

Vaccines Import Process

Air Modal

Version 001

Stakeholders



MINISTÉRIO DA
INFRAESTRUTURA



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Introduction

The COVID-19 health crisis, declared a pandemic by the World Health Organization (WHO), triggered numerous adversities and continuous uncertainty, significantly affecting people's lives.

The vaccines developed to combat COVID-19 are extremely important, since the only expectation to change or reverse the world's current situation is through vaccination.

According to the International Air Transport Association (IATA), 8000 aircrafts Model 747, will be necessary to transport only one dose of the vaccine to approximately 7.8 billion people around the world.

Within this context, Procomex convened with Public and Private Sector representatives to:

- Enable the exchange of knowledge, information, and experiences between public and private stakeholders involved in the logistic, storage, and Customs processes related to the import of COVID-19 vaccines; and
- Elaborate an integrated checklist to ensure that the reception of the imported COVID-19 vaccines occurs in a fast, secure, and reliable manner, maintaining the integrity of the vaccines and fulfilling all the necessary regulations and requirements.

This Guide, elaborated by relevant border agencies and regulatory agencies, describes all the processes involved in the import of COVID-19 vaccines, starting from when the vaccines are first loaded for shipment, up to their delivery to the Importer. Its main objective is to disseminate the information regarding each stage of the process to all its stakeholders, aiming at proliferating knowledge in order to enable immediate actions, guaranteeing the cargo's speedy import, clearance, and release, without interruptions.

Propagating knowledge about vaccine import operations, and all the regulatory and procedural frameworks that support them, will contribute to organizing the massive logistical flow expected to occur once large-scale distribution begins.

The vaccines will be imported by air transport, thus, the procedures set out in this guide list the documents and operational requirements relevant to the processes for this mode of transportation.

The following airports (and their operations) were used as a basis for the development of this material:

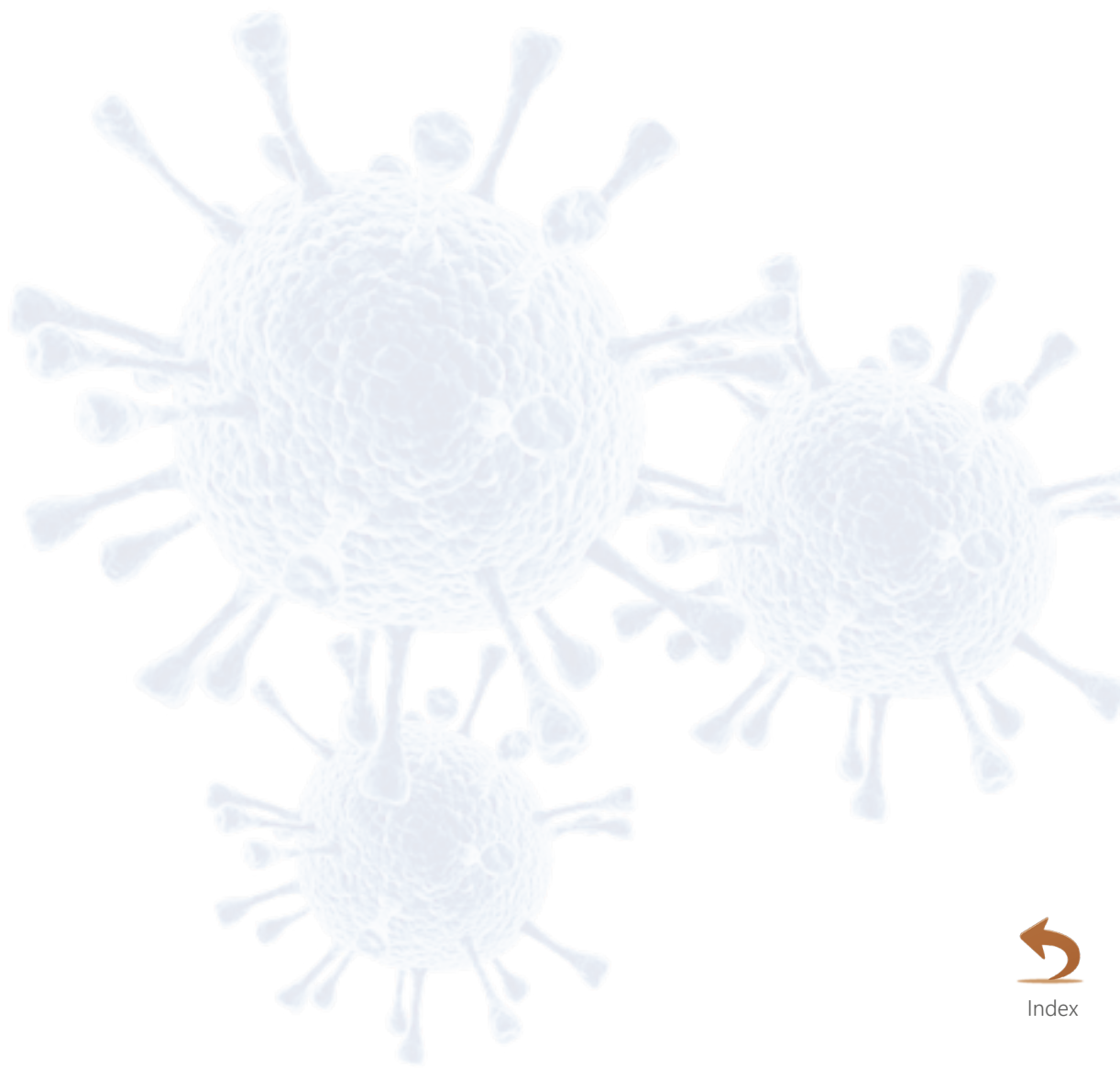
- São Paulo International Airport – Guarulhos, SP;
- Viracopos International Airport – Campinas, SP; and
- Rio de Janeiro International Airport – Ilha do Governador, RJ.

The content of this document includes the rules, regulations, and procedures of the main agencies involved in the vaccine import process, such as:

- The requirements related to boarding and air transportation, aiming at flight safety and maintaining the quality and security of the vaccines;
- All the regulations related to the health authority's approval, ensuring the vaccine is safe for human use; and
- Customs clearance, involving several actors who need to take fast, safe, and effective actions to clear the imported vaccines.

It is important to highlight that the procedures described in this document do not exempt Importers, and other stakeholders mentioned throughout the guide, from complying with all current regulations established by the involved agencies. This guide should be used as an informational support for conducting COVID-19 import operations.

It should also be noted that this guide is a dynamic document that can be updated at any time, as legislative and procedural changes occur, or if adjustments and improvements are needed.



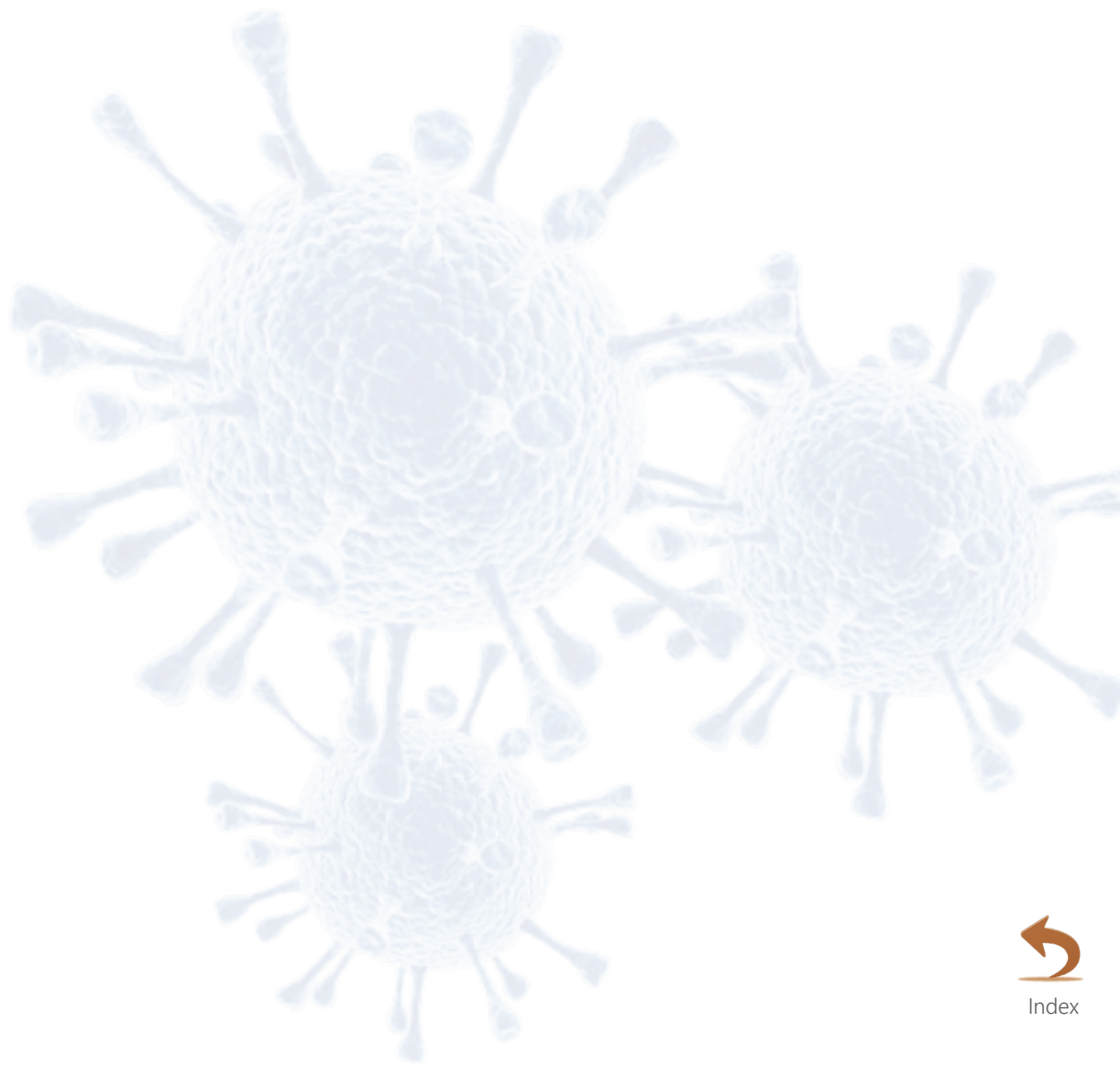
Acknowledgment

This booklet was developed during difficult times; however, difficult times unite people and strengthen hope.

Through the union of a determined group (whose names are listed at the end of this guide), in less than a month, the necessary content was developed to describe the process of importing COVID-19 vaccines, from when the cargo is loaded at the origin, passing through all necessary approvals, handling, and Customs clearance, until the vaccines are delivered to the Importer.

All involved dedicated their knowledge, experiences, and hours of work to make this material possible.

To all those involved in the development of this guide, thank you for your contribution during such a difficult time, which we will certainly overcome.



Glossary

AFE	Autorização de Funcionamento	Authorization to Operate: document required for transporting vaccines.
AFRFB	Auditor Fiscal da Receita Federal do Brasil	RFB Tax Auditor
Anvisa	Agência Nacional de Vigilância Sanitária	Brazilian Health Regulatory Agency
Avalizar	Directly translates to "Endorsing". Step in which the cargo's data is validated in Siscomex Mantra.	
AWB	Air Waybill: A bill of lading is a legal document, used specifically in air transport, issued by a carrier to a shipper that details the type, quantity, and destination of the goods being carried (applicable to goods that are not consolidated).	
CAMEX	Câmara de Comércio Exterior	Chamber of Commerce
Cartilha PEI	Cartilha do Peticionamento Eletrônico de Importação	Manual to help guide the Peticionamento Eletrônico de Importação process.
CAT	Coordenadoria de Administração Tributária	Tax Administration
Certidão da Dívida Ativa Estadual	Overdue Liabilities Certificate	
Certidões de Regularidade Fiscal Estadual	State Tax Compliance Certificates	
Certificado de Regularidade Técnica	Certificate of Technical Regularity issued by CRF, Coren, or CREA.	
CI	Comprovante de importação	Proof of Import
CNH	Carteira Nacional de Habilitação	National driver's license
CNPJ	Cadastro Nacional de Pessoa Jurídica	National Register of Legal Entities
COANA	Coordenação Geral de Administração Aduaneira	General Customs Administration
Coren	Conselho Regional de Enfermagem	Regional Nursing Council
COVID-19	Coronavirus disease is an infectious disease caused by a newly discovered coronavirus.	
CPF	Cadastro de Pessoa Física	Brazilian individual taxpayer registry identification.
CREA	Conselho Regional de Engenharia e Agronomia	Regional Council of Engineering and Agronomy
CRF	Conselho Regional de Farmácia	Regional Pharmacy Council
CTE	Conhecimento de Transporte Eletrônico	Registration of transportation information, registered electronically by the Carrier.
DAI	Documento de Arrecadação de Importação	Import Fees Collection Document
DARJ	Documento de Arrecadação do Estado do Rio de Janeiro	State of Rio de Janeiro's Tax Collection Document

Datalogger	System that logs data, such as temperature, humidity, etc.	
DI	Declaração de Importação	Import Declaration
Diretoria Colegiada da Anvisa	Anvisa's Collegiate Board of Directors	
Encerramento	Directly translates to "Closing". Equivalent to the Cargo Arrival Declaration in Siscomex Mantra	
ETA	Estimated Time of Arrival	
Ex-Tarifario	Import duties reduction (applied as an exception).	
Exoneração	Exoneration: free from payment of Import taxes and fees, such as ICMS.	
GARE	Guia de Arrecadação Estadual	State Tax Collection Form
GECEX	Comitê Executivo de Gestão	Executive Management Committee
GLME	Guia para Liberação de Mercadoria Estrangeira, sem Comprovação do Recolhimento do ICMS.	Form for The Release of Foreign Goods, exonerated from the ICMS.
GNRE	Guia Nacional de Recolhimento de Tributos Estaduais	National Form for the Collection of State Taxes
GRU	Guia de Recolhimento da União	Federal Tax Payment Form
Guia de Procedimentos para transporte de vacinas contendo gelo seco	ANAC's Guide regarding Procedures for Transporting Vaccines Containing Dry Ice	
HAWB	House Airway Bill: Bill of Lading, used specifically in air transport, issued by the freight forwarder for each consignee.	
IATA	International Air Transport Association	
ICAO	Organização de Aviação Civil Internacional	International Civil Aviation Organization
ICMS	Imposto sobre Operações Relativas à Circulação de Mercadorias e Sobre Prestações de Serviços de Transporte Interestadual, Intermunicipal e de Comunicação	Tax on circulation of goods and services
IN	Instrução Normativa	Normative Instruction: an administrative act that regulates some aspect of a law, detailing the law, but not changing it.
Informações complementares	Complementary/Additional information, field required in the Import License.	
LI	Licença de Importação	Import License
Licença Substitutiva	Substitute License, used in cases where the original Import License requires changing or correcting.	
Linha Saúde Importação	Health Line Import form	
LUC	Loan Unit Control. Used to formalize an airline loan of pallets, containers, or any material used to palletize cargo.	
MAWB	Master Airway Bill: document issued by the Airline when the cargo is consolidated by the freight forwarder.	
Mercadorias Sujeitas a Entrega Antecipada – Emergência De Saúde Pública de Importância Nacional	Goods Subject to Early Delivery – National Public Health Emergency	

Metade da Taxa da LI	Half of the LI fee, applied to the Licença Substitutiva's GRU	
Módulo "Tratamento Administrativo"	Management of Administrative Issues module	
NCM	Nomenclatura Comum do Mercosul	Mercosur Common Nomenclature (NCM) is based on the Harmonised Commodity Description and Coding System developed by the World Customs Organization (WCO). The NCM adopts WCO tariff subheadings (six digits) and adds two more digits to provide a greater level of detail, resulting in eight-digit codes.
NF	Nota Fiscal	Brazil's equivalent to an invoice, but functions as a fiscal document beyond an actual invoice.
PCCE	Pagamento Centralizado de Comercio Exterior - Modulo de Pagamento do Portual Unico.	Centralised Payment for Foreign Trade - PUCOMEX Payment Module.
PCM	Phase Change Material	
Petição Secundária	Filed to address any further concerns Anvisa may still have after all Import License documents and information have been sent.	
Peticionamento (system)	The Peticionamento system allows the formalization of orders with Anvisa, by filling out specific forms.	
Peticionamento Eletrônico de Importação	A service that allows the company to formalize its request with Anvisa, as well as to obtain information by completing specific forms (any and all requests submitted to Anvisa which result in a manifestation by the Agency, which may result in approval (satisfactory result) or rejection (unsatisfactory result) of the request.	
Portal Único de Comércio Exterior/PUCOMEX	Brazil's Foreign Trade Single Window System	
Procomex	Aliança Pró-modernização Logística de Comércio Exterior	Alliance for the Modernization of Foreign Trade Logistics
RDC	Resolução da Diretoria Colegiada	Resolution of the Collegiate Board
Retificar Declaração de Importação	Rectify Import Declaration: function in Siscomex used to Rectify the Import Declaration.	
SCDI	Sistema de Controle de Declaração de Importação	Import Declaration Control System used in Rio de Janeiro
Siscomex	Sistema Integrado de Comércio Exterior	Integrated Foreign Trade System
Solicita System	The Solicita System is an intermediate solution that integrates areas in order to incorporate the entire documental process, from submission to publication. The system includes reporting and post-market monitoring of services and products under health surveillance. The system will eventually allow for a paperless process, aiming to reduce bureaucracy and streamline Anvisa's processes.	
SUS	Sistema Único de Saúde	Brazil's publicly funded health care system
TECA	Terminal de Carga	Cargo Terminal
Termo de Entrada	Arrival Term: used to signal the plan has landed, along with all the necessary processes required during its stay.	
Tratamento Administrativo	Management of Administrative Issues, module in Siscomex.	
UF	Unidade da Federação	Corresponds to a State or the Federal District
ULD	Unit Load Devices	
Visão Integrada System	Allows for the transparency and traceability of the progress of a documental process.	
Visar	Directly translates to "Verifying". Usually an automatic system verification that there are no discrepancies in the registered information. In case a discrepancy is found, RFB must be alerted so they may conclude this step manually.	
WHO	World Health Organization	

Chapter I

Import Licensing



1 **Import licensing and management of administrative issues in vaccine import operations**

The Import License (LI) is an electronic document, registered by the Importer, or their legal representative, in the Foreign Trade Integrated System (Siscomex, Sistema *Integrado de Comércio Exterior*), which contains information regarding the import operation and the goods to be imported, such as: Importer, Exporter, manufacturer's country of origin, Exporter's country of origin, tax regime, currency exchange, etc.

To find out if the intended import requires import licensing, the interested party can consult the "*Tratamento Administrativo*" (Management of Administrative Issues) module in Siscomex (through this [link](#)) using the product's tax classification (NCM, *Nomenclatura Comum do Mercosul*, Mercosul Common Nomenclature). In addition to informing whether the requested import is subject to import licensing, this module also points to which government agencies are responsible for analyzing and authorizing the import.

Once the Import License is registered in Siscomex, the interested party must wait for the relevant border agencies to analyze and approve the request, signaling that the cargo is approved for import.

2 **The tax classification/NCM of the vaccines used to battle COVID-19**

The vaccines used to combat COVID-19 are commonly classified in the sub-items of the NCM listed below, as established by the Chamber of Foreign Trade's Executive Management Committee through the [Resolução GECEX/CAMEX/ME nº 90](#), which included the referred sub-items to the *Anexo Único* of the [Resolução GECEX/CAMEX/ME nº 17](#):

3002.20.19	Ex 001 – COVID-19 vaccine, not presented in measured doses and/or packings for retail sale
3002.20.29	Ex 005 – COVID-19 vaccine, presented in measured doses and/or packings for retail sale

The Importer is responsible for informing the correct tax classification for the goods being imported. It is essential that the *Ex-Tarifario* (import duties reduction) number is informed, when applicable, in the field "*Descrição da mercadoria*" (description of goods). This will allow the temporary reduction of the Import Tax rate to be applied at Customs clearance.

3 *Registering the product with Anvisa and its subsequent import authorization*

The COVID-19 vaccines are submitted to Anvisa, the regulatory agency responsible for the product's registration and its approval to import, which are distinct processes that need to be controlled.

Product Registration

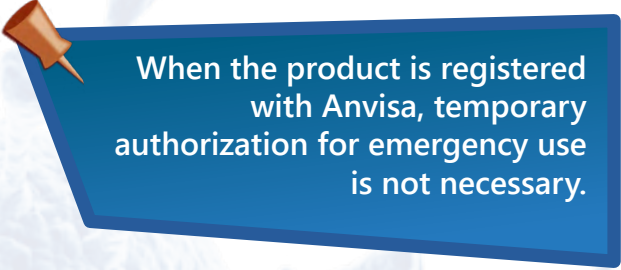
According to Article 6 of Anvisa's [Resolução da Diretoria Colegiada – RDC nº 55](#), from December 16, 2010, product registration is mandatory for vaccines. Thus, only vaccines registered with Anvisa, manufactured or imported by duly authorized establishments, may be imported, commercialized, and distributed in the country.

In view of the pandemic caused by COVID-19, Anvisa published the [Resolução da Diretoria Colegiada – RDC nº 475, from March 10, 2021](#), providing authorization for vaccines used to combat COVID-19 on an emergency-use, temporary, experimental basis. In this scenario, the vaccine will not undergo the product registration process, since in an emergency it will be regularized by the temporary authorization, as per RDC nº 475/2021.

Approval to Import

After being submitted to the product registration process, in the case of COVID-19 vaccines, their import will be approved after the Import License's registration and approval.

Therefore, in order to import COVID-19 vaccines without Anvisa's product registration, it is necessary to obtain a temporary authorization for emergency use and, subsequently, start the import licensing process for import approval.



When the product is registered with Anvisa, temporary authorization for emergency use is not necessary.

4 *Documents required when requesting vaccine import approval*

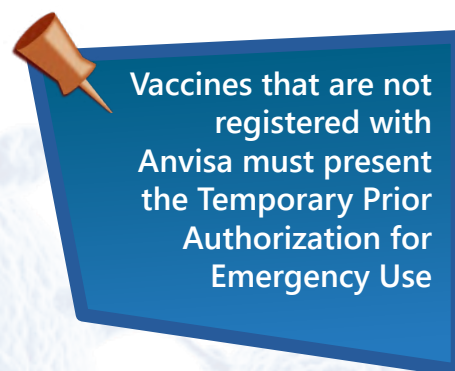
According to Procedure 2A – Serums and Vaccines, found in Chapter XXXIX of Anvisa's [Resolução da Diretoria Colegiada – RDC nº 81, from November 05, 2008](#), the Import License application must be accompanied by the following documents:

- Application for health/sanitary inspection and clearance;
- Commercial invoice;
- Air Waybill;

- Analytical quality control report of the active pharmaceutical ingredient and finished product, per lot or batch, issued by the manufacturer, except in the case of imports of primary reference standards;
- Release certificate of the batch of the finished product, issued by the health authority of the country where the vaccines and serums are manufactured, except in the case of imports of primary reference standards.
- The batch reference number declared on the certificate must match the invoice;
- The term of responsibility required for biopharmaceuticals and for vaccines, as per Article 4, of Anvisa's [Resolução da Diretoria Colegiada – RDC nº 234 from August 17, 2005](#);
- Federal tax payment form (GRU, *Guia de Recolhimento da União*), with proof of payment. The GRU is generated automatically, as is the processing of its payment. The GRU and the payment receipt do not have to be attached to the Import License application, but the receipt of payment is necessary for the application to be analyzed.

Pontos de Atenção

- In addition to the information required as per Art. 557, [Decreto Nº. 6.759/2009](#), the invoice should also include the batch number, manufacturing date, and expiration date;
- The payment of the GRU must consider the deadline for the bank to process the payment, as the analysis of the licensing application will only start after the payment is processed;
- Failure to present the BL with the *Peticionamento* will not result in an absolute rejection. Instead, the missing information must be presented within 30 days. Deferral will only occur once the missing information is submitted;
- The BL should contain data regarding the temperature and conditions in which the vaccines must be transported and stored.



5 Vaccine Import License (LI) registration in Siscomex

Based on the documents listed in item 4, the Importer can register the Import License in Siscomex and submit the application for analysis and subsequent approval by Anvisa (the Import License registration can also be requested by the Importer's legal representative, authorized in the Import Module in Siscomex, which can be accessed through this [link](#).)

The Import License application can be submitted before the cargo is loaded abroad. As a result, licensing approval can potentially be obtained before the arrival of the cargo. If

the license is granted before the cargo arrives, the pre-arrival declaration can be registered, contributing to the cargo's speedier release.

In Siscomex's Import Licensing module, the applicant will need to fill out four forms: "*Ficha Básica*", "*Ficha Fornecedor*", "*Ficha Mercadoria*", and "*Ficha Negociação*" ("Basic Form", "Supplier Form", "Goods Form", and "Negotiation Form").

Vaccines that have completed Anvisa's Product Registration

Vaccines that are registered (product registration) with Anvisa, must include the following information in the "*Descrição da Mercadoria*" (Description of Goods) field at the moment of the Import License registration in Siscomex:

- Number and description of the *Ex-Tarifario*, if applicable;
- Product's commercial name;
- Active ingredient;
- Physical description of the product;
- Number and expiration date of the Product Registration with the Ministry of Health;
- Batch; and
- Manufacturing and expiration dates.

In the Import License's field, "*Informações complementares*" (Additional Information), the following sentence must be entered: *IMPORTAÇÃO DE VACINA PARA COMBATE À COVID-19*.

The following information must also be registered in the Import License's "*Informações complementares*" field:

- Company's authorization to operate number;
- Authorized drug-related activities;
- Number and expiration date of the operating health license; and
- Name, e-mail, and phone number for contact.

Vaccines that do not have a Product Registration with Anvisa – Authorization for Emergency Use

Vaccines not yet registered with Anvisa, can be authorized for import through the Emergency Use Authorization. The data below must be provided when registering the Import License in Siscomex.

The following sentence must be written in the Import License's field regarding the description of the goods: *AUTORIZADA PARA USO EMERGENCIAL*.

In addition to the text above, the information below must also be provided:

- Number and description of the *Ex-Tarifario*, if applicable;
- Product's commercial name;
- Active ingredient;
- Physical description of the product;
- Number of temporary prior authorization for the product, issued by the Ministry of Health;
- Batch; and
- Manufacturing and expiration dates.

In the Import License's "*Informações complementares*" field, the following sentence must be entered: *IMPORTAÇÃO DE VACINA PARA COMBATE À COVID-19*

The information below must also be registered in the Import License's "*Informações complementares*" field:

- Company's operation authorization number;
- Authorized drug-related activities;
- Number and expiration date of the operating health license; and
- Name, e-mail, and phone number for contact.



If the company is not authorized for storage, the location and name of the third-party company that will store the product must also be registered, as well as all the documents and information in the storage location's authorization licenses (applicable to both cases, whether vaccines have product registration or not).

6 *Registering the Import License information in the Portal Único and the Solicita System*

In order to continue the Anvisa approval request process, the Importer, or their authorized legal representative, must provide the *Peticionamento Eletrônico de Importação* (a service that allows the company to formalize its request with Anvisa, as well as to obtain information by completing specific forms), in the *Visão Integrada* System in the Foreign Trade Single Window (PUCOMEX, *Portal Único do Comércio Exterior*), available through this [link](#) and in the *Solicita* System – *Peticionamento Eletrônico*, available at this [link](#).

To fill in the data, applicants should follow the guidelines provided by Anvisa, in the PEI Guide – External User Version 4.3 (*Cartilha PEI – usuário externo Versão 4.3*), which can be accessed through this [link](#).

The following documents must be attached to the *Peticionamento* when dealing with vaccines that have the product registration with Anvisa:

- Invoice;
- Packing List;
- Air Waybill;
- Certificate of Analysis;
- Batch Release Certificate;
- Import License statement; and
- Term of Custody.

For vaccines that do not have the product registration with Anvisa, but do have temporary authorization for emergency use, the following documents are required for the *Peticionamento*:

- Invoice;
- Packing List;
- Air Waybill;
- Certificate of Analysis;
- Batch Release Certificate;
- Import License statement;
- Declaration by the Importer, stating that the product is for emergency use;
- Temporary authorization granted by Anvisa's Collegiate Board of Directors (*Diretoria Colegiada da Anvisa*); and
- Term of Custody.

After issuing the *Peticionamento*, an e-mail must be sent to the following address: GCPAF@anvisa.gov.br, with the title: **VACINA COVID 19 Anuência em LI nº xx/xxxxxxx-x**, to prioritize the license application's analysis. The applicant should fill their respective LI number in the title.

After attaching the relevant documents to the *Peticionamento*, the applicant must wait for the GRU to be generated before it can be paid. The GRU is automatically generated by the system, after the documents are filled and attached. The GRU must be paid before the confirmation number can be issued. The GRU for registered vaccines must be generated with one of the codes below:

CODE 90024	Import by legal entities for industrial and commercial purposes
CODE 9611	Sanitary inspection of goods under sanitary supervision, imported by the Ministry of Health or entities linked to SUS, and which are destined to a public health program

For the vaccine that does not have a product registration with Anvisa, one of the codes mentioned below must be selected in order to issue the GRU:

CODE 9557	Samples of drugs under clinical research – Sanitary Inspection for Import Approval of up to 20 samples of drugs under clinical research (processed through SISCOMEX)
CODE 9611	Sanitary Inspection for Import Approval of 21 to 50 samples of drugs under clinical research (processed through SISCOMEX)

7 *The analysis process for granting the Import License*

Once the applicant has fulfilled all the requirements mentioned in the previous items, Anvisa will proceed with the analysis process required for granting Import Licenses. Before approving the Import License, the goods may be subjected to a health inspection at Anvisa's discretion (as per [RDC nº 81/2008](#)).

Although the Import License will be granted, a term will appear in the licensing, making the Importer responsible for presenting the cargo's temperature records throughout the entire transport to Anvisa (through the LI dossier), as well as the batch release certificate issued by the Importer's Quality Assurance, attesting that the batch meets all requirements (including temperature), as per Art.4 in [RDC nº 234/2005](#). Thus, the details specified in the LI alert the Importer that there is a pending issue they must address after clearance.

8 *The deadline for analyzing and granting the Import License*

The legal deadline for border agencies to perform the analysis of Import Licenses is 60 days, counting from the date the Peticionamento's confirmation number was issued, according to Article 23 in the [Portaria SECEX nº. 23, from July 14, 2011](#).

Anvisa is prioritizing all requests for import approvals for COVID-19 products. The organization has established a communication channel with the Private Sector to prioritize the analysis and approval of Import Licenses, especially of imported vaccines to combat COVID-19.

9 *Checking the progress and status of the Import License application analysis process*

The Importer, or their authorized legal representative, can follow the progress and status of the analysis of the Import License request in the Import Module in Siscomex, through this [link](#) in the *Consulta LI* option, or in PUCOMEX's *Visão Integrada* System, through this [link](#).

10 **Registering a substitute Import License**

The applicant must register a *Licença Substitutiva* (Substitutive License) in Siscomex whenever the information registered in the original Import License diverges from the reality of the actual shipment.

To register a *Licença Substitutiva*, the Importer must recover the initial license (which may have been approved or is awaiting complementary information) and request the registration of a *Licença Substitutiva*, linked to the recovered license. After linking the *Licença Substitutiva* to the previous license, the applicant must correct the deviating data and submit the replacement license to registration. The *Licença Substitutiva's* statement must be attached to the *Peticionamento*, along with the GRU and the payment receipt.

The GRU for the *Licença Substitutiva* should be generated with the code informed below: CODE 9605 – *Metade da Taxa da LI* (Half of the LI fee). This will be issued whenever there is a need to change the original LI.

11 **Compliance with Anvisa's Import Licensing application requirements**

In case Anvisa has further requirements, these need to be addressed through the *Petição Secundária*, in the *Visão Integrada* System in PUCOMEX, available at this [link](#) and available through the *Peticionamento Eletrônico* in the *Solicita* System through this [link](#).

Anvisa's guidelines for submitting information are in the *Cartilha PEI – usuário externo Versão 4.3*, available through this [link](#).

12 **The Import License's expiration**

Licenses that are not linked to the DI (Import Declaration) will be canceled automatically, after 90 days from the date it was granted (in the case of a license granted without restrictions regarding the shipment date).

The licensing may be extended only once for an equal period, as established in Article 25 of the [Portaria SECEX nº 23, from July 14, 2011](#).

13 **Releasing the Term of Custody and Responsibility in order to clear the goods for use**

After Customs clearance, the Importer or their legal representative, must submit the request to release the Term of Custody and Responsibility to Anvisa, through the *Peticionamento* System. This request must include the "Datalogger" temperature monitoring information, confirming the cargo's temperature throughout the entire international and national transport. Additionally, the request should also include the Batch Release Certificate, issued by the Importer's Quality Assurance, and the proof of payment of the Sanitary/Health Inspection Fee, automatically generated by the system after the documents have been filled and attached.

The GRU must be generated with one of the following codes:

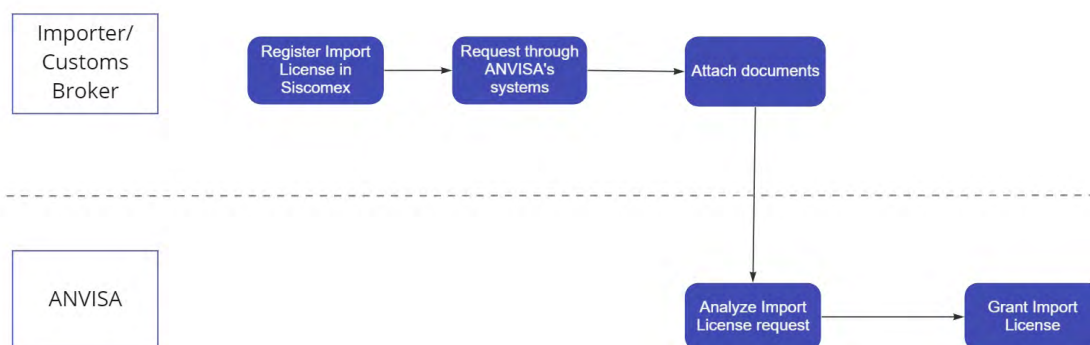
CODE - 9596	Same state as clearance
CODE - 9597	Same state, different cities
CODE - 9598	Other state

After all the relevant documents have been presented, Anvisa will conduct the analysis and release of the pending sanitary issue, addressed in [item 7](#) of this guide.

This release from the obligations determined in the Term of Custody and Responsibility will be noted in the term itself, after Anvisa's manifestation.

1

Chapter I - Import Licensing



Macro Flow – Chapter I

14 *Legal bases and additional guidance*

- [Decreto no. 6759, from February 05, 2009](#)
- [Portaria SECEX nº. 23, from July 14, 2011](#)
- [Resolução de Diretoria Colegiada – RDC nº. 234, from August 17, 2005](#)
- [Resolução de Diretoria Colegiada – RDC nº. 81, from November 05, 2008](#)
- [Resolução de Diretoria Colegiada – RDC nº. 55, from Thursday, December 16, 2010](#)
- [Resolução de Diretoria Colegiada – RDC nº. 475 from March 10, 2021](#)
- [Resolução GECEX/CAMEX/ME nº 17, from March 17, 2020](#)
- [Resolução GECEX/CAMEX/ME Resolution nº 90, from September 16, 2020](#)
- [Anvisa's Guide on the minimum requirements for submitting a request for temporary authorization for emergency use, on an experimental basis, for COVID-19 vaccines, nº 42/2020](#)

15 *Communication channel*

Urgent matters should be directed to the following e-mail: GCPAF@ANVISA.GOV.BR

Chapter II

Pre-Arrival Customs Clearance – Import Declaration



1 **List of products that can be submitted to the Early Registration of the Import Declaration**

The products subject to Early Declaration and Delivery, which include COVID-19 vaccines, are those included in Annex II (Mercadorias Sujeitas a Entrega Antecipada – Emergência De Saúde Pública de Importância Nacional, Goods Subject to Early Delivery – National Public Health Emergency) of the [Instrução Normativa SRF nº 680, from October 2, 2006](#).

2 **Import Pre-Arrival Clearance**

The Import Clearance begins with the registration of the Import Declaration (DI). All imported goods must be cleared, as per [Decreto nº 6759, from February 5, 2009](#), and [Instrução Normativa SRF 680, from October 2nd, 2006](#).

The Import Declaration must be registered in Siscomex, which can be accessed through this [link](#).

When pre-arrival clearance is allowed, the DI must be registered before the goods are unloaded at the RFB unit in which the clearance will take place, as per Instrução [Normativa SRF nº 680, from October 2nd 2006](#) (art. 17, item VIII, line “b”, combined with art. 50), and the [Portaria Coana nº. 1, from January 06, 2021](#), (applicable to the import of products listed in [Annex II of Instrução Normativa SRF 680/2006](#) – COVID-19 vaccines are listed in this annex).

3 **The early registration of the Import Declaration (DI)**

The Import License must be approved before registering the Import Declaration. The Importer, or their legal representative must attach the approved Import License to the Import Declaration when registering the DI.

For more information regarding Import License procedures, see [Chapter I – Import Licensing](#) of this Guide.

The early registration of the DI may occur before the unloading of the cargo at the Customs clearance location, as long as all requirements for obtaining an approved Import License have been met. The Import Declaration’s early registration must be done in Siscomex through this [link](#). The type of unloading should be marked as “Antecipado” (early).

The information must be provided in six different tabs in Siscomex: *Importador, Básicas, Transporte, Carga, Pagamento*, and *Adições* (Importer, Basic, Transport, Cargo, Payment, and

Additions), which, in turn, is composed of other tabs: *Fornecedor*, *Mercadoria*, *Valor Aduaneiro*, and *Tributos* (Provider, Merchandise, Customs Value, and Taxes).

The information regarding the Cargo Arrival Date (Cargo tab) and Cargo Arrival Document and Identification (Transport tab) are not required in this first moment, as they will be informed at the moment of the DI rectification, according to the guidelines of [item 8](#).

The guidelines for filling out the DI can be found in the Import Manual, accessible through this [link](#).

When importing COVID-19 vaccines, the DI's Complementary Information field should note that this is a product destined to fight the COVID-19 pandemic.

After filling the DI in Siscomex, the registration must be processed before the system can provide the Import Declaration number.

Upon the DI's registration, all applicable taxes will be charged.

Important

- When receiving the documents related to the cargo's loading, the Importer, or their legal representative, should conduct a new analysis to validate the data in the approved Import License, comparing it with the data in the Air Waybill, regarding information such as: quantity, weight, etc. If there is a divergence in information at this point, a *Licença Substitutiva* for Import must be registered and submitted to a new analysis, according to [item 10 in Chapter I](#) – Import Licensing.
- The early registration of the Import Declaration can only be used if the DI only contains products intended to combat COVID-19. There must be no other types of goods in the same DI.
- The early registration of the Import Declaration must occur before the vaccines are unloaded at the RFB unit for clearance.

4 **Instructional documents regarding import clearance and document attachment**

The documents below are used in the import operation:

- Air Waybill, or an equivalent document;
- Original copy of the commercial invoice, signed by the Exporter; and
- Packing list, when applicable;

The documents listed above do not exempt the presentation of the documents referenced in Chapter I of this Guide.

DIs registered before arriving at the Customs clearance location may be directed to any

risk-management channel, according RFB's risk-management selection for Customs clearance channels.

The Importer, or their legal representative must attach the documents mentioned above, regardless of the risk-management channel, according to the [Portaria Coana nº 1, Portaria Coana nº. 1, January 6, 2021](#), and [Notícia Siscomex Importação nº 002/2021](#).

To begin the attachment process, a dossier must be created in the Siscomex Portal, which can be accessed through this [link](#). The documents must be attached to the electronic dossier, which must, in turn, be linked to the registered DI.

More information about the procedures for attaching documents to the DI, can be found at this [link](#).

5 *Cargo Arrival Declaration*

The Cargo Arrival Declaration occurs when the Bonded Warehouse registers the import cargo's arrival and reception.

More information about the Cargo Arrival Declaration can be found in [item 7 in Chapter III](#) of this Guide.

6 *Rectifying the DI for the Cargo Arrival Declaration*

The DI will need to be rectified in order for it to be updated with the cargo's date of arrival (in the Cargo tab). The Cargo Arrival Document and Identification will also have to be added to the Transport tab.

In order to rectify the DI, the Importer or their legal representative must access Siscomex, in the "*Retificar Declaração de Importação*" (Rectify Import Declaration) function. Siscomex can be accessed through this [link](#). The cargo can only be delivered to the consignee after the DI has been rectified.

More information about the procedures involved in the DI rectification can be found in this [link](#).

7 **Risk-management selection for Customs clearance channels and distribution**

The risk-management selection process for Customs clearance channels (green, yellow, red) for the Import Declaration will define if the DI will be released with or without Customs inspection.

The DI selected for verification or inspection in the yellow and red channels will be assigned to an RFB Tax Auditor (AFRFB, *Auditor Fiscal da Receita Federal do Brasil*), who will be responsible for the Customs clearance process.

The Import Declaration for vaccines will be directed to the RFB's on-call team for analysis and clearance. According to the [Instrução Normativa SRF nº 680/2006](#), the DIs for products destined to fight COVID-19 (such as vaccines), have priority-status for processing by RFB.

The DIs directed to the green risk-management channel (which does not require Customs verification), will be cleared. The cargo will thus be available to the Importer (though there may still be further requirements to be addressed before it can be released).

Regardless of the risk-management channel to which the DI is directed, RFB still has the prerogative to verify or inspect the cargo.

8 **Early delivery**

After registering the corresponding Import Declaration, the Importer may, at their discretion, regardless of the risk-management channel, arrange for the delivery of the goods even before the completion of the Customs verification, as per Annex II in [Instrução Normativa SRF nº 680/2006](#).

In order to request the early delivery, the DI must be rectified, manifesting the request for early delivery, stating the legal basis that supports such a request (which in this case is found in Article 47-B, of [Instrução Normativa SRF nº 680/2006](#). As stated in Article 47-D in the [Instrução Normativa SRF nº 680/2006](#), the processing of requests and releases related to vaccines will be given priority treatment. AFRFB responsible for the cargo's clearance will receive and analyze the authorization for early delivery request.

9 *Customs Clearance*

Customs clearance marks the end of the import clearance process. After clearance, the Importer must comply with any other requirements necessary for the cargo's release, set out in [Chapter IV](#).

10 *Returnable packaging and accessories*

All of the following foreign equipment will automatically be submitted to the temporary admission or temporary export regime, as long as they are reusable and not intended for commercialization:

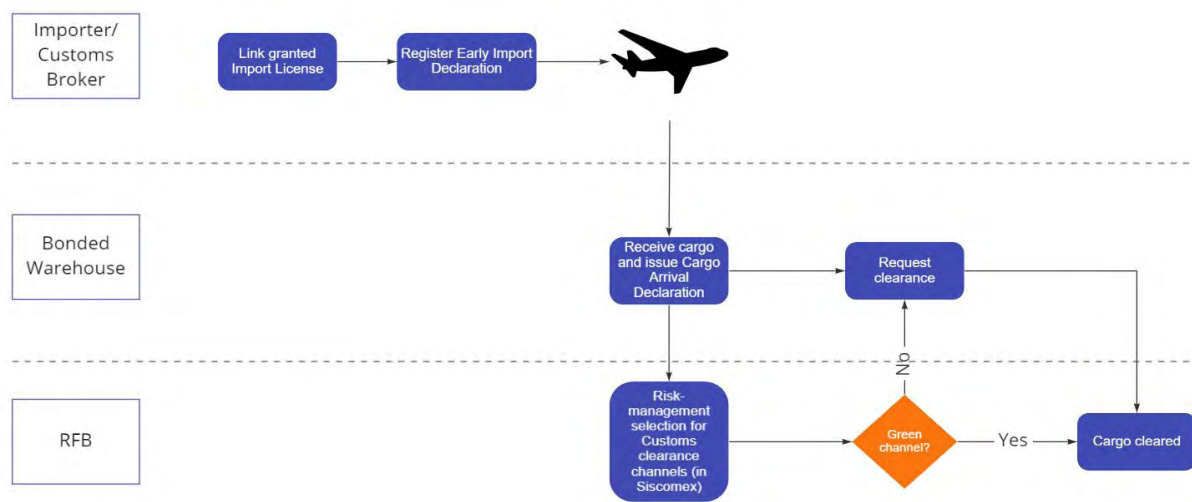
- Transportation units (such as containers) and their accessories;
- Security equipment;
- Location-tracking equipment;
- Cargo-preservation equipment;
- Equipment for recording temperature or humidity conditions; and
- Items intended for packaging, transport, preservation or registration of temperature conditions during the import or export process.

The Import/Export Declaration do not have to be registered for this type of operation, as per Article 5, item XI and Article 92, item V, of [Instrução Normativa RFB nº 1.600, from December 14, 2015](#), and [Notícias Siscomex Importação nº 004 /2021](#) and [Siscomex Exportação nº 005/2021](#) .

11 *Point of attention*



The Import Customs Manual, made available by RFB, should be consulted, as it addresses issues related to Customs Clearance. The Manual can be consulted through this [link](#).



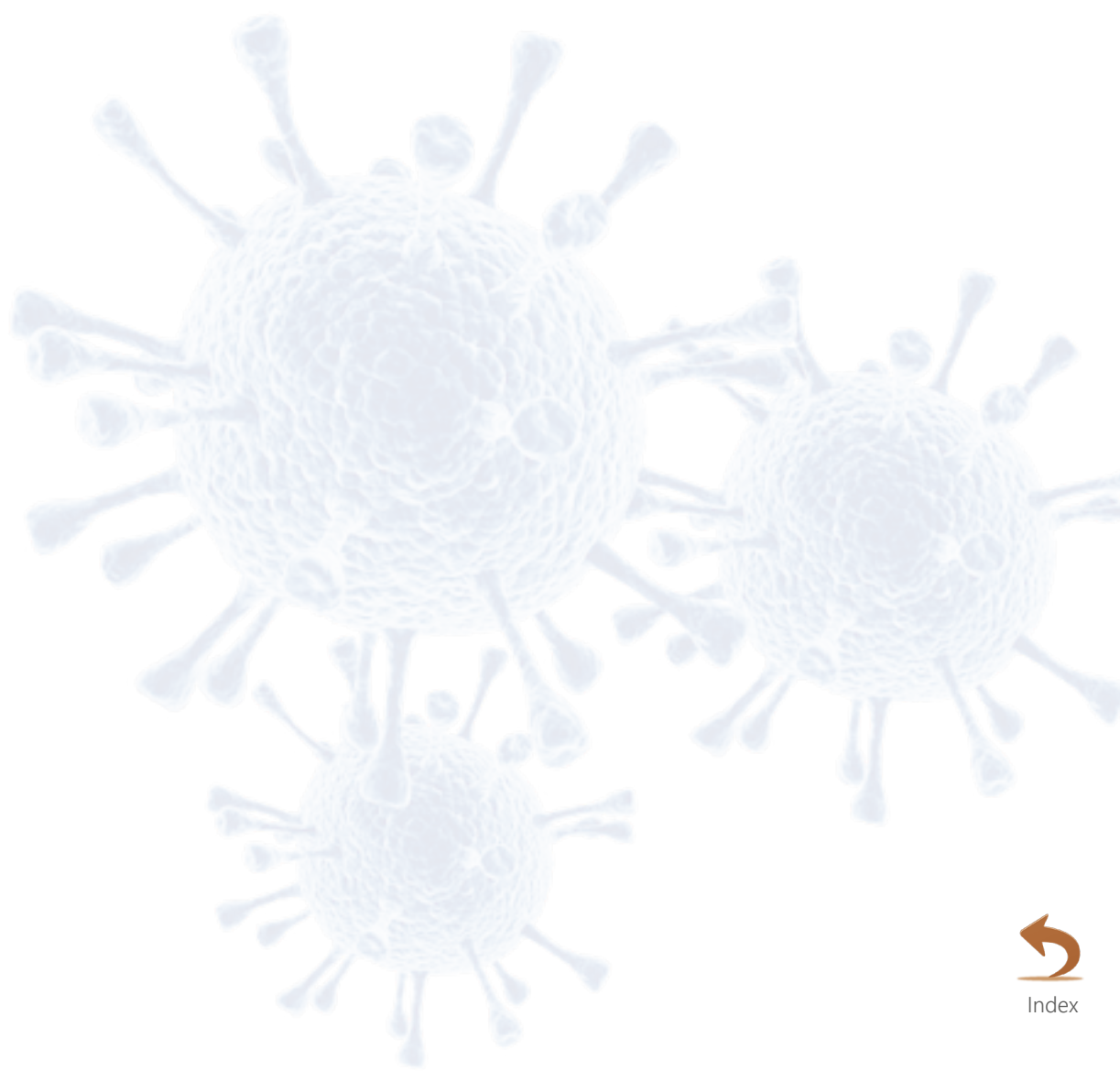
Macro Flow – Chapter II

12 *Legal bases and additional guidance*

- [Decreto no. 6759, from February 5, 2009](#)
- [Instrução Normativa SRF nº 680, from October 2, 2006](#)
- [Instrução Normativa RFB 1600, from December 14, 2015](#)
- [Portaria Coana Nº 1, from January 06, 2021](#)
- [Notícia Siscomex Importação nº. 002/2021](#)
- [Notícia Siscomex Importação nº. 004/2021](#)
- [Notícia Siscomex Importação nº 005/2021](#)
- [Guide – Customs Import Manual](#)
- [Guide – Completing the DI](#)
- [Guide – Document Attachment](#)
- [Guide – DI Rectification](#)

Customer Service

- São Paulo International Airport Customs
Telephone: (21) 3398-6081
E-mail: atendimento@rfb.alfgig@rfb.gov.br
- Alfândega do Aeroporto Internacional de São Paulo (São Paulo International Airport Customs)
Telephone: (11) 2445-5024/ (11) 2445-5546
- Alfândega do Aeroporto Internacional de São Paulo (São Paulo International Airport Customs)
Telephone: (19) 997636590



Chapter III

Shipping, Arrival, and Handling of Cargo Containing Vaccines



1

The general conditioning characteristics of passive and active systems

Proper transportation of vaccines is critical to ensure their preservation, purity, and effectiveness.

This guide contains recommendations for passive and active packaging systems, used in the transportation of vaccines that need to be kept in special temperature conditions.

Passive System

Passive packaging is the main passive system method for temperature control which will be used in transporting vaccines. This method uses insulating and refrigerating materials, in order to maintain the internal temperature according to the cargo's specification. The use of a passive packaging system requires planning, as it is necessary to evaluate and define the transport route prior to shipment. This evaluation must consider the temperature of the external environments to which the packages containing the vaccines will be submitted, in order to maintain the stability of the product throughout its route.

When using passive systems it is recommended that test shipments are made, accompanied by temperature measurements, in order to evaluate the reliability of maintaining the product's stability. The result of this evaluation demonstrates whether the passive systems are adequate to withstand the conditions under which they will be submitted, considering the temperature specification of the vaccines, the routes determined, and other aspects evaluated in the tests.

The following are the recommended systems, according to the temperature at which the vaccines must be kept:

- From +35,6°F to +46.4°F (+2°C a +8°C): High-tech insulating systems, with refrigerating materials, preferably with PCM (Phase Change Material – materials chemically modified to have their melting and freezing point at the target temperature, in this case, at +41°F, or +5°C).
- -4°F (-20°C): Insulating systems with PCM or with dry ice, the latter being the most common, as long as the goods can withstand extremely low temperatures, without altering its quality.
- -94°F (-70°C): Packaging Systems containing dry ice.

Active System

Active Systems, commonly called Active Air Containers, require power, as they use electricity to maintain the desired internal temperature and can adapt to external temperature changes. The main types of Active Air Containers currently in the market are the following:

- Containers with a dry ice compartment. The temperature from the dry ice compartment is blown to the compartment in which the cargo is located, maintaining the cargo's target temperature based on thermometers. These types of containers run on battery power. It is imperative to ensure that the batteries are charged in

order to maintain their continuous operation, keeping the container at the required temperature conditions. This type of packaging is commonly used in cases that require negative temperature.

- Containers that have compressors, which are responsible for maintaining the temperature in the internal compartment.



Important
According to ANAC regulations, containers that get their energy from batteries, classified as dangerous materials (such as lithium-ion batteries or lithium metal), are not allowed.

All active air containers have internal thermometers.

2 *Information Prior to the cargo's arrival*

Imported cargo that require specific equipment for the handling stage, must inform the required equipment prior to shipment. The request must be forwarded to the airport terminal where the cargo will be unloaded.

Additionally, the Importer or their legal representative must also send the Pre-Alert, to the Bonded Warehouse, before the vaccines are loaded abroad. The Pre-Alert is a document that lists information about the loading operation, allowing operators unloading the aircraft and moving the cargo at the destination to have the ability to conduct their operations in an organized and safe manner.

The information below should be included in the Pre-Alert that will be sent to the Bonded Warehouse:

- Aircraft's expected date and time of arrival;
- Flight number;
- Airline;
- Air Waybill (AWB)/House Air Waybill (HAWB);
- Unit Load Devices – ULD (pallet/container) number;
- Weight (by volume and total);
- Number of volumes;
- Nature of the Cargo;
- Information regarding unloading cargo based on packaging and cold storage;
- Need to plug the equipment into a power outlet in order to charge its battery;
- Telephone for 24-hour contact; and
- Expected date and time of arrival of the vehicles that will pick up the cargo, as well as their license plate number. If this information is not available prior to the cargo's arrival, they must be provided no later than one hour before the expected vehicle-loading time.

The Pre-Alert must be sent by e-mail, according to the procedure defined by each Bonded Warehouse.



The service channels for each airport are listed below.

Rio Galeão Airport

To send a Pre-Alert notification for pharmaceutical cargo, access the following link [Customer Service – Rio Galeão \(riogaleao.com\)](http://Customer Service – Rio Galeão (riogaleao.com)) and send an e-mail to: controlecarga@riogaleao.com at least 24 hours prior to the arrival of the cargo.

Important
If there is a change in the cargo arrival date, the Pre-Alert needs to be sent again, since the previous one will be considered only for the original date.

Viracopos Airport

This should be used to access the Health Line Import form (*Linha Saúde Importação*).

The completed form should be sent to: corecarga@viracopos.com

Guarulhos Airport

The Importer or their legal representative must be registered to access the GRUAIRPORT site, through which they will fill the *Linha Saúde* form.

For more information, access this [link](#), which provides instructions on how to register and fill out the form.

Important

- All fields on the form must be filled out.
- In situations where there is more than one AWB/HAWB, a form should be sent for each.

3 Cargo identification and labeling

All air cargo coming from abroad must have identification labels, regardless of the type of cargo or packaging.

The following information must appear on the cargo identification tag:

- Master Airway Bill number;
- House Airway Bill number (if applicable);
- Exporter's name (Shipper);
- Importer's name (Consignee);
- Number of volumes (Piece/Total piece);
- Gross weight;
- Airport of origin; and
- Airport of destination.

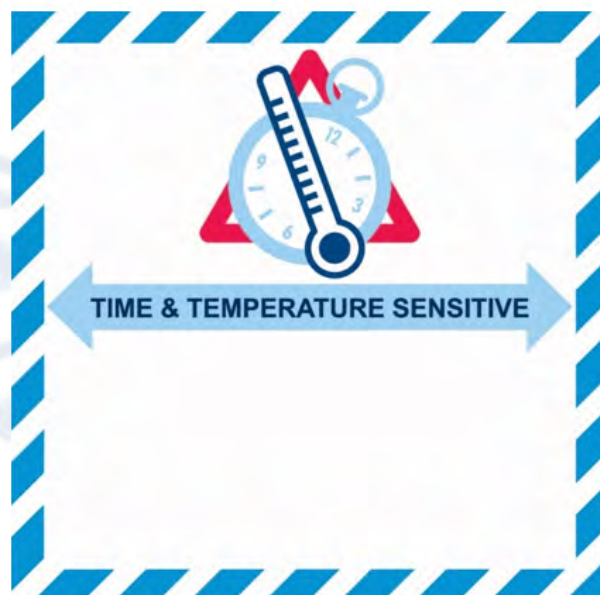
Example Label:

SHIPPER		CONSIGNEE	
ORIGIN	DESTINATION	PIECE	TOTAL PIECE
MASTERBILL			
HOUSEBILL			
WAREHOUSE NUMBER		WEIGHT	
			

IMPORTANT

In addition to the information mentioned above (which must be included on every imported cargo) the information related to the temperature range must also be properly labeled on the package (for transportation and storage).

The International Air Transport Association (IATA) provides a label model that can be used in cargo containing vaccines. The label must be filled out correctly and must indicate the correct storage temperature in the space below the "TIME & TEMPERATURE SENSITIVE" line:



Source: IATA

The ANAC regulations for the transportation of vaccines containing dry ice must be met, when applicable. More details can be found in ANAC's Guide regarding Procedures for Transporting Vaccines Containing Dry Ice (*Guia de Procedimentos para transporte de vacinas contendo gelo seco*), at this [link](#).

4 *Aircraft arrival*

To ensure the necessary agility required in the vaccine importation process, it is essential that the following actions are taken before arrival. This will allow those involved in the processes related to the aircraft's arrival and the unloading of the vaccines to plan and prepare, guaranteeing operational priority and safety:

- For the ideal positioning of the aircraft, close to the Cargo Terminal (TECA, *Terminal de Cargas*), the Airline or the contracted service provider for cargo handling must contact the Airport Operations Center at least six hours before the flight's arrival. This information will ensure agile cargo handling once the aircraft is unloaded;
- The airline must provide the airport's TECA with the name of the ramp service provider hired to unload the cargo from the aircraft. The airline must also inform the specific amount of required equipment to aid in the unloading process, as well as their identification number. This will ensure the organization of the goods reception area and the appropriate cargo prioritization. The airline should also coordinate with the ramp service provider in order to coordinate the exchange of information regarding the arrival of imported cargo intended to fight COVID-19. Data such as the ULD identification number and loading position inside the aircraft must be reported, so that the proper unloading and transportation measures can be prepared in advance.
- Security service providers also need to be previously informed by the Airlines, about the arrival of imported cargo destined to combat COVID-19. Information such as the ULD identification number, need to be made available so that equipment can be monitored after unloading and transferring to the TECA.

The aircraft arrival record corresponds to the opening of the Termo de Entrada (Arrival Term) in Siscomex Mantra, as stated in [Instrução Normativa SRF nº. 102, from December 20, 1994](#). The Airline is responsible for including, in Siscomex Mantra, information related to the flight.

Upon the aircraft's arrival, the Airline must present the Cargo Manifest and the respective Air Waybill belonging to the Manifest, as well as register the time of arrival of the flight in Siscomex Mantra. RFB will consider the cargo as manifested once the aircraft's arrival has been registered in Siscomex Mantra.

The [Notícia Siscomex Importação nº 050/2020](#) defines new "Nature of Cargo" codes, which identify cargo destined to fight against COVID-19, aiming to implement prioritization measures throughout the operation. These should be used at the time of manifestation in Siscomex Mantra.

According to Siscomex chart 73, the codes are as follows:

- COV COMBATE À COVID-19
 - Destined to combat COVID-19

- COA COMBATE À COVID-19, ARMAZENAR ENTRE -18 E 0 GRAUS C
 - Destined to combat COVID-19, store between -0.4 and 32°F
- COB COMBATE À COVID-19, ARMAZENAR ENTRE 2 E 8 GRAUS C
 - Destined to combat COVID-19, store between 35.6 and 46.4°F
- COC COMBATE À COVID-19, ARMAZENAR ENTRE 9 E 15 GRAUS C
 - Destined to combat COVID-19, store between 48.2 and 59°F
- COD COMBATE À COVID-19, ARMAZENAR ENTRE 16 E 22 GRAUS C
 - Destined to combat COVID-19, store between 60.8 and 71.6°F
- COE COMBATE À COVID-19, ARMAZENAR EM COND ESPECIAIS
 - Destined to combat COVID-19, store in special conditions

These new codes were created analogously to the codes that currently exist for perishable cargo. The code COV should be used for cargo that does not require storage under special conditions, and the code COE for cargo requiring storage under special conditions. The other codes, COA, COB, COC, and COD, should be used for cargo requiring refrigeration in their respective temperature ranges.

In the case of using the COE category code, the Importer or their representative must inform the special conditions for storage, identifying, as applicable, the storage needs in different temperatures for each cargo in the same MAWB/HAWB.

5 *Unloading the aircraft*

The Airline must provide their ramp service providers, in advance, with information related to the cargo (such as date/time of arrival, among other relevant information), so that the cargo is unloaded as soon as possible, always taking into account the necessary safety rules. The transfer of the ULDs containing COVID-19 cargo from the ramp to the import depot should take place as quickly as possible.

When unloading, the airline must make all cargo containing vaccines immediately available to the Bonded Warehouse. These have priority and must be unloaded before other goods that may be on the same flight.

The Airline's ramp service provider, must provide dollies in good conditions for the cargo's transport, thus avoiding possible damage, incidents, or even breaking the equipment during the handling process.

Important the following points should be taken into account:

- The distance between the aircraft parking position and the TECA, which may vary depending on the airport;
- The availability of an adequate number of dollies, as well as back-up dollies for unloading and transporting the ULDs.

6 **Cargo entry at the TECA/Cargo terminal**

The Airline must instruct and coordinate with the ramp service providers the needs and urgencies of the operation. Immediately after unloading, the ULDs containing COVID-19 vaccines must be transported to the TECA, avoiding their exposure to the weather conditions (which they will be subject to while remaining on the ramp).

Ramp service providers need to take note that the ULDs containing COVID-19 vaccines must enter on a priority basis. Thus, the entry of cargo into the storage unit occurs quickly and without interruption. Vaccines may not remain in the TECA access lines, nor be subjected to any other situation that may stall or delay the entry process at the TECA.

The supervisors for the ramp service provider and the TECA should have established contact, as they should be in communication in case they may need to deal with issues that require immediate action or decision.

7 **Cargo Arrival Declaration**


When the cargo is received at the TECA, the data presented by the Airline in Siscomex Mantra is compared to the cargo physically present. This procedure consists in checking: weight, number of packages, type of packaging, and any existing malfunctions. After finishing this validation, if no discrepancy is found, the Bonded Warehouse can conclude the cargo reception in Siscomex Mantra. This conclusion, which is equivalent to the Cargo Arrival Declaration, is denominated in Siscomex Mantra as *Encerramento* (Closing).

The *encerramento* of cargo used to battle COVID-19 in Siscomex Mantra is a priority. The registration of the other cargo in the flight does not need to be finalized in order to continue with the steps that follow the *encerramento* in Siscomex Mantra.

Attention Points

In order to avoid complications, the following points are necessary in the registration of the Cargo Arrival Declaration:

- In order for the vaccines to be received and stored without opening the refrigerated equipment and in compliance with the current legislation, the manifest must reflect that the equipment corresponds to the packing that was shipped. The weight and the quantity of volumes must represent the quantity of equipment and not the quantity of units contained inside the packaging.



Importante
For the cargo to be received as a priority, it is necessary that the flight's **Termo de Entrada** (Arrival Term) be open and properly deconsolidated in **Siscomex Mantra**.

- The Air Waybill identification (MAWB/HAWB) must be on a label attached to the equipment;
- In cases in which the weight or volume verified upon arrival is different from that manifested, Siscomex Mantra can mark the cargo as “unavailable”. If this event occurs, RFB must be informed so that it may address the discrepancies and release the cargo in the system;
- If any volume lacks identification labels, RFB should be notified so they may address the pending requirement;

8 **Deconsolidation in Siscomex Mantra**

Deconsolidation is an action performed in Siscomex Mantra and is related to the documental part of the import operation.

In the cases of consolidated cargo, if the information is available in Siscomex Mantra, it will be possible to proceed with the deconsolidation in the system even before the flight arrives.

9 **The validation procedures in Siscomex Mantra**

After the Bonded Warehouse registers the cargo arrival declaration, the Airline must monitor Siscomex Mantra in order to validate the information provided by the Bonded Warehouse. This act is known as *Avalizar* (Endorsing), thus validating the cargo’s reception and storage data in Siscomex Mantra. The Airline may agree or have reservations regarding the information entered by the Bonded Warehouse.

For COVID-19 import cargo, it is important that this “*Avalizar*” step in Siscomex Mantra occurs immediately after concluding the cargo arrival declaration. RFB’s verification must occur, immediately after the *Avalizar* step.

Importante
At this stage, the Airline and the Bonded Warehouse should be in constant contact to ensure the fluidity of the operation.

This verification consists in validating the data registered by the Bonded Warehouse and the Airline. The confirmation of this verification in Siscomex Mantra will occur automatically as long as there are no discrepancies between the Bonded Warehouse’s storage registration and the data in the Airline’s declaration. This step is called “*Visar*” (Verifying) in Siscomex Mantra.

However, if there are discrepancies between the data provided by the Bonded Warehouse and the Airline, the verification stage will not occur automatically and the Importer will have to contact RFB so they can address these discrepancies. To prevent this type of “unavailability” from occurring, it is important to follow the information described in [item 7](#) – Cargo Arrival Declaration.

The Chart below demonstrates all the stages that occur in the registration of Cargo in Siscomex Mantra:

Etapa	Agente Executor Responsável
Registrado	Depositário
Encerrado	Depositário
Avalizado	Companhia Aérea
Visado	RFB

If COVID-19 cargo is in the same *Termo de Entrada* as non-COVID-19 cargo, in order not to have to wait for the whole flight to be processed, RFB can record the “*Visar*” step manually, thus allowing the operation to proceed.

10 Depalletizing

Based on the cargo’s information, which was sent early, the Bonded Warehouse will direct the necessary aeronautical equipment to a “dedicated” service line, aiming to speed up the depalletization of the cargos containing vaccines.

If the cargo information that guarantees the amount of adequate equipment is not sent early, it is not possible to segregate or prioritize the cargo at the moment of reception for subsequent depalletization.

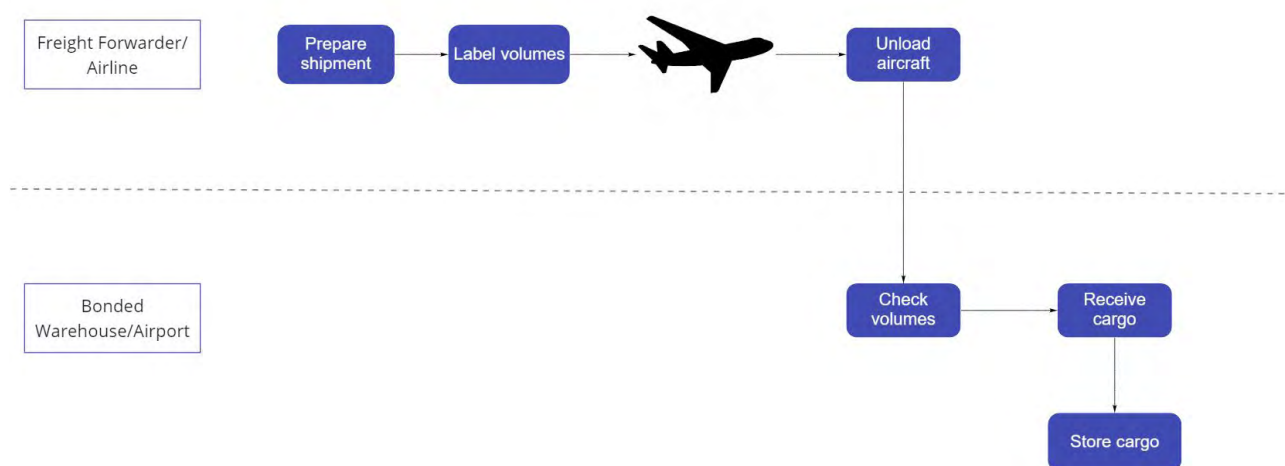
11 General observations

- Se houver necessidade de correção de informações, a Companhia Aérea deverá •
If the declared information needs to be corrected, the Airline must supervise the physical inspection process, carried out by the Bonded Warehouse. If this process finds that adjustments are necessary, the airport’s operations supervisor must be informed immediately, so they may apply corrective measures, always respecting the deadlines set. Depending on the adjustment needed and the time that has elapsed, the correction request must also be reported to RFB.
- In cases in which dry ice needs to be replaced, the Airline and the Bonded Warehouse must communicate and coordinate this replacement process. The replacement will occur upon the Exporter or Importer/proxy’s explicit request, following the requirements for opening and closing the package, according to the International Civil Aviation Organization (ICAO)’s [RBAC nº. 175 from ANAC and the Doc. 9284](#).
- If the air container has a low battery level, its unloading must be prioritized. The container must then be plugged in, as its final release to the Importer will only occur when the battery is charged to a safe level (minimum 60%).

- Equipment (packaging, including air containers) that arrive with physically visible signs of damage that may interfere with the integrity of the cargo must be immediately reported to the Importer or their legal representative, so that they can make a decision regarding unloading or releasing the cargo in its current state. It is essential that the designated point of contact is available 24 hours per day, in case they may need to be contacted in the eventual case that urgent action need to be taken.
- The best practices listed above have the objective of ensuring that import cargo containing COVID-19 vaccines be released immediately upon arrival, eliminating the stage in which cargo dwells and is stored in airport storage facilities. However, if the cargo must be stored for any reason, the airports must have a structure that meets any storage needs. The large airports that handle cargo have refrigerated chambers or infrastructure for powering refrigerated containers. In view of this and considering the large volume of vaccine imports that the country tends to receive, as well as the characteristics related to the appropriate temperature for the vaccines, the Importer must previously inform the Bonded Warehouse of the intention to keep the imported cargo stored at the airport.

3

Chapter III – Shipping, Arrival, and Handling of Cargo Containing Vaccines



Macro Flow – Chapter III

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Legal bases and additional guidelines

- [Instrução Normativa SRF nº 102, from December 20, 1994](#)
- [Notícia Siscomex Importação nº 050/2020](#)
- [Resolução da Diretoria Colegiada - RDC nº 234 from 17/08/2005](#)

- [Resolução da Diretoria Colegiada - RDC nº 38 from 18/08/2010](#)
- [Resolução da Diretoria Colegiada - RDC nº 55 from 16/12/2010](#)
- [Resolução da Diretoria Colegiada - RDC nº 430 from 08/10/2020 ANVISA;](#)
- [Resolução da Diretoria Colegiada - RDC nº 475 from March 10, 2021](#)
- [Instrução Normativa Anvisa nº 77, from November 17, 2020](#)
- [Regulamento Brasileiro da Aviação Civil – RBAC nº 175](#)
- [Guide Regarding the Procedures involved in the Transport of Vaccines Containing Ice – ANAC](#)

13 *Communication*

- **Guarulhos International Airport Concessionaire – GRUAIRPORT Cargo Customer Service Center**

Telephone: 11 2445-5000 | 11 2445-5127

E-mail: cac.cargas@gru.com.br

- Cargo Operational Control Center – CCO TECA (Operational Planning):
Telephone: 11 2445-5140

- **Viracopos International Airport Concessionaire – Viracopos Brazil Airport**

Core Cargo Viracopos – 24h Telephone Service:

Telephone: +55 19 3725 5238 / +55 19 3725 6726

E-mail: corecargo@viracopos.com

Mobil Telephone: +55 19 99942 4432 – WhatsApp

Site: https://www.viracopos.com/pt_br/carga/

- **Rio De Janeiro International Airport Concessionaire – Rio Galeão**

Customer Service Center – 24h E-mail Service:

E-mail: cac@riogaleao.com

- CCO – Operational Control Center – 24-hour service

Telephone: +55 21 3398-6069 / +55 21 3398-6071

E-mail: controlecarga@riogaleao.com

Site: <https://www.riogaleao.com/cargo>

Capítulo IV

State Treasury Department (SEFAZ)'s Cargo Release and its Delivery to the Importer



In order for the imported cargo to be released, in some situations the Importer may need to pay the ICMS to the State Tax Authorities (a tax on transactions related to the circulation of goods, Interstate and Intermunicipal transportation, and communication services) or they may be exonerated from payment.

The Concessionaire that manages the airport (which also functions as a Bonded Warehouse) must validate if the obligations relating to the ICMS were fulfilled before delivering the cargo to the Importer.

In order to release the imported goods, the Importer must follow the regulations of their State/Federal District (UF, *Unidade da Federação*). Each UF's regulation will define the guidelines for the imported goods' ICMS exemption or payment.

According to the current ICMS regulations, and as detailed below, the release of imported goods is subject to the presentation of the Exoneration Form, or the ICMS Collection Form with proof of payment.

- **Exoneration Form**

The Form for The Release of Foreign Goods, exonerated from the ICMS (GLME, *Guia para Liberação de Mercadoria Estrangeira, sem Comprovação do Recolhimento do ICMS*), commonly known as the Exoneration Form, is used in cases where the Importer is exonerated from paying the ICMS, as per [Convênio ICMS nº. 85 from September 25, 2009](#).

- **ICMS Collection Form**

This ICMS tax collection form must be presented, along with proof of payment, in order for the cargo to be released for pick-up.

The Form may have different names depending on which State cleared the goods. For example, the State of São Paulo uses the State Collection Form (GARE, *Guia de Arrecadação Estadual*), while the State of Rio de Janeiro uses the State of Rio de Janeiro's Collection Document (DARJ, *Documento de Arrecadação do Estado do Rio de Janeiro*). These are only issued when Customs clearance occurs in the consignee's respective State.

The National Form for the Collection of State Taxes (GNRE, *Guia Nacional de Recolhimento de Tributos Estaduais*) is a tax document issued by all States whenever the consignee is from a different State than where Customs clearance occurred. The tax document for imported products is based on the Import Declaration, as detailed in [Chapter II](#).

The procedure for generating the tax collection forms is different in each UF. More detailed information on the generation of the forms is available in the State Treasury websites. Some State Departments also provide manuals to guide users. Some examples are provided below:

- [State Treasury Department of São Paulo – SEFAZ/SP](#)
- [State Treasury Department of Rio de Janeiro – SEFAZ/RJ - 01](#)
- [State Treasury Department of Rio de Janeiro – SEFAZ/RJ - 02](#)
- [State Treasury Department of Pernambuco – SEFAZ/PE](#)
- [State Treasury Department of Rio Grande do Sul – SEFAZ/RS](#)
- [State Treasury Department of Paraná – SEFAZ/PR](#)
- [State Treasury Department of Santa Catarina – SEFAZ/SC](#)



Important

Some UFs require the Importer's legal representative to be previously registered before they can conduct operations with SEFAZ on the Importer's behalf.

2 **PUCOMEX's Foreign Trade Centralized Payment Module (PCCE)**

The manual request to digitally attach documents to the Import Declaration can be made in the PCCE module, according to the options provided by each State. The PCCE can be accessed through this [link](#).

Requests in the PCCE also apply to cases where the Import Statement has more than one tax treatment.

The PCCE replaces the ICMS statement in Siscomex. Thus, the ICMS statement is unnecessary when using the PCCE. In these cases, SEFAZ must be alerted, so they can analyze the documents.

The following links offer further guidance on how to use the PCCE:

[Link 1](#)

[Link 2](#)

[Link 3](#)



Important

SEFAZ's guidelines must be evaluated (for the respective State where the operation will take place) before using the PCCE.

3 **Generating the Form – SEFAZ SP and RJ**

The generation of the Tax Collection Form on the SEFAZ website must comply with each UF's guidelines.

[Item 10](#) – Legal Basis and Additional Guidelines provides links to some manuals with guidelines provided by some UFs.

The following is a general explanation of the procedures established by the States of São Paulo and Rio de Janeiro for the generation of the Form directly on the website.

SEFAZ - São Paulo

Follow this [link](#) to generate the Forms directly through the SEFAZ/SP website.

Após registro da DI, a declaração do ICMS deve ser preenchida no Siscomex Importação Web. After the registration of the Import Declaration, if the relevant State documents are generated through the SEFAZ/SP website, the ICMS statement must be completed in Siscomex Web.

After generating the Form, the Importer should consult the SEFAZ/SP website to check on the status of the Import Declaration (this is possible if the GLME or GARE/GNRE must be paid). If the status appears as "*Dirigir-se ao Recinto Alfandegado para Retirar a Mercadoria*", the Importer may pick up the goods from the Bonded Warehouse.

If the status check shows that there are pending requirements, it will present a message asking the Importer to go to the Tax Office. In these situations, the Importer must present the documents in electronic format, via PCCE (paper documents do not need to be delivered in-person). After submitting the documents in the PCCE, the Importer should also send an e-mail, with the title: *Vacina COVID*, to one of the addresses below, depending on where the cargo was unloaded.

- Viracopos Airport: pfviracopos@fazenda.sp.gov.br;
- Guarulhos Airport: pfguarulhoscomex@fazenda.sp.gov.br
- For the Importer/consignee from São Paulo, if the clearance occurs in another UF (not São Paulo), the e-mail must be sent to the following address: bagagemleilão@fazenda.sp.gov.br
- For other clearance locations in SP, outside the Guarulhos and Campinas region, or if the cargo is cleared outside SP for an Importer from São Paulo, the e-mail must be sent to the following address: bagagemleilão@fazenda.sp.gov.br

More detailed instructions regarding the Import Release Procedure can be accessed through this [link](#).

SEFAZ - Rio de Janeiro

The Tax Collection Forms for the State of Rio de Janeiro can be generated through the following links:

- [Link 1](#)
- [Link 2](#)

If the Form is not processed automatically, the GLME must be filled out in the SCDI through the Fiscal Duty mode. Documents must also be attached in the PCCE, and an e-mail must be sent (to the following address: ife02@fazenda.rj.gov.br) informing the number of the Import Declaration. The title of the e-mail should be: "*Exoneração COVID*", in order to prioritize the analysis and release of imported products to destined to battle COVID-19.

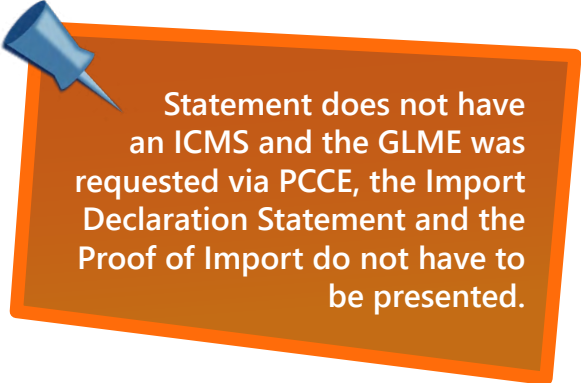
4 Documents required for release

Each UF has the autonomy to define the procedures related to the ICMS. Thus, it is important to consult the instructions for the relevant UF.

The documents used by the States of São Paulo and Rio de Janeiro are listed below.

São Paulo - As per Portaria CAT Ordinance no. 24/2020, Article 1, § 3, the main documents required for cargo release are listed below:

- CNPJ;
- Import Declaration statement;
- Proof of Import – (CI, *Comprovante de Importação*);
- Invoice;
- International Air Waybill; and
- Letter of attorney.



Statement does not have an ICMS and the GLME was requested via PCCE, the Import Declaration Statement and the Proof of Import do not have to be presented.

Rio de Janeiro

- State Tax Compliance Certificates (*Certidões de Regularidade Fiscal Estadual*);
- Overdue Liabilities Certificate (*Certidão da Dívida Ativa Estadual*);
- Invoice;
- International Air Waybill; and
- Letter of attorney.

5 Scheduling for cargo delivery

After the imported goods have gone through all the procedures required for their release (required by Anvisa, Customs, SEFAZ, etc.), the Bonded Warehouse is officially authorized to deliver the cargo to the Importer.

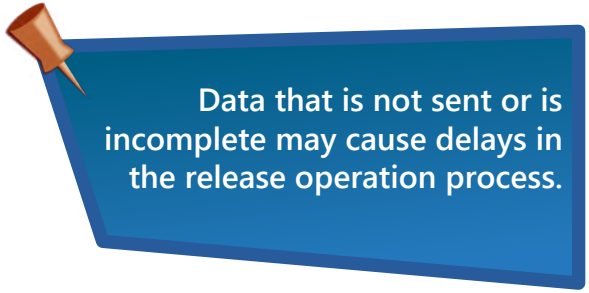
However, the Importer needs to comply with some final requirements, such as scheduling the cargo delivery, before the goods can be released. Scheduling requires presenting information, such as the Carrier's ETA for cargo pick-up, along with the vehicle's plates, driver's information, etc.

If some of this data, such as vehicle's license plates, are not available when presenting the Pre-Alert, they may be reported up to one hour before cargo-loading. This data may be presented together with the Pre-Alert prior to the arrival of the cargo, as per [Item 2, Chap III](#) of this Guide.

Presenting this data early, will ensure a speedier cargo release, considering that, if the

cargo is cleared, the airport can prioritize its departure immediately after SEFAZ's release.

If the cargo-pick-up data are not presented when the Pre-Alert is sent, they must be presented electronically in the Bonded Warehouse's system, at which point, the cargo pick-up time and the vehicle's license plate information must be informed.



Data that is not sent or is incomplete may cause delays in the release operation process.

After this, the vehicle must be directed to the Registration area, according to each airport's vehicle entry and release process.

6 Documents required for cargo pick-up

In order to pick up the cargo, the following documents must be submitted:

- Nota Fiscal or equivalent document, as per State legislation;
- Air Waybill;
- Electronic Air Waybill (CTE, *Conhecimento de Transporte Eletrônico*);
- Identification document belonging to the person responsible for the cargo pick-up; and
- Proof of Payment of the Import Collection Document (DAI, *Documento de Arrecadação de Importação*), which refers to storage fees and other expenses that were not yet directly billed to the Importer.

7 Bonded Warehouse verification

Once the Bonded Warehouse received the cargo delivery request, it is responsible for taking the following actions:

- Confirm that the cargo is cleared by RFB and released by SEFAZ;
- Validate the documents submitted by the Importer in [Item 6](#); and
- Register the following in its system:
 - The date and time the cargo was delivered;
 - CPF number belonging to the person responsible for the cargo's pick-up (according to the information provided upon the Import Declaration's registration);
 - Road Carrier's CNPJ number;
 - License plate number for the pick-up vehicle; and
 - Driver's CNH number.

The Bonded Warehouse must file the documents received, along with the record of the information above, as per [Decreto nº. 6,759 from February 5, 2009](#) and the [Normativa SRF nº. 680 from October 2, 2006](#).

The Bonded Warehouse must register the cargo's delivery in Siscomex Mantra.

8 **Authorized vehicles**

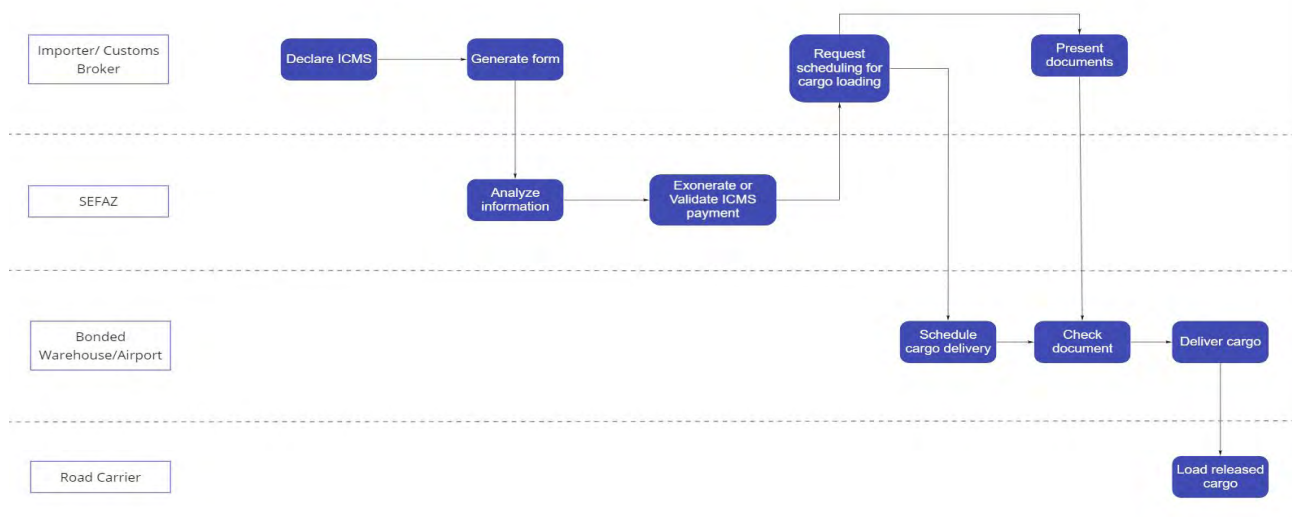
The Carrier that is able to transport vaccines, must have the following authorizations:

- Authorization to Operate (AFE, *Autorização de Funcionamento*), for transporting vaccines;
- Certificate of Technical Regularity (*Certificado de Regularidade Técnica*) issued by CRF, Coren, or CREA;
- Health Inspection License; and
- Good Practice Manual.

Storage and temperature requirements must be guaranteed throughout the route, as per [Resolução de Diretoria Colegiada - RDC Nº 430, from October 8, 2020](#).

9 **Attention Points**

- Once the cargo is loaded, if active equipment (also known as "Envirotainers") must leave the airport, the Importer, or their legal representative, must sign the Term for withdrawing equipment (also known as "LUC", Loan Unit Control) issued by the Airline or Freight Forwarder. By signing the LUC, the Importer or their legal representative agrees to return the equipment (packaging);
- Partial Cargo Clearance: if only part of the COVID-19 vaccine shipment arrives, RFB may authorize, on an exceptional basis, its regularization in Siscomex Mantra. This allows the "partial shipment" to be collected by the Importer, in order to ensure the quality of the vaccines. Once the rest of the shipment arrives, the Importer or their legal representative must immediately request that RFB verify these volumes, so that its status may be updated in Siscomex Mantra. These missing volumes are thus linked to the partially authorized Import Declaration.



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10 *Legal basis and additional guidelines*

- [Lei Complementar nº 87, from September 13, 1996](#)
- [Convênio ICMS nº 85, de 25 from September 25, 2009](#)
- [Portaria Cat nº 24, from 10-03-2020](#)
- [Procedimentos do Importador para geração de GARE / GNRE – Importação e Guia para Liberação de Mercadoria Estrangeira – SEFAZ São Paulo \(Procedures for generating the Import GARE/GNRE – SEFAZ São Paulo\)](#)
- [Procedimentos do Importador para geração de GARE / GNRE – Importação e Guia para Liberação de Mercadoria Estrangeira – SEFAZ São Paulo – Covid-19 \(Procedures for generating the Import GARE/GNRE for the release of foreign goods – SEFAZ São Paulo – COVID-19\)](#)
- [Step-by-step procedure to fill out the DARJ/GNRE – SEFAZ Rio de Janeiro - 01](#)
- [Step-by-step procedure to fill out DARJ/GNRE – SEFAZ Rio de Janeiro - 02](#)
- [Reference Guide – SEFAZ Paraná](#)
- [Reference Guide – SEFAZ Santa Catarina](#)
- [Manual PCCE](#)
- [PCCE Statement – COVID-19](#)

- [Q&A - PCCE](#)
- [Decreto N° 6.759, from February 05, 2009](#)
- [Instrução Normativa SRF N° 680, from October 2, 2006](#)

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Communication

- **SEFAZ/SP** - pfviracopos@fazenda.sp.gov.br; pfguarulhoscomex@fazenda.sp.gov.br

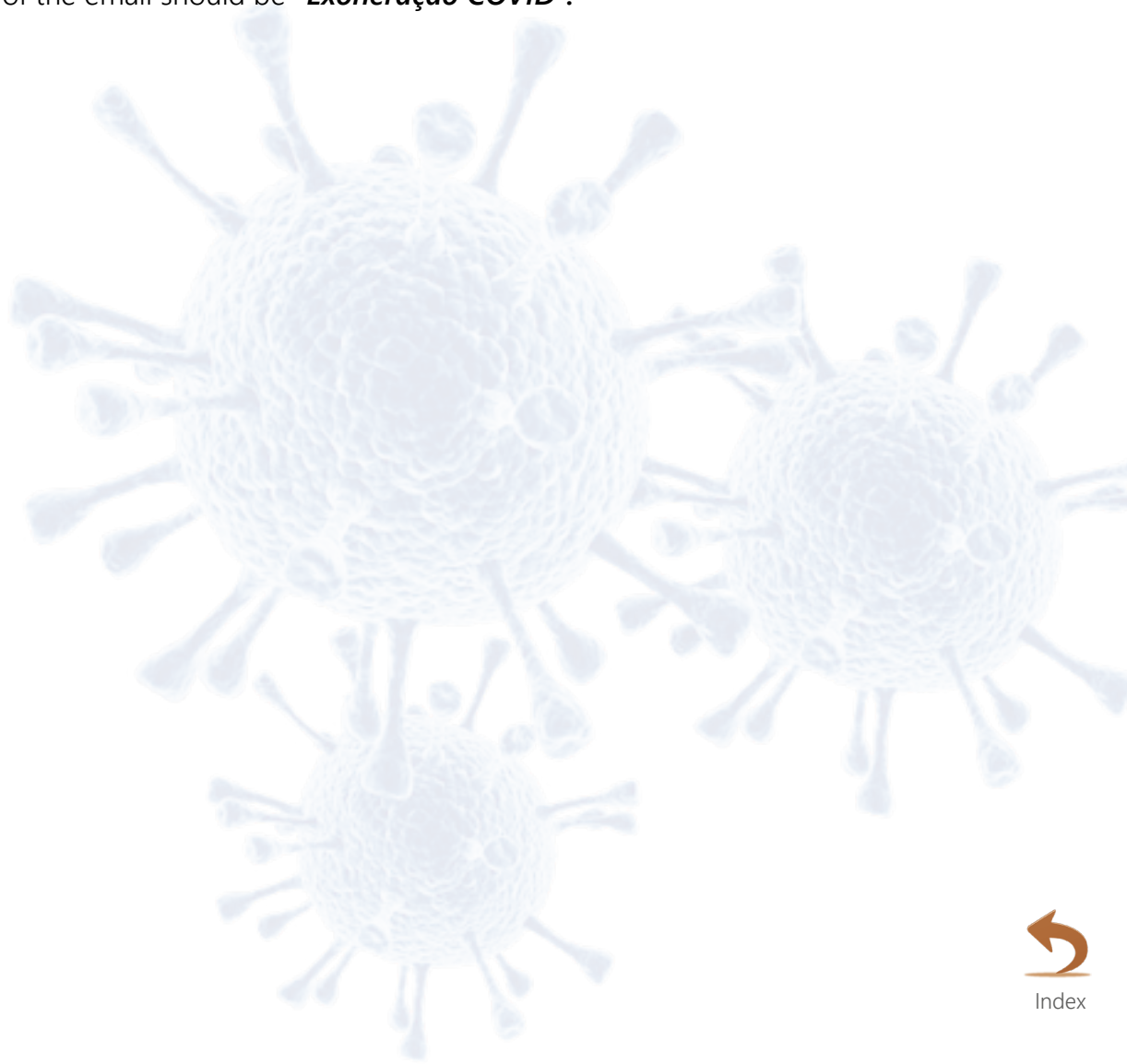
The title of the email should be **"Vacina COVID"**.

The body of the e-mail should contain the information of the request made in the PCCE.

Note: For State of São Paulo taxpayers, if cargo clearance occurs in a different UF, other than São Paulo, the e-mail must be sent to bagagemleilao@fazenda.sp.gov.br

- **SEFAZ/RJ** - ife02@fazenda.rj.gov.br

The title of the email should be **"Exoneração COVID"**.



Chapter V

Contingency Measures Applied in Cases of Instability or Systems Failure



1 **Anvisa systems**

In case of system unavailability or inoperability, an e-mail must be sent to gcpaf@anvisa.gov.br, reporting the error and requesting the next steps and necessary procedures for the COVID-19 vaccine Import License analysis.

Contacting this e-mail should be restricted to reporting systems issues and not specific cases, unrelated to systems.

Anvisa considers the following as system instabilities:

- Error in the *Petição* system, lasting for longer than one day;
- Error in generating the Payment Form, making it impossible to complete the process; and
- Error in Anvisa's system, lasting for longer than one day;

2 **Siscomex**

If the Siscomex Portal presents instability, for a period lasting longer than three hours (provided it is not during Siscomex Portal's daily system maintenance time), the Importer must send a message to diimp.coana.df@rfb.gov.br, reporting the event and, if possible, demonstrating the error through the screenshots.



Participants

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Antonio Oliveira - SAC/MINFRA
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Bruno Favruzzo - World Courier
Caio Pimenta - DB Schenker
Camila Dias - PFIZER
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Carlos Fabiano Ramos de Oliveira - RFB
Carlos Murilo - FEDEX / ABRAEC
Celso Squilanti - AZUL
Charles Silva - DB Schenker
Claudio Lanelli - ANAC
Claudio Santos - World Courier
Cleoneice Araujo - Kuehne Nagel
Cristiano Ramos - Viracopos - ABV
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Daniela Almeida - Terumo Medical
Demetrios Rodrigues - CROSS RACER
Denis Caputo - CSAFE
Diana Ferreira - ANAC
Diana Oliveira - DHL
Diego Xavier da Silva - Sindusfarma
Ditmar Schoendorf - DHL / JURCAIB
Douglas Almeida - ANEAA
Douglas Pacheco - AZUL
Edlaine Barroso - Itacolomy
Edson Napedre - PFIZER
Eduardo Calderelli - Rio Galeão
Elisa Boccia - ANVISA
Elmo Zenobio - RFB
Elson Ferreira Isayama - TCEX / Sindasp
Emerson Ramos - CROSS RACER
Erica Guarany - Rio Galeão
Everaldo Santos - Viracopos - ABV
Fabiana Todesco - SAC/MINFRA
Fabiano Coelho - RFB
Fabio Ciocca - Brasil Multivias
Felipe Leliard - Asia Shipping
Fernanda Negrão - MARKEN
Fernanda Orsi - BUTANTAN
Fernanda Santos - Rio Galeão
Fernanda Sobral - DSV
Fernando Amaral - SWISS
Fernando De La Cruz - AVIANCA
Fernando Piza - Asia Shipping
Filipe Thome - RFB
Flávia Novaes - UNIÃO QUÍMICA
Gabriel Moredo - PROTEGE
Gleiciane Rocha - Rio Galeão
Guilherme Theo Sampaio - CNT
Helio Dapena - Rio Galeão
Helio Takashi - Asia Shipping
Henrique Pedrosa - Terumo Medical
Igor Maia - SECEX
Igor Munekata - Sindusfarma
Ingrid Mathia - Terumo Medical
Isac Florêncio - HAIDAR
Jackson Campos - Asia Shipping
Jackson Corbari - RFB
Jessica Riviere - AMT BRASIL
Jessica Urso - Johnson & Johnson
Joana Lages - RFB
Johanna Londono - AVIANCA
Jorge Lobarinhas - Viracopos - ABV
José Barreto de Andrade - ANAC
José da Costa - DMS Log
Joseanny Kirts - Pharma Log
Juliana Cavalcanti - Boehringer
Juliana Mattos - Terumo Medical
Juliane Montecheze - Johnson & Johnson
Júlio César Caraúna - Viracopos - ABV
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Ligia Santos - ANVISA
Lucy Nunes - ELEKTA
Luís Abe - RFB
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Luiz Haully - Pharma Log
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Marcelo Arnoni - SEFAZ/SP
Marcelo Ferreira - Ebimex
Marcia Camargo - Asia Shipping
Marco Mucci - RFB
Maria Claudia Murta - Rio Galeão
Maricy Busato - Terumo Medical
Marina Hass - Asia Shipping
Maritse Silveira - ANVISA
Marli Oliveira - UNITRADE
Milene Ferreira Aguiar Alve - GRU Airport
Mirela Batista - RFB
Nérilton Souza - ANVISA
Oswaldo Marangoni - ANVISA
Patricia Goncalves Barboza - DHL
Patricia Guimaraes - Terumo Medical
Patricia Miranda - RFB
Paula Vilalba - FEDEX
Paulo Júnior - SEFAZ/RJ
Paulo Possas - SAC/MINFRA
Pedro Bellintani Baleotti - FINARDI
Pedro Parigot - Viracopos - ABV
Priscila Onuki - MARKEN
Raquel Mazocolo - Sindusfarma
Regina Neves - ANAC
Regina Terezin - CUALIDAD / Sindasp
Ricardo Luize - Viracopos - ABV
Roberto Cardoso - Rio Galeão
Rogéria de Nadai - AZUL
Rosana Mastellaro - Sindusfarma
Samara Pinto - DB Schenker
Sandra Vitali - RFB
Sergio Alencar - RFB
Sheila Strack - SAC/MINFRA
Taigoara Finardi Martins - FINARDIE
PROCHET
Tales Mateus - UPS
Tamy Hanada - DENTSPLY
Tatiana Almeida - FEDEX
Thiago Cavalcante - AVIANCA
Tiago Barbosa - SECEX
Tiago Wietholter - PFIZER
Vagner Battaglioli - ABRAEC
Valter Souza - CNT
Vanessa Mello - AZUL
Vania Barbosa - SEFAZ/SP
Vânia Campelo - ANVISA
Victor Rios - HAIDAR
Vidal Melo - USP
Vitor Manhaes - DHL
Vladimir Macedo - SECEX
Wagner Borelli - American Airlines / Jurcaib
Walban Souza - ABIMED
Yessy Hernandez - AVIANCA

Procomex

*Aliança Pró Modernização Logística de
Comércio Exterior*