016

⁷ Travellers must check WHO International travel and health website (<http://www.who.int/ith/en/>) to check the list of Brazilian states to which yellow fever vaccination is recommended. As at May 2016, WHO recommendations are: "travellers aged 9 months or over going to the states of Acre, Amapá, Amazonas, Distrito Federal (including the capital city of Brasília), Goiás, Maranhão, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Pará, Rondônia, Roraima and Tocantins, and designated areas of the following states: Bahia, Paraná, Piauí, Rio Grande do Sul, Santa Catarina and São Paulo. Vaccination is also recommended for travellers visiting Iguazu Falls. Not recommended for travellers whose itineraries are limited to areas not listed above, including the cities of Fortaleza, Recife, Rio de Janeiro, Salvador and São Paulo".

⁸ World Health Assembly resolution WHA67.13 of May 2014, which amended the IHR 2005, stipulates that as from 11 July 2016, the period of validity of the yellow fever vaccination will be changed from the current 10 years to the duration of the life of the person vaccinated

⁹ Article 37 of IHR 2005

The declaration must state the actual sanitary conditions on board and be accompanied by reports of medical occurrences or health measures¹⁰ performed during the voyage and upon arrival at the port, details of which should be described in the schedule.

If there is a stowaway on board, for example, his/her identity, place of boarding and health status and behaviour must also be informed in the declaration.

Failure to report suspected cases of a disease of compulsory notification or evidence of a public health risk¹¹ on board is a violation of the health regulations.

IHR 2005 identifies and lists specific international diseases (smallpox, poliomyelitis due to wild-type poliovirus, influenza caused by a new subtype and severe acute respiratory syndrome – SARS) for which notification to the health authorities must compulsorily be made. Other diseases, such as cholera, pneumonic plague, yellow fever, VHFs, West Nile fever, and diseases of national or regional reach, such as dengue, Rift Valley fever and meningococcal disease, must be reported if it is considered an unusual or unexpected event with significant risk of international spread.

4.3. Ship sanitation certificates (SSCC/SSCEC)

With the adoption of the IHR 2005, the Deratting Certificate and Deratting Exemption Certificate issued under the earlier International Health Regulations (IHR 1969) are no longer valid since 2007, when they were fully replaced by the much broader Ship Sanitation Certificates (SSC)¹² introduced by the new regulations.

Unlike the decommissioned certificates, the SSC is not limited to control of rodents. It identifies and records evidence of health and sanitary conditions on board and its issuance demands the application of comprehensive and detailed inspection procedures and techniques to prevent and control public health risks.

Although the deratting certificates were phased out, the vessels are still required to implement and maintain an adequate integrated vector management plan (IVM) that includes evidence of deratting and disinsection.

There are two types of SSCs under the IHR 2005:

Certificate	Condition
Ship Sanitation Control Certificate (SSCC)	A SSCC is issued when there is evidence of a public health risk on board and health measures have been satisfactorily completed. The evidences found and control measures taken are recorded in the SSCC
Ship Sanitation Control Exemption Certificate (SSCEC)	The SSCEC is issued when there is no evidence of public health risk and the competent authority is satisfied that the vessel is free from infection or contamination, including vectors

¹⁰ Under IHR 2005 definition, a 'health measure' "means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures".

¹¹ Under IHR 2005 definition, a 'public health risk' "means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger".

¹² Article 39 of IHR 2005

The SSCC is valid for a maximum of 6 (six) months and the control measures must be completed before a new certificate is issued. The SSCEC has the same validity as the SSCC but is extendable, only once and for a maximum of 30 (thirty) days after expiry date if the inspection for renewal or application of control measures, as may be required, cannot be accomplished at the port of arrival.

If a valid SSC issued at a port authorised to renew or extend SSCs – the so-called 'IHR authorised ports' – is not produced on demand, or if there is evidence of a public health risk on board, the vessel may be considered as an affected conveyance subject to health measures in which case the granting of the free pratique will be conditioned to the vessel obtaining a new SSC, certainly ensuing delays, loss of hire and extra costs.

The list of IHR authorised ports is regularly updated and available for free consultation and download from the WHO public website¹³. Notable absentees from the list are the United States where no port at all is authorised to issue or extend SSC¹⁴.

SSCs issued by non-authorised ports or by private clinics, even if strictly in the WHO format, will be rendered invalid and the vessel must be issued with a new certificate resulting in the need of a further sanitary inspection and additional expenses.

All IHR authorised ports in Brazil issue both SSCC and SSCEC and extensions for an official tariff¹⁵, payable through the official banking system, with no cash payment directly to the health inspectors. ANVISA's sanitary inspection for the issuance or extension of SSCs must be booked through the Paperless Port (PSP)¹⁶ system in advance of vessel's arrival and vessels should be well-prepared to undergo the sanitary inspection, as discussed in the next chapter.

In most Brazilian ports, the inspection only takes place during business days from 08:00 to 17:00 hours (local time). The actual working hours must be double checked with the agents ahead of vessel's arrival.

Some ports and terminals in Brazil would not allow a vessel to enter without a valid free pratique issued by ANVISA, meaning that in places where the sanitary inspection is not carried out at anchorage, such as in the Port of Santos, the vessel has to firstly come alongside a layby berth, when and if available, to be inspected and granted the free pratique before being allowed to proceed to the operative berth whether the cargo and/or passengers operations were originally scheduled to take place.

¹³ IHR 2005 authorised list of ports and other information submitted by the States Parties concerning ports authorized to issue SSCs can be downloaded at: http://www.who.int/ihr/ports_airports/portslanding/en/

¹⁴ US ports adopt the purportedly stricter Vessel Sanitation Program (VSP) of the U.S. Center for Disease Control and Prevention (CDC) that operate under the authority of the Public Health Service Act (42 U.S.C. Section 264 Quarantine and Inspection Regulations to Control Communicable Diseases)

¹⁵ As at February 2017, ANVISA published tariff to issue/extend SSCs is BRL 1,772.90 with boat transportation, if any, for owners' account

¹⁶ *Porto Sem Papel* – PSP (Paperless Port) is a single-window electronic system managed by the Secretariat of Ports (*Secretaria dos Portos*), Ministry of Transports (*Ministério dos Transportes*), through which mandatory documents are furnished by carriers and cargo interests to the intervening regulatory agencies and governmental authorities

Since the SSC is valid for 6 (six) months, the renewal of the certificate should be scheduled and planned with sufficient time in advance of its expiration date otherwise the vessel might face delays, extra costs, expenses and loss of hire.

It is recommendable that the renewal be scheduled at least 40 (forty) days before expiration and no less than 20 (twenty) days for vessels on a regular line to ensure that the vessel reaches an IHR authorised port within local working hours and with sufficient time during the call to undergo sanitary inspection and health control measures, if required.

Instead of relying solely on the advice of the local agent, the vessel's operators or managers themselves should consult WHO website list to make sure that the intended port of call is in fact a listed IHR authorised port.

4.4. Certificate of free pratique (CLP)

The Free Pratique shall be required by vessels operating on deep sea, cabotage, inland navigation, maritime support and port support performing the following services: fresh water supply and storage; discharge of solid residues or sewage; storage or handling of food and industrialised water; and storage of raw material, semi-processed and products under sanitary surveillance, ready for consumption.

If observed by ANVISA, after analysis of documents mentioned on item 5.2.1, that there is no risk or evidence of a health or sanitary risk on board, the vessel may receive the Free Pratique via radio, albeit, still subject to a sanitary inspection as per ANVISA's officers discretion.

4.4.1. Validity

For vessels operating on deep sea trade, the Free Pratique shall be valid during her stay in the port. Free pratique to vessels flying the Brazilian flag and operating in the cabotage or inland trades are valid for 90 days, same for off-shore supporting ships.

4.4.2. Exemption

The following types of vessels are exempted from the need of having a Free Pratique, however, subject to sanitary inspection at any time and in view of that, ANVISA must be kept informed about medical events, accidents related to dangerous goods and/or services rendered involving the travellers:

- Non-commercial fishing boats and leisure crafts;
- Port support vessels, except the types listed above;
- Brazilian Navy vessels and the vessels invited by the Brazilian Navy without commercial interests;
- Classified as fixed platforms, located within Brazilian waters;
- Vessels out of operation due to repairs and unable to navigate due to judicial blockage or sea worthiness and trawlers out of operation due to fishing restriction;
- Barges and pontoon barges.

It is important to bear in mind that ANVISA may revoke the Free Pratique in a case of sanitary infractions and/or medical incidents to be clarified.

5. Sanitary inspection

5.1. Purpose and conditions

A sanitary inspection is required by ANVISA for the purpose of issuing certificate of free pratique (CLP) or ship sanitation certificate (SSC), investigating a public denounce or applying health measures and controls. It must be booked in advance in the PSP system¹⁷ and paid through the official banking system.

Vessels without free pratique must keep the Quebec flag up and refrain from moving cargo, stores or persons until the CLP is issued, emergency situations and essential operational personnel exempted.

As far as practical, the sanitary inspection is scheduled according to the chronological order of arrival of the applying vessels, except in exceptional circumstances that take precedent, such as the existence of a dead person, a stowaway, a person in need of urgent medical assistance or an event of public health risk that requires immediate response.

In some ports, the sanitary inspection takes place at anchorage, subject to favourable sea and weather conditions and with transportation costs borne by the owners, while in other ports it is performed only after the vessel is all fast alongside a berth with the gangway ladder down, which is notably the case of Santos, the largest and busiest Brazilian port.

5.2. Scope

Although the health regulations and guidelines apply nationwide, the rigour applied in their interpretation and enforcement varies regionally and subjectively. The Master must then ensure that the vessel is at all times prepared to undergo a thorough inspection to confirm compliance.

It is important that the officers assigned to follow the ANVISA inspectors have full knowledge and familiarisation of the processes and management plans applying on the areas to be inspected and are able to answer questions and clarify questions by the inspectors objectively. Some inspectors would not be fluent in English and the local agent should preferably be present to assist.

All officers and crewmembers taking part in the inspection must wear and ensure that the visitors also wear appropriate personal protective equipment (PPE) in the required compartments.

The sanitary inspection basically consists of two parts. A review of the documentation provided and a physical examination of all relevant areas, equipment, facilities and shipboard systems and control plans existing on board. The sequence of the inspection is at the discretion of ANVISA's inspectors, though WHO suggests that it commences in clean areas (inside accommodations) and continues in the technical areas (engine room, cargo holds, water and sewage systems) to avoid cross-contamination from inspection activities¹⁸.

¹⁷ ANVISA inspects vessels in all major ports daily from 08:00 to 17:00 hours (local time) and on weekdays only in smaller ports. The actual working hours of the port must be checked with the local agent before vessel's estimated arrival

¹⁸ Annex 3 (Sequence of inspection areas) of the International Health Regulations (2005): handbook for inspection of ships and issuance of ship sanitation certificates, 2011

5.2.1. Documentary review

The first part of the inspection usually consists of a review of vessel's certificates, records and logs pertaining to sanitary and health related issues and perusal of management plans for potable and recreational waters, ballast water, waste, vectors and reservoirs control, air quality, sewage, medical facilities and housekeeping.

The non-exhaustive list below features the set of documents that must ordinarily be available for scrutiny by ANVISA inspectors in the course of the sanitary inspection either for the issuance of the free pratique and/or ship sanitation certification.

Category	Description
a) IHR 2005 documents	<ul style="list-style-type: none"> ▪ Maritime Declaration of Health * ▪ Ship Sanitation Control Exemption Certificate (SSCEC) or ▪ Ship Sanitation Control Certificate (SSCC) * ▪ International Certificate of Vaccination or Prophylaxis
b) IMO documents	<ul style="list-style-type: none"> ▪ Crew List/ Passenger List/ Supernumeraries List/ Stowaways List * ▪ General Declaration ▪ Cargo Declaration ▪ Ship's Stores Declaration ▪ Dangerous Goods Manifest ▪ Crew Effects Declaration ▪ International Sewage Pollution Prevention Certificate
c) Management plans	<ul style="list-style-type: none"> ▪ Water Safety Plan (or Water Management Plan) ** ▪ Ballast Water Reporting Form*/ Ballast Water Record Book ▪ Waste Management Plan ▪ Food Safety Plan *** ▪ Integrated Vector Management Plan + ▪ Garbage Management Plan/ Garbage Record Book ▪ HVAC System Management Plan ++
d) ANVISA required documents	<ul style="list-style-type: none"> ▪ Notice of Arrival * ▪ Certificate of Free Pratique of previous Brazilian port, if any * ▪ Application for Certificate of Free Pratique * ▪ List of ports of call within past 30 days * ▪ ANVISA Ballast Water Reporting Form * ▪ Sewage plant manufacturer's instruction and operation manual ▪ Hospital Logs +++ ▪ Narcotics List/Medicines List

* Mandatory for granting of free pratique

** Including potable water analysis reports

*** Including temperature record logs

+ Including records and logs of vector and reservoirs control

++ Including records and logs of periodical maintenance

+++ Including records of health events on board, if any

5.2.2. Physical inspection and assessment

The second part of the sanitary inspection involves a physical examination of key areas of the vessel for observation of the prevailing hygienic-sanitary conditions on board, testing of equipment, collection of water/food samples, and verification of management plans to confirm that all points of hygiene and health concern have been identified, and that control measures have been implemented or corrective actions applied, as the case may be.

The table below provides guidance – albeit non-exhaustive – on points that are frequently verified during a thoroughly sanitary inspection and usual sources of deficiencies that lead to the need of corrections, re-inspections and potential fines for non-compliance.

Item/location	Situation
a) IHR 2005 documents	<ul style="list-style-type: none"> ▪ All persons on board must be in possession of vaccination certificates issued strictly in the WHO format, up-to-date and free from erasures and amendments ▪ Stowaways, events of death, illness and injuries and health measures performed during the voyage must be mentioned in the health declaration and schedule ▪ Vessel must carry an up-to-date SSC issued strictly in the WHO format, by an IHR authorised port listed in the WHO website
b) Quarters	<ul style="list-style-type: none"> ▪ All accommodations must be clean, free from vectors and reservoirs and maintained in good conditions of sanitation and hygiene ▪ Toilets must have potable water and be equipped with proper hand-washing and drying facilities (ideally liquid soap and electric dryers or preferably disposable paper towels) ▪ Flushing systems must be maintained free from leaks, overflows and backups ▪ Trash bins must be equipped with pedal-operated lid
c) Hospital and medical care	<ul style="list-style-type: none"> ▪ All vessels carrying 15 persons or more and engaged in a voyage of more than 3 days must be fitted with a hospital accommodation exclusively for medical purposes and separated from food-storage and food-preparation areas and provided with at least one toilet, one washbasin with hand-washing (liquid soap) and hand-drying (disposal paper towels) station and one tub or shower ▪ Brazilian-flagged vessels (except Navy, leisure and sports) in deep sea trade must carry a nurse or a health aide on board; passenger vessels in cabotage longer than 48 hours and cargo vessels in cabotage longer than 72 hours must also carry a nurse or a health aide on board¹⁹ ▪ Medical facilities must be clean, ventilated and well lit, free from vectors and reservoirs and maintained in good conditions of sanitation and hygiene ▪ Hand-washing (liquid soap) and hand-drying facilities (disposable paper towels) must be available, ideally with hot and cold water ▪ Medical logs must be kept to record cases of all health and medical events with indication of medication and treatment dispensed) ▪ Expired medicines must be replaced with fresh ones, packaged, segregated in dedicated storage and disposed in accordance with the waste management plan ▪ Controlled pharmaceuticals must be well secured against unauthorised access

¹⁹Normas da Autoridade Marítima para Embarcações Empregadas na Navegação em Mar Aberto 2005' (Maritime Authority Norms for Vessels Used in Deep Sea Navigation) - NORMAM-01/DPC, issued by the Brazilian Navy's *Diretoria de Portos e Costas* – DPC (Directorate of Ports and Coasts)

d) Galley, pantry, service areas and stores

- All areas must be clean, ventilated, well lit, free from vectors and reservoirs and maintained in good conditions of sanitation and hygiene and a cleaning, disinfection and maintenance programme with written logs of activities must be available for verification
- A food safety plan based on the HACCP²⁰ principles for food procurement, preparation, storage, handling and distribution must be evidenced in writing
- Food contact surfaces, utensils and equipment must be made of corrosion-resistant, non-toxic, non-absorbent, easily cleanable, smooth and durable materials; wooden cutting boards, for example, are not accepted
- At least one dedicated hand-washing station (preferably with liquid soap) and means of hand-drying (preferably disposable paper towels) must be installed
- Food waste must be handled in accordance with waste management plan and the vessel must be equipped with facilities for safe storage of food refuse
- Food handlers and galley crew must adhere to safety practices of personal hygiene, wear adequate, clean clothes and PPE, and have appropriate training in safe food procedures and foodborne disease controls
- Food provisions must be supplied from reputable sources and purchase receipts, food storage in-out records and food management logs must be available for verification. It is important to avoid the use of cardboards in the provisions room as most of the sanitary officers recommends the removal of same to avoid proliferation of cockroaches and other insects
- All foodstuffs, including those cooked and/or processed on board, must display the corresponding expiry date, be properly packaged, segregated and stored in dedicated food-storage places at least 15cm above the floor, away from sources of infection or contamination and maintained in adequate temperature
- Raw and prepared food must be kept separated from each other and food and non-food stores must also be separated
- Foodstuffs must be checked regularly, with out-dated or spoiled food discarded in accordance with the waste management plan and control
- Refrigerators and freezers must have visible thermometers and temperature records (cooling logs and thermometers readings) must be available for verification. Temperature of refrigerated food must be kept at 5° C or below, frozen food at - 18°C or below and dry food between 10°C and 25°C
- Cleaning chemicals and materials must be duly labelled and locked in a dedicated storage outside food area

e) Main deck, holds and engine room

- The decks, cargo holds, cranes, ventilation ducts and engine room must be free from food waste, contaminated materials, gases, foreign materials and reservoirs
- The drainage system must be adequate with independent drain lines to discharge to open, unobstructed drain wells
- When alongside, the gangway ladder must be properly and safely landed on the quayside, fitted with a protective net underneath its entire bottom and sides and rat-proofing features
- Effective rat-proofing collars (rat guards) must be tightly installed in all tending lines at suitable distance from the vessel, able to withstand wind action and regularly monitored and adjusted
- Standing water on deck and in cargo holds open spaces, depressions and culverts that are capable of holding insect larvae and vectors must be eliminated
- Service outlet of cold-air and hot-air systems extending from the deck directly into engine room must have both ends covered with vector-proof protections
- A washbasin with hand-washing and hand-drying station must be available in the engine room

²⁰ Hazard analysis and critical control points (HACCP) for food safety

f) Potable water

- Constructional drawings for the potable water system, water safety plan, drinking-water analysis report must be available for verification
- Water for human consumption processed on board by way of an approved water system cannot be collected from polluted areas, harbours or anchorage
- When treated with chlorine, after disinfection the water must present a minimum residual free chlorine level of 0.5 ppm and be maintained between 0.2 ppm and 2 ppm – other disinfection procedures may be adopted, if efficiency is confirmed
- At least four potable water samples must be collected from different locations within the vessel every 15 days and analysed for the presence of pathogenic microorganisms – the records of potable water analysis must be kept for 1 year
- The fresh water tank must be cleaned and disinfected before being placed in service, once a year and after repairs or dry-docking, with the logs kept for 1 year
- Potable water, ideally hot and cold, must be delivered to all wash-basins, bathtubs, showers and other places where water is used for human consumption
- Potable water tank(s) must be clearly labelled 'POTABLE WATER' and cannot be located adjacent to the hull plating or tanks not holding potable water
- Potable water pipes must be in good operational and sanitary conditions, free from sources of contamination and colour identified

g) Recreational water facilities

- Water treatment procedures must be properly executed and documented through a management plan to control the risk of exposure to pathogens and water analysis records must be kept for 1 year
- Water offered swimming pool and spas must meet international standards concerning safety, be clear, bright, colourless and free from irritants, infectious agents, algae, suspended and colloidal matters
- Free chlorine must be in the range of 1 ppm and 7 ppm in swimming pools and between 3 ppm and 10 ppm in whirlpool spas; if treated with bromine, it should be maintained in the range 4 ppm and 10 ppm, with turbidity less than 0.5 NTU²¹ and pH maintained and regularly adjusted in the range 7.2 – 7.8, for chlorine disinfectants, and 7.2 and 8, for non-chlorine processes
- Swimming pool can be filled with seawater or potable water and the respective supply system must have backflow preventers or other mechanisms to avoid cross contamination of the drinking water system
- Seawater can only be collected at least 12 nautical miles away from the shore. If the pool is not drained before arrival in the port, the seawater filling system must be closed at least 12 nautical miles before reaching the shore, and the water recirculation system must be used with proper filtering and halogenation
- Individual spas must be cleaned and disinfected after each use and those installed in single cabins must be cleaned and disinfected weekly or between occupancies, whichever comes first
- Spas (and similar hot tubs) must be fitted temperature-control device to prevent the water from exceeding 40°C
- Pool hygiene practices for the promotion of use of toilet and showering before entering into swimming pools and spas must be properly documented and available for verification and signage posted around the pool and social areas
- Faecal or vomit accident response procedures must be documented and records and logs of events and corrective measures available for verification

²¹ Nephelometric turbidity unit (NTU) is a measure of the 'cloudiness' of water measured by a nephelometre

h) Ballast water system

- ANVISA Ballast Water Reporting Form and IMO Ballast Water Reporting form²², ballast water record book, and ballast water management plan²³ must be available for verification
- Ballast water treatment plant not approved by IMO must be kept with the discharge lines and valves closed at all times while vessel is in a port or anchorage
- No untreated or unexchanged ballast water can be discharged into the port basin, rivers and protected areas²⁴
- Failure to comply with the relevant Brazilian ballast water management regulations may result in substantial fines by the maritime authority²⁵ which may be cumulative with other sanctions by ANVISA, environmental agencies and public prosecutors
- In case of specific recommendation or evidence of sanitary risk in certain geographic areas, the discharge of ballast water taken in such area within Brazilian waters must be done after analysis and approval from ANVISA
- The vessels with ballast water control system are subject to ballast water sampling to identify the presence of harmful and pathogenic agents, chemical components and physical indicators

i) Sewage system

- Sewage system must fully comply with Annex IV of MARPOL 73/78 as amended²⁶ Discharge of non-treated sanitary effluents into the area of the ports is forbidden
- Manufacturer's operation and maintenance manual must be available for verification
- Vessels with approved sewage treatment plant and issued with a valid ISPP certificate²⁷ are allowed to discharge effluents in ports and anchorages but only if all service valves and overboard valves are kept closed and sealed
- Sewage treatment plant not certified by an authorised Classification Society must have its bypass valve, discharge line and valves closed and sealed while in is port – the system actually in operation on board must be the same as described in the certificate
- Vessel over 400 GRT carrying more than 15 persons must have a sewage holding tank of sufficient size and capacity in isolated position, equipped with a level indicator, high level alert, cleaning access and an overflow system
- If discharge of effluents from the holding tank is not effected into a proper land-based facility, it will have to be made at least 12 nautical miles away from the shore at performed at moderate flow rate with vessel underway
- Equipment and utensils used in the operations of collection, storage and treatment of effluents must be fully operative, in good conditions of hygiene and subject to systematic procedures of cleaning and disinfection
- The tablets of chorine used in the sewage plant must be of the same size and format as the inlet pipe, with broken or fragmented tablets taken out of use

²² 'Normas da Autoridade Marítima para o Gerenciamento da Água de Lastro de Navios, 2014' (Maritime Authority Norms for Ballast Water Management 2014) - NORMAM-20/DPC, issued by the Brazilian Navy's *Diretoria de Portos e Costas* – DPC (Directorate of Ports and Coasts), requires all vessels arriving in Brazil to conduct a ballast water exchange (by either using the sequential method, the flow through method or the dilution method) at not less than 200 nautical miles from the nearest point ashore in water depth of at least 200 metres; if not possible, it will be accepted that the exchange takes place not less than 50 nautical miles from land in water depth of at least 200 metres – if the flow through or dilution method is used, the volume of the ballast tank must be re-circulated 3 times. To ensure at least 95% of the volume of the tank is exchanged. This information must be recorded in a ballast water reporting form (different to that required by ANVISA) that is sent directly to the harbour master (for the granting of the inward pass)

²³ Under NORMAM-20/DPC, the ballast water management plan (BWMP) of Brazilian-flagged vessels or vessels chartered to Brazilian companies with a '*Autorização de Inscrição Temporária*' – AIT (temporary enrolment permit) must be approved by a Classification Society recognised in the country. BWMP of foreign-flagged vessels must be approved by a Classification Society accepted by the Flag or by the own Flag administration

²⁴ NORMAM-20/DPC, in particular, prohibits discharge of ballast into ecologically sensitive areas and in natural conservation units and requires vessels sailing by sea between distinct hydrographical basins must perform ballast exchange if not carrying a ballast water management system and a valid International Ballast Water Management Certificate

²⁵ Federal Decree 6,514 of July 2008 (regulates the infractions and administrative sanctions, the federal administrative proceeding of these infractions and provides other regulations) stipulates fines ranging from BRL 5,000 to BRL 50 million

²⁶ Annex IV "Prevention of Pollution by Sewage from Ships", 2003, to the "International Convention for the Prevention of Pollution from Ship", 1973, as modified by the Protocol of 1978 (MARPOL 73/78)

²⁷ "International Sewage Pollution Prevention Certificate" issued under MARPOL 73/78

j) HVAC management

- Heating, ventilation and air-conditioning systems (HVAC) must be kept in good conditions of maintenance, operation, control and cleaning and association records and logs must be available for verification
- Permanent (non-disposable) filters must be cleaned as recommended by the manufacturer; in smoking areas or similar, the filter must be checked frequently on monthly basis, cleaned and disinfected as necessary
- Disposable filters must be changed no later than every 3 months or earlier if recommended by the manufacturer
- Intake air openings are located must be free and the respective areas must be used exclusively for the HVAC system the presence of any other materials forbidden
- Public areas of the vessel should ideally be maintained at room temperature between 23-26°C, when occupied by passengers or crew

k) Vector management

- All areas of the vessel must be free from vectors and reservoirs
- An integrated vector management plan (IVM) must be in place to define strategies for vector control, monitoring and inspection
- Records and logs of the IVM, including details of application of approved pesticides and insecticides (methodology and technic applied, dosage, concentration and active substance) available for verification
- Chemicals used in the IVM must be duly labelled with identification of the active substance, expiration date and manufacturer's recommendations for dilution
- Sleeping quarters, mess rooms, dining rooms, indoor recreational areas, as well as food spaces must be effectively screened or protected against while the vessel remains in areas where flies and mosquitoes are prevalent
- Refuse stores must be screened or protected with doors tightly closed and regularly inspected for elimination of breeding flies and other vermin

l) Waste management

- A garbage management plan, including procedures for medical and hazardous chemical waste handling, storage and disposal, must be in place and record books kept for at least 2 years and made available for verification
- Removal of liquid and solid wastes in ports by approved companies must be authorised by ANVISA beforehand through the PSP system. No solid waste can be discharged into the estuary of the port
- Proper signage must be displayed in relevant areas notifying crew and passengers of the processes for garbage collection, separation, processing, storage and disposal
- Waste containers must be watertight, non-absorbent, easily cleanable in accordance with Annex IV of MARPOL 73/78

m) Housekeeping

- Procedures for systematic and periodic maintenance, cleaning and disinfection evidenced through a cleaning and disinfection plan
 - Housekeeping crewmembers must wear disposable PPE for cleaning cabins of ill passengers or crew after events of death, faeces, vomit, urine and other bodily fluids or contaminating materials
 - Cleaning equipment and materials used in the cleaning and disinfection (brooms, brushes, squeegees, gloves etc. must be disposed or submitted to disinfection after use and properly stored in separated area exclusive for this purpose
-

6. Sanitary and health offences

6.1. Liabilities

The ultimate responsible for all aspects of the crew safety on board is vested with the Master, as delegated by the vessel's owners and operators. Amongst other duties, he must ascertain and report to the relevant health authorities at the point of entry, through the maritime declaration of health and other reporting systems, the prevailing hygiene and health condition on board, inform those on board of the health measures recommended by the relevant authority at the port of call, and ensure that the vessel is free of all sources of infection and contamination, including vectors and reservoirs.

Failure to comply with the port health regulations may result in the application of health measure controls, fines and criminal sanctions.

6.2. Sanitary infractions

Under the relevant federal law²⁸, deficiencies, nonconformities and offences to the sanitary and health regulations expose the vessel's owners to penalties that vary from a warning, seizure or destruction of products, interdiction to fines that are levied by ANVISA in the course of an administrative proceeding, without prejudice to other civil and criminal liabilities.

The possible types of sanitary infractions are detailed in specific regulation²⁹ that lists hundreds of possible actions and omissions that may be typified as sanitary infractions and the corresponding legal basis for imposing the respective penalties.

The liability for the sanitary infractions can only be excluded in the event of fortuitous case or force majeure.

The time bar for the issuance of the notice of infraction (or deed of infringement) is five years counted from the year subsequent to that when the infraction was verified.

6.2.1. **Administrative proceeding and defences**

ANVISA issues the notices of infraction against the vessel's owners through the local agents and an administrative defence can be filed within 15 (fifteen) days from the receipt of the notice, with a right to an appeal to a higher administrative instance.

It is only after completion of the administrative proceeding that an eventual fine is quantified and issued for payment within 30 (thirty) days from receipt. A 20% discount is given if the fine is paid within 20 (twenty) days waiving the right of appeal.

A decision in respect of the defence can anytime from weeks to several years to be rendered and the infractor has the right of challenging the imposition of the penalties through the federal court system in which case the amount of the fines should be deposited into an interest-bearing judicial account until the rendering of a final and unappealable sentence.

²⁸ Federal Law 6,433 of August 1997 "defines infractions against federal sanitary legislation, establishes the respective sanctions and provides for other matters"

²⁹ ANVISA RDC/31 of 2001 "approves the demonstrative table of possible types of sanitary infractions in ports, airports and ground crossings, with indication of the respective legal disposition offended and the legal framing of the fines, in the terms of Law 6,437 of 1977"

6.2.2. Level of fines

The amount of the fine depends on the type and seriousness of the infraction, as detailed in the regulations, and may be doubled in case of relapse of the infractor. The fines may be framed in one of three levels of gradation:

Level	Range of fine
Light infraction	▪ From BRL 2,000 to 75,000 – when the infractor may benefit from attenuating circumstances
Serious infractor	▪ From BRL 75,000 to BRL 200,000 – when one aggravating circumstance is verified
Very serious infraction	▪ From BRL 200,000 to BRL 1,5 million – when two or more aggravating circumstances are verified

6.3. Financial security and undertakings

Since the amount of an eventual fine would rarely be known before vessel's departure, the agents involved may demand a cash guarantee from the vessel's Owners to cover them for eventual sanitary infractions verified during call at that port. Letters of undertaking issued by P&I clubs (or by the correspondents on club's behalf) are widely accepted by agents as a form of security in respect of sanitary fines.

The reason for the agent seeking security from the Owners, particularly when they were appointed by the Charterers, lies on the fact that despite long-established jurisprudence ruling that the shipping agent is not liable for sanitary or administrative offences committed on board the vessels, which understanding has been well settled by the Office of the Attorney-General³⁰, ANVISA's inspectors would occasionally issue notices of infraction and fines against the agents instead of the Owners of the offending vessel. In these situations, administrative or judicial appeals should be filed.

³⁰ Súmula (Abridgement) no. 50 of 13 August 2010 issued by the *Advocacia-Geral da União* – AGU (Attorney General of the Union) establishes that “No liability should be attributed to the shipping agent for sanitary or administrative offences performed inside the vessels” (free translation). AGU is the institution that represents the Federal Union judicially and provides legal consultation and assistance to the Executive Power

7. Conclusion

Sanitary inspections for receiving free pratique or renewing ship sanitation certificates may be particularly stringent in some Brazilian ports even though the relevant regulations governing the matter are at federal levels and, therefore, should be equally applied in our ports within the Brazilian federation.

The next chapter offers recommendations for further reading and authoritative guidance from Brazilian and international health authorities.

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8. References and annexes

8.1. International Maritime Organisation (IMO)

- Annex IV: Prevention of pollution by sewage from ships; (1978) Annex V: Prevention of pollution by Garbage from ships; in International Convention for Prevention of Pollutions from Ships 1973 (amended 1978) (MARPOL 73/78) – 1978
- International Convention for the Control and Management of Ships' Ballast Water and Sediments – 2004
- Annex 5: Certificates and documents required to be carried on board ships; in Convention on Facilitation of International Maritime Traffic 1965 (2006 Edition), 2006

8.2. World Health Organisation (WHO)

- International medical guide for ships: including the ship's medicine chest (3rd Edition) – 2007
- International Health Regulations (2005) (2nd Edition) – 2008
- Handbook for inspection of ships and issuance of ship sanitation certificates – 2011

8.3. Brazilian Directorate of Ports and Coasts (DPC)

- NORMAM 04/DPC: Norms for the Operation of Foreign-Flagged Vessels in Brazilian Jurisdictional Waters – 2013
- NORMAM 08/DPC: Norms for the Traffic and Permanence of Vessels in Brazilian Jurisdictional Waters – 2013
- NORMAM 20/DPC: Norms for Ballast Water Management – 2014

8.4. Brazilian federal laws

- Law-Decree No. 2,848, dated 07/12/1940 – Penal Code (crimes against Public Health)
- Law No. 6,259 dated 30/10/1975 (Provides for the organization of the actions of Epidemiological Surveillance on the National Immunization Program, establishes rules for the compulsory notification of diseases, and other measures)
- Law No. 6,437 dated 20/08/1977 (Sets violations of federal health legislation establishes their sanctions, and other measures)
- Law-decree No. 8,080 dated 19/09/1990 (Provides for conditions of promotion, protection and recovery of health, the organisation and functioning of relevant services and other matters)
- Law No. 12,305 dated 02/08/2010 (Establishes the National Policy on Solid Waste, amends Law No. 9,605 dated 12/02/1988 and other measures)
- Decree No. 87 dated 15/04/1991 (Simplifies the health requirements for entry and stay of foreigners in the country, amending Decree No. 86,715, dated 10/12/1981, and other provisions)
- Law No. 9,782 dated 26/01/1999 (Defines the National Sanitary Surveillance System, created the National Health Surveillance Agency, and other measures)
- Decree No. 7,616 dated 17/11/2011 (Provides for the declaration of Emergency Public Health of National Importance and establishing the National Strength Unified Health System – SUS)

8.5. National Health Surveillance Agency (ANVISA)

- RDC No. 345, dated 16/12/2002 (Provides for the approval of the Technical Regulations for Operating Permit from companies interested in providing the interest of public health services in land vehicles that operate international public transport of passengers, vessels, aircraft, terminals waterway, organized ports, airports, border crossings and customs areas)
- RDC No. 346, dated 16/12/2002 (Approves as Annex I, the Technical Regulation for Special Operating Permit and Operating Permit for companies interested in operating the activity of storing goods under sanitary surveillance in Waterway Terminals, Ports Organized, airports, Frontier and Customs)
- Resolution RE 09, dated 16/01/2003 (Technical Guidance on reference standards of indoor air quality in artificially air conditioned environments)
- RDC No. 56, dated 06/08/2008 (Provides for the Technical Regulation of Good Sanitary Practices in Solid Waste Management in the areas of Ports, Airports, Flights Border and Customs)
- RDC No. 72, dated 29/12/2009 (Provides for the Technical Regulation which aims to promote health in ports installed sanitary control in the country, and vessels transiting through them, as amended by ANVISA RDC No. 10, dated 09/02/2012) and RDC No. 125, dated 30/11/2016
- ANVISA Sanitary Guide for Cruise Ships 2011, updated 2014

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