MANUAL: PETICIONAMENTO DE LICENÇA DE IMPORTAÇÃO POR MEIO DE LPCO

GERÊNCIA DE CONTROLE SANITÁRIO DE PRODUTOS E EMPRESAS EM PORTOS, AEROPORTOS, FRONTEIRAS E RECINTOS ALFANDEGADOS (GCPAF)

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CEO

Rômison Rodrigues Mota (substitute)

Director of the Fifth Directorate
Daniel Meirelles Fernandes Pereira

General Management of Ports, Airports, Borders and Customs Areas – GGPAF
Gabriela

Management of Health Control of Products and Companies in Ports, Airports, Borders and Customs Areas - GCPAF
Elisa da Silva Braga Bowl

Prepared by:
Caroline Nayanna Rodriguez Santos
Monica Cristina Antunes Figueirêdo Duarte

gcpaf@anvisa.gov.br

SUMMARY

1. OBJECTIVE AND SCOPE

The Management of Sanitary Control of Products and Companies in Ports, Airports, Borders and Customs Areas – GCPAF in the exercise of the powers conferred upon them, in article no. 163 of Anvisa's Internal Regulations, RDC no. 585 of December 10, 2021, prepared this Manual aiming to establish the flows related to the integration of LPCO (License, Permit, Certificate and Other Documents) with the Import License (LI).

With the integration of LPCO with LI, there will be a simplification for both the importer and the approving body, as it will not be necessary to replicate or check the information in two systems.

This material is not intended to replace the Anvisa Solicita Manual nor the LPCO Import Request Manual from the Single Portal, but only complement them in specific aspects, regarding the electronic LI petition flow in the context of Anvisa.

We suggest reading the Solicita Manual in detail, available at https://www.gov.br/anvisa/pt-br/sistemas/peticionamento/arquivos/9378json-file-1 and LPCO Application Manual, available at http://siscomex.gov.br/wp-content/uploads/2021/02/Manual-de-Preenchimento-LPCO-Importador.pdf for the complete understanding of the use of systems.

2. BASIS

The Brazilian Federal Revenue Service (RFB) and the consenting bodies must migrate the import process to the Single Foreign Trade Portal, which must be used as a single window for users to make requests and payments with all public bodies involved in the import process. Measure aligned with a proposal for a single service window, provided for in the Trade Facilitation Agreement Exterior, Decree 9.326/2018.

The integration of LPCO with LI is not yet part of the New Import Process and will not use the Single Import Declaration (Duimp) at this time. However, it will reduce the number of steps that the importer must complete to file a petition import processes subject to Anvisa's approval.

According to RDC No. 74, of May 2, 2016, which provides for petitioning electronically in the import of goods and products subject to health surveillance, the document with

guidelines on the use of electronic petitioning will be available on the website
Anvisa's electronic system.

3. DEFINITIONS

For the purposes of this Manual and its context of application, the following must be considered: following definitions:

Electronic signature: process of identifying a document electronically, with the purpose of demonstrating the identity of the person signing.

Signature with digital certificate: form of electronic signature made through digital certificate. It is a subset of the "electronic signature" category. It uses a certification-based digital ID issued by a trusted certification authority third parties.

Electronic document: is the native-original document; originally created in a digital medium. electronic.

Digitized document: document obtained from the conversion of a non-digital document. digital.

Primary Petition: petition that generates an import process. It uses subject codes that define the class of products, the purpose of the import and the procedure to be followed in Anvisa.

Secondary Petition: petition that does not generate an import process. It must always be linked to a primary petition (process), using a specific subject code.

4. REGISTRATION WITH ANVISA

The petition for matters included in the scope of this Manual at Anvisa must be carried out by the importing company that has registered the Import License in the Siscomex.

The protocol is restricted to users linked to the petitioning company's registration with to Anvisa with the following profiles:

- Security manager or legal representative;

- Regulatory Petition User.

Anvisa provides a step-by-step explanation for companies on how they should register in the system - https://www.gov.br/anvisa/pt-br/sistemas/cadastros/cadastro-de-

companies. It is in the company's registration that the security managers must be indicated. This manager, using the registered email and password, will be responsible for accessing the Solicita system for the import process demand protocol. It is interesting that the company register more than one security manager, thus avoiding all communication with Anvisa is in charge of a single person.

Companies that must have AFE to import medical devices must have the Anvisa registration updated, but pay attention to the need for changes in processes of AFE, according to specific standards.

Companies that are exempt from AFE to import must also maintain registration the system is always updated, both in relation to data validated by the Federal Revenue Service, and legal and technical responsibility. This demand is necessary to avoid notifications of requirements that delay customs clearance of goods, due to conflicting information in the import process and registration with Anvisa.

After completing the registration, the company will be able to access the Solicita system for purposes of import process protocols at Anvisa. The step-by-step guide to accessing Solicita can be found in the Solicita Manual, available at https://www.gov.br/anvisa/pt-br/systems/petitioning.

5. SYSTEM REQUESTS

Solicita is Anvisa's system used for electronic petitioning of processes import of products under the Agency's approval. Its dynamics allow the association of company registration data, with the types of matters of interest to Anvisa and the generation of the Union Collection Guide, the GRU, for payment of the Inspection Fee in Health Surveillance (TFVS).

This system has already been the subject of two Webinars, which are available on the Anvisa Webinars, in the "Cross-Cutting Themes" section. Recordings of the webinars are available there. events, the question and answer documents and the presentations made. The first Webinar, held on 07/22/2019, aimed to present the system when it was inaugurated; the second Webinar, held on 03/08/2021, showed the system's new features and clarified the main doubts received by users.

For more information and a user manual for the System, visit https://www.gov.br/anvisa/pt-br/sistemas/peticionamento.

6. GENERAL GUIDELINES

- **Documents must be submitted in electronic format, in addition to being legible and signed electronically with a digital certificate as provided for in art. 3 of RDC No. 74/2016 and in art. 5 of Decree No. 10,278/2020. Proof of validation of the digital signature can be carried out by consulting the VALIDAR system - https://validar.iti.gov.br/.**
  - **There are three types of electronic signatures (levels):**
    - **ÿ simple**
    - **ÿ advanced – this is the case of gov.br.**
    - **ÿ qualified - issued by ICP-Brasil certification bodies.**
  - **RDC 74/2016, which provides for electronic petitioning for the import of goods and products subject to health surveillance, indicates that it must have a signature issued by certifying authorities recognized by the Brazilian Public Key Infrastructure - ICP/Brazil. Therefore, the gov.br signature does not comply with RDC 74/2016.**
- **We recommend submitting documents in searchable PDF format to speed up the process. analysis by the inspection team.**
- **Documents for instructing the import process must be attached to the LPCO itself.**
- **Document types for which there is more than one for the same LPCO may be attached in a single file. Example: certificate of analysis for several batches of the same product may be attached in a single file. However, certificates of analysis of different products, contained in the same LPCO, must be presented in files individual electronics, by product. The protocol in Solicita is mandatory for Anvisa to analyze the of Import Licensing that depends on its manifestation. This protocol refers to both primary and secondary petitions.**
- **Considering the closing of the Electronic Import Petition – PEI on 03/31/2023, from that date onwards, secondary primary petitions filed through the PEI must be filed through the Solicita system. The subject codes described must be used in item 25 of this Manual.**
- **Requirement notifications will only be registered on the Single Foreign Trade Portal, so it is up to the importer to consult them periodically and carry out the respective protocol secondary petition for compliance in the Request and respond to the requirement in the LPCO.**
- **To access the LPCO module of the Single Portal and Siscomex Importação Web, you must use of a digital certificate. This requirement is intended to ensure that only people authorized and identifiable users to access the system. Only these users will be able to: access, view and attach documents.**

- **The LPCO "Prioritization Criteria" field should only be filled in if a some of the situations provided for in this Manual. Proof must be provided in accordance with defined criteria and documents. If there is no proof of compliance with the criteria prioritization, the import process will be summarily rejected.**
- **For import processes carried out by road, Direct unloading of bulk, or import of microspheres, the importer has up to five calendar days, counted from from the process protocol at Anvisa, to complement the process with the documentation missing by means of a petition for an addendum to the process. Documentation attached without due petition in Solicita will not be evaluated and the LI/LPCO will be rejected.**
- **Anvisa will accept the original or non-negotiable physical bill of lading or E-AWB, as long as it is signed by the issuer and dated, proving the shipment of the cargo, for the instruction of the import process. The submission of the Draft (document issued before the official bill of lading), and the bill of lading without signature and date of boarding.**
- **In the case of outsourced imports, the inspection and health surveillance fee will be calculated according to according to the size of the holder of the product's regularization with Anvisa, and, therefore, it is not payment of an additional fee is required.**
    - **o Imports of products exempt from regularization, even in the case of operations on behalf of and order or request, are not considered outsourced, as there is no holder of regularization. Incorrect markings on the form will result in the rejection of the LI/LPCO.**
- **The importer can monitor the deadline for distributing processes for analysis through of the Distribution Queue Panel, available at: https://www.gov.br/anvisa/pt-br/accesstoinformation/opendata/analytical-information/import.**
- **From 11/06/2023, only import processes registered in the new LPCO models available for registration at PUCOMEX. Protocols in Requests from the on 11/06/2023, with old LPCO models, the LPCOs will be rejected.**
- **The processes filed with Anvisa until 11/05/2023 will be analyzed in the LPCO models old, until the deadline of 04/03/2024, after 150 days of its protocol, according to the validity of the process under item 11 of Chapter III of the Annex to RDC No. 81/2008.**

7. IMPORT PROCESS – LPCO INTEGRATION WITH LI

The import process protocol in Solicita regarding the Siscomex modality will require the LPCO number and the Import License number. Therefore, the importer must start the process by registering the LI in Siscomex, followed by making the LPCO request

on the Single Foreign Trade Portal. After these steps, there must be a protocol for the process import in Solicita.

With the integration of LPCO with LI, when informing the LI number in the Single Portal of Foreign Trade, the system will load the LI data into the LPCO, so that it will no longer be It is necessary to type all items again.

8. LI REGISTRATION

The first step in the process of importing goods or products subject to surveillance sanitary is the registration of the LI in Siscomex.

This step does not have any specific aspect of Anvisa and must be carried out in accordance with the LI Web Primer, available at http://siscomex.gov.br/informacoes/manuais/.

ATTENTION

The Product Description in the LI must cite the product identification, trade name, business model, business presentation, composition and components.

The absence of this information will result in the rejection of the LI/LPCO.

9. APPLICATION FOR IMPORT LPCO ON THE SINGLE PORTAL OF COMEX

After registering the LI, the importer must register the LPCO on the Single Portal Foreign Trade, as detailed below.

The user must inform the LI number that will be incorporated into an LPCO, always respecting the relationship 1 LI = 1 LPCO and 1 LI item = 1 LPCO item.

ATTENTION

Only LI in a situation pending analysis may be reported in the LPCO.

9.1 INCLUDE LPCO REQUEST

To include LPCO request for import of products subject to the approval of Anvisa, the user must access the Single Foreign Trade Portal at the address https://portalunico.siscomex.gov.br/portal/, log in with a digital certificate and select the import module (imp).

Click on LPCO >> Add Order

9.1.1 Select LPCO model

To select the LPCO model to be requested, follow these steps:

a) You can start the search by the approving body or by the name of the LPCO model.

b) According to the chosen consenting body, the system will only show the models of the LPCO of the respective body. Only the model is mandatory.

c) A new LPCO can be included from an existing one of the same model.

d) After selecting the model or entering the existing LPCO number, click on "Continue".

9.1.2 Link LI

This new feature makes the system load LI data directly in the LPCO, so the importer does not need to enter them again. The importer must enter the LI number and click on LINK LI.

When linking LI, the system loads all LI data into LPCO.

When trying to link an LI already linked to an LPCO, the system will display the following error screen:

ATTENTION

Although the Single Foreign Trade Portal prevents the linking of a same LI to more than one LPCO, this restriction does not occur in the Solicita System Anvisa. Therefore, it is up to the importer to make the correct link in the System Request.

9.1.3 Filling in the data

In the "LPCO Form" tab, the form data must be filled in, which are divided into: general data and LPCO items.

The general data contains the importer's identification information that is automatically filled in based on the importer's registration on the Single Portal and the general import information.

ATTENTION

Fields marked with an asterisk (*) are mandatory and can be differ for each LPCO model.

Manual inclusion of an item in the LPCO will not be allowed, even after importing the THAT.

Within the General Data section of the LPCO, there is the Basic Data tab, which will contain information migrated from the LI and fields to be filled in by the importer.

Guidelines on filling in these fields are listed in item 9.1.5 of this document. Manual.

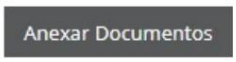
Then, for each item in the LPCO, the importer must complete the following: fields:

*** Example of Medical Device LPCO template. Each regulatory product category will have fields specific.**

Guidelines on completing the fields for all regulatory categories are listed in item 9.1.5 of this Manual.

After filling in all the mandatory fields, the importer must click on the button

After registration, new tabs will appear, including "Attached Documents" for the attachment of documents for procedural instruction.

To attach documents, click on the button 

and then select the "Document type", select Anvisa to access the document and then click on the button

Then click the button  **and locate the file on your computer to upload it.**

Repeat the previous steps until you have uploaded all the necessary documents, check the box option "I am aware that from the inclusion of the bodies the documents will be available for the same" and click on the button 

A new tab has been added with LPCO Integration with LI, called "LPCO GROUPED". This functionality must be informed by the importer in order to group licenses for products that are part of the same operation or are physically grouped in a container or cargo unit. Thus, the consenting party has information to process these licenses together.

The new tab will display a list of LPCOs grouped with the following columns: Number LI, LPCO Number, LPCO Status, Bill of Lading Number, Date of inclusion in the Grouping and Date of exclusion from the Grouping, and Actions. This screen will allow that the user can include a new LPCO in the Grouping or delete a linked LPCO.
There is no restriction on the model or status of the LPCO. However, it must be of the same consenting body.

- **LPCOs can be grouped at any time.**
- **The approval of a grouped LPCO does not indicate the approval of the others, being only a direction for analysis.**

9.1.4 Completing the form fields, according to LPCO models

The choice of the LPCO model must be made according to the product's NCM and code of petition subject at Anvisa to be chosen by the importer.

ATTENTION

The selection of an LPCO model that differs from the one indicated, as tables in item 24 of this Manual, for the subject code, leads to rejection of LI and LPCO, as each model has fields for filling in information mandatory and necessary for the analysis of the process.

The Mercosur Common Nomenclature (NCM) codes available for each LPCO model are listed in tabs 02 and 03 respectively of the "TA_LPCO_ATT_IMP" spreadsheet available on the "Administrative Treatment Single Portal" page.
If the product's NCM code does not have the LCPO model available for the classification in the specific petition subject, it is necessary to communicate to Anvisa by through the service channels, available at https://www.gov.br/anvisa/pt-br/canais_atendimento, for inclusion assessment. The request to Anvisa must be made prior to the import process protocol, considering that the use of a model incorrect will result in the rejection of the import process. In the request, the importer must inform the NCM number, the LPCO model for which the NCM must be included and details about the product covered by this NCM.

9.1.5 Fields common to all forms

The fields to be presented may vary depending on the LPCO model. There are conditioned fields that vary according to responses selected in specific items of the form.

*** Example of Medical Device LPCO template. Each regulatory product category will have fields specific.**

Below are guidelines for filling in the LPCO fields:

General Data		Filling guidelines
Field	**Description**	
Subject code of petition primary*	**Selection field.**	**Select from the list the subject code of primary petition of the process to be registered in the Anvisa Request, as per petition mirror.** **Choose according to the table in item 25.1 of this Manual. Subject code divergence reported in the LPCO in relation to the**

		filed with Solicita leads to the rejection of the LI/LPCO due to discrepancies in information as provided for in item 1.3 of Chapter II of the Annex to RDC No. 81/2008.
Subject code of petition secondary	**Selection field.**	**Select the subject code from the list secondary of the process to be filed in the Request from Anvisa, according to mirror of petition.** **Choose according to the table in item 25.2 of this Manual. Subject code divergence reported in the LPCO in relation to the filed in the Request gives rise to the rejection of LI/LPCO due to discrepancy information as provided in item 1.3 of Chapter II of DRC Annex No 81/2008.**
Type of operation import*	**Selection field.**	**Select the type of operation from the list import.** **Divergence of the type of operation reported in relation to the documents presented in the LPCO leads to the rejection of the LI/LPCO due to divergence of information according to the provided for in item 1.3 of Chapter II of the Annex from DRC No. 81/2008.** **1-By a company whose product is exempt from regularization at Anvisa/SNVS** **NOTE: the product is included in some category regulatory (medicine, medical device, cosmetics, food, sanitizing agents, etc.) but are not subject to regularization at Anvisa or SNVS.** **2-By a company whose product is not subject to health intervention** **NOTE: The product is not subject to intervention sanitary, but the NCM has a marking for mandatory Anvisa approval.** **3-By company holding regularization of product at Anvisa/SNVS**

		NOTE: The holder of the regularization (or its branch) are the importers of the product import process regularized at Anvisa. or SNVS. **4-By health unit, institutions such as foundations, civil society organizations of public interest (OSCIPs), health plan operators, State Secretariats of Health, Municipal Health Departments or Military Organizations** **NOTE: The importer is one of the listed actors above and the product is subject to regularization at Anvisa or SNVS.** **5-Outsourced on behalf of and by order of a third party for the purchaser (holder of regularization in the Anvisa/SNVS or health unit)** **NOTE: The importer is a Trading company, operating on behalf of and order, regularized product in Anvisa, from another company that owns its regularization.** **6-Outsourced by order of a third party to the orderer (holder of regularization in Anvisa/SNVS or health unit** **NOTE: The importer is a Trading company, operating by order, regularized product in Anvisa, from another company that owns its regularization.** **7-Outsourced by a company with AFE from the DRC No. 16/2014 to import or manufacture, whose regularization of the product at Anvisa/SNVS is from another company** **NOTE: The importer is a company with AFE or AE to import from RDC No. 16/2014, of product regularized by Anvisa, otherwise company holding its regularization.** **8-By the Ministry of Health or entities public entities linked to SUS**

		NOTE: The importer is the Ministry of Health or public entities LINKED to the SUS, of products subject to regularization by Anvisa or SNVS. **9-For a company whose import purpose is exempt from regularization at Anvisa/SNVS** **NOTE: The purpose of importing the product exempts it from regularization - scientific research, clinical, testing, fairs, supply of resources international transport, etc.** **Note: For the import of input or raw material (for cosmetics, cleaning products or food) must be reported as the type of operation for import, Item 1.** **For import of product exempt from regularization, even in the case of account and order or order, Item must be indicated** **1.** **For import of semi-finished and bulk products operation must follow the same understanding of finished products.** **For import for research purposes scientific, clinical, test, fair, etc., which exempt to regularize the product, indicate item 9.**
CNPJ Holder of the regularization	**Text field (number)**	**Indicate the CNPJ of the holder of the product regularization, as stated in the publication of the Anvisa. The field must be filled in even in the situation of import by the branch, whose holder of the regularization is the matrix, thus as in the case where the import has** **been carried out by the holder of the record.** ***Product regularization is registration, notification, registration, model release, communication of first import or other**

		form of control regulated by Anvisa/SNVS. **For products without regularization, leave this field blank.** **In the case of IFA, the CNPJ must be informed. of the registration holder in the case of an import by a distributor. In the case of import for the manufacture of medicine regularized, the CNPJ of the holder of the drug registration in which will be used.** **Discrepancy in the Holder's CNPJ number of the regularization informed in the LPCO in relation to product regularization data at Anvisa/SNVS leads to the rejection of the LI/LPCO due to discrepancies in information as provided in item 1.3 of Chapter II of DRC Annex No. 81/2008.**
Entity linked to the THEIR, Law 9782/99?	**Yes/No**	**The "Yes" option must be selected if import by a public entity linked to the SUS, as defined in Art. 23 of the Lei n° 9,782/1999.** **Private entities linked to SUS should mark as "No".** **Discrepancy in this information in relation to that provided in the Request, the registered subject code and documents attached to the LPCO leads to the rejection of the LI/LPCO due to divergence of information according to the provided for in item 1.3 of Chapter II of the Annex from DRC No. 81/2008.**
CNPJ of the Venue Storer:*	**Text field (number)**	**Indicate the CNPJ of the Storage Facility the product will be stored before its customs clearance.** **In the road mode, the dispatch URF must be filled in with the CNPJ number of the premises where the cargo will be cleared. If**

		clearance takes place at a transit point, without a linked customs storage area, should to be indicated 00.000.000/0000-00. For Direct Bulk Unloading, the field of CNPJ of the storage facility, must be filled in with the number of the non-customs warehouse that will receive the DDG cargo, after the goods have been cleared. This location must have a health license or health permit to food storage. Divergence of Warehouse CNPJ number informed in LPCO in relation to documents presented gives rise to the rejection of the LI/LPCO due to discrepancies in information as provided in item 1.3 of Chapter II of DRC Annex No. 81/2008.
Purpose and Import Anvisa:*	Selection field.	Select the import purpose from the list. Divergence of the import purpose selected in the LPCO in relation to the registered subject code and documents attached to the LPCO leads to the rejection of the LI/LPCO due to discrepancies in information as provided for in item 1.3 of Chapter II of DRC Annex No. 81/2008. If the importer understands that the purposes available do not meet your request, must, prior to registering the LPCO, submit request for inclusion of a new order by Anvisa's official communication channels. 1. Supply of wards, pharmacies or mid-board medical set international transport 2. Cells and tissues for therapeutic purposes 3. Commercial

		4. Compliance with legal action to treatment of specific patients 5. Special Customs Deposit 6. Laboratory diagnosis 7. International donation 8. Proficiency test 9. Teaching or training with device doctor 10. Religious, sporting and social events large door 11. Fairs or events 12. Industrial 13. Duty free shop 14. Not subject to health intervention 15. Scientific, technological or involving human beings 16. Clinical Research 17. Cosmetics market research, food or sanitizing products 18. Public health program 19. Assistance programs (compassionate use, expanded access, post-study) 20. Return from repair or event abroad of medical device 21. Return for repair in the country of medical device 22. Return due to rejection of goods at exterior 23. Doping control test 24. Equipment testing 25. Testing for new development cleaning products, cosmetics or food 26. Testing for safety and efficacy trials of cosmetic 27. Quality control testing

		28. Tests for packaging evaluation or food or cosmetic labeling 29. Tests for product regularization purposes in the SNVS **30. Exclusive use of health unit** **31. Personal use by an individual** **32. Drug enforcement agency**
Criterion of prioritization:	**Selection field**	**Select the appropriate prioritization from the list order.** **Attach proof of prioritization as per described in item 21 of this Manual. The indication prioritization without proper proof leads to the rejection of the LI/LPCO due to divergence of information according to the provided for in item 1.3 of Chapter II of the Annex from DRC No. 81/2008.**
Type of subject merchandise has intervention sanitary:*	**Selection field**	**Select the type of merchandise from the list.** **Field applicable only to LPCO model Other Subjects.** **The following types of authorized goods are available:** **• Baby bottles, pacifiers, nipples and teethers • Human cells, tissues and organs** **• Human biological sample** **• Standard/Substance/Reference material for Proficiency Test** **• Standard/Substance/Reference material for Quality Control** **• Standard/Substance/Reference material for Marketing**
Provider's CNPJ from the test of proficiency	**Text field (number)**	**Attribute conditioned on the selection of the Purpose import "Proficiency Test".** **Indicate the CNPJ of the national provider. International providers fill in with 00.000.000/0000-00.**

CNPJ do recipient who will perform the test of proficiency	**Text field (number)**	**Attribute conditioned on the selection of the Purpose import "Proficiency Test".** **Indicate the CNPJ of the recipient who will execute the proficiency test in the country.**
LPCO Items		**Filling guidelines**
Number and regularization in the SNVS:	**Text field.**	**Indicate the product's regularization number at Anvisa.** *** Product regularization is registration, notification, registration, model release, communication of first import or other form of control regulated by Anvisa/SNVS.** **Field not applicable to the LPCO model of Other goods subject to intervention sanitary.** **In case of device components doctors, indicate the regularization number of the finished medical device.** **In the case of cosmetic inputs, sanitizing agents and food, leave the field blank.** **In the case of a product without regularization, leave the blank field.** **If there is more than one regularization of product, enter all numbers separately by ";" (semicolon).** **In the case of IFA indicate the number of registration record or registration number of the medicine in which it will be used, in the case import for drug manufacturing regularized**
Subcategory of (cosmetic/device) had doctor/medicaments of use	**Selection field**	**Select from the list the product subcategory that most closely matches the finished product, even in the case of products exempt from regularization.**

human/food /sanitising):*		**Note: In the case of inputs or materials, raw materials (medicines, cosmetics, cleaning products or food) select at least one category that most closely resembles the finished product, even in the case of products exempt from regularization. In the case of kits with more than one product category, the company must select at least least one of the categories present in the kit.**
CAS – DCB:	**Selection field**	**Field applicable to LPCO models of Medicines, Special Control and Others subjects. Select from the list the DCB number of the product. In the event that the product is not medicine, or not have DCB on the list, leave the field blank.**
Shape Pharmaceutical:*	**Selection field**	**Field applicable to LPCO models of Medicines and special control. Select the pharmaceutical form from the list product. If the pharmaceutical form is not listed in the model, select the one most similar to the product.**
Ordinance List SVS/MS nº 344/1998:*	**Selection field**	**Field applicable to the Special Control LPCO model. Select from the list SVS/MS Ordinance No. 344/1998:** **• List A1, A2, A3, B1, B2, C3 or D1** **• List C1, C2 or C5** **• List E and F**
Technical Name of the Device Doctor:*	**Selection field**	**Field applicable to the LPCO model of Medical Devices. Select the technical name that most closely matches the list. approximates the product description, including its parts and accessories, as per regularization of the finished product. To products exempt from regularization, including**

		its parts and accessories, indicate the technical name that most closely matches the product. This field will not be grounds for rejection. The full list can be found at https:// consultas.anvisa.gov.br/#/nomes-technicians/
Contains derivative of animal ruminating:*	Selection field.	Select Yes if the product has it in its composition some animal derivative ruminant in its composition. Field applicable to LPCO models of Medical Devices, Special Control, Medicines and Other Subjects. Fields: Yes or no.
Expiration date of the product:*	Text field.	The description must be in days, months or years, counting from the date of manufacture of the product, or the expiration date can be informed. Products with expired shelf life or expire within the next 30 days (except those with an expiration date of less than 180 days) will be banned, in accordance with item 4 of Chapter V of RDC No. 81/2008. Products with an indefinite shelf life must have an indication of this condition in the field. The deadline entered must coincide with the validity period of the stability study approved by manufacturer, as per information on product regularization, if be liable to such legal obligation. (Ex: 5 years, 60 months, 5 days, 36 hours, Undetermined).
Internship of manufacturing:*	Selection field.	Select the internship option from the list manufacturing. 1. Finished product 2. Bulk 3. Semi-finished/Intermediate 4. Raw material/Input 5. Piece of equipment

		6. Equipment accessory
Conditions and merchandise:*	**Selection field.**	**Field applicable to the LPCO model of Medical Devices.** **Select the condition of the merchandise from the list:** **1. New** **2. Used** **3. Refurbished**
Conditions of storage:*	**Selection field.**	**Select the condition option from the list storage of the product as validated in the regularization of the product or indicated by the manufacturer (in the case of products exempt from regularization):** **1. BELOW -20°C** **2. BETWEEN 0 AND -20ºC (FREEZER)** **3. BELOW -70° C** **4. OTHER SPECIAL CONDITIONS** **5. BELOW 25ÿ C** **6. BETWEEN 0 AND 8ºC** **7. BETWEEN 15 AND 30°** **8. BETWEEN 2 AND 8° C** **9. BETWEEN 9 AND 15° C** **10. DOES NOT SHOW CARE CONSERVATION SPECIALS** **11. BELOW -150° C** **12. BELOW 30° C**
Conditions of transport:*	**Selection field.**	**Select the condition option from the list transportation of the product as validated in regularization of the product or indicated by the manufacturer (in the case of products exempt from regularization):** **1. BELOW -20°C** **2. BETWEEN 0 AND -20ºC (FREEZER)** **3. BELOW -70° C** **4. OTHER SPECIAL CONDITIONS** **5. BELOW 25ÿ C** **6. BETWEEN 0 AND 8ºC** **7. BETWEEN 15 AND 30°**

		8. BETWEEN 2 AND 8° C 9. BETWEEN 9 AND 15° C 10. DOES NOT SHOW CARE CONSERVATION SPECIALS 11. BELOW -150° C 12. BELOW 30° C
Batch number, serial or part number:*	Text field.	Indicate the batches, serials or part numbers of the products, for all purposes of import or production stages.
Data of manufacturing:*	Campo data.	If there is more than one lot or partnumber for the product, but all with the same date of manufacturing, insert in batch in a single text the lots separated by ";", indicating the date of manufacturing per day/month/year. If there is more than one lot or partnumber for the product, with different manufacturing dates, indicate one lot or partnumber at a time, clicking "Add New" for each batch with specific manufacturing. Regarding the Date of Manufacture, in cases where that the day of manufacture is unknown, The last day of the month of manufacture can be entered.

* Mandatory fields

LI Highlight:

ATTENTION

The "Highlight LI" field that is required to be filled in the models LPCO are not evaluated by Anvisa. The highlight that Anvisa evaluates is the one indicated in the LI record. This way, this field can be randomly selected by importer.

9.1.6 Split delivery

RDC 81/2008 establishes the possibility of fractional deliveries for the import of goods or products under health surveillance. In this sense, we guide the protocol form of the import process with Anvisa:

- **The initial protocol of the import process must be carried out with the LI/LPCO with all the import volume. The analysis of the process will be carried out through documentary analysis of the first shipment of the cargo. The importer must attach to the LPCO a letter indicating if it is a "Fractional Delivery" citing the schedule of future shipments (quantity and scheduled date), signed by the company's legal representative.**
- **In case of split delivery, the importer must send, via addendum, the cargo manifest containing the quantity of volume and the knowledge registered with each lot of the fraction, according to the schedule initially presented to Anvisa. The LPCO will only be granted after adding all fractions.**
- **The LI will be granted, but the LPCO will remain in technical requirement, awaiting the amendment with the information on which fraction is being cleared on that date, according to the letter from company according to the schedule presented.**
    - **o The postponement is a secondary petition, which must be filed in the process of import.**
        - **ÿ The LI will be granted and the LPCO will remain in the "In demand" status with the following text: "PRODUCT UNDER FRACTIONAL DELIVERY. RELEASE TO EXPOSURE OR DELIVERY FOR CONSUMER OF FRACTIONAL SHIPMENTS PARTIES OF THIS IMPORT LICENSING WILL BE GIVEN BY "SATISFACTORY INSPECTION BY THE HEALTH AUTHORITY"**

9.1.7 Direct Bulk Unloading

- **The bill of lading and the original invoice, due to the specific type of flow, are not documents mandatory initial procedural instruction. However, after 05 consecutive days, counted from of the import process protocol at Anvisa, the Bill of Lading and Invoice originals must be added to the LPCO/PUCOMEX. If the shipping date can be changed, inform the date of the bill of lading.**
- **The CNPJ field of the storage facility, in this case, must be filled in with the number of the non-bonded warehouse that will receive the DDG cargo.**
- **The LI will be granted and the LPCO will be required until the importer sends all the applicable documentation.**

9.1.8 NCM reclassification by the Brazilian Federal Revenue Service

For cases that require a new statement from Anvisa in Licensing of Imports that had their products reclassified under other NCMs different from previous protocols at Anvisa, the procedures below must be followed, which were published at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/saiba-como-file-import-license-after-reclassification-of-ncm-by-federal-revenue.

A change takes place in view of the possibility of reviewing the NCM classification by Federal Revenue, according to the agency's specific procedures. Follow:

1. Original LI protocols through the PEI system – without LPCO:

i. **Register the replacement LI in Siscomex;**

ii. **Register a new LPCO linked to the replacement LI in the Siscomex Single Portal;**

iii. **File a new import process request indicating in the initial petition the new LPCO and replacement LI; and**

iv. **Attach justification to the LPCO for carrying out the protocol.**

2. Original LI protocols by Solicita with disabled or cancelled LPCO model – LPCO protocols until 11/5/2023:

i. **Register the replacement LI in Siscomex;**

ii. **Register a new LPCO linked to the replacement LI in the Siscomex Single Portal;**

iii. **File a secondary petition for a replacement LI in the process of original import.**

3. Original LI protocols in the new LPCO model – protocols from 11/6/2023:

i. **Register the replacement LI in Siscomex;**

ii. **Rectify the LPCO by linking the replacement LI. Changes in the fields of the LI will be carried out after the linking, since this LPCO model has integration with Siscomex-LI; and**

iii. **File a secondary petition for a replacement LI in the original process granted.**

4. Original LI protocols by Solicita with canceled LPCO model – protocols of LPCO as of 6/11/2023:

i. **Register the replacement LI in Siscomex;**

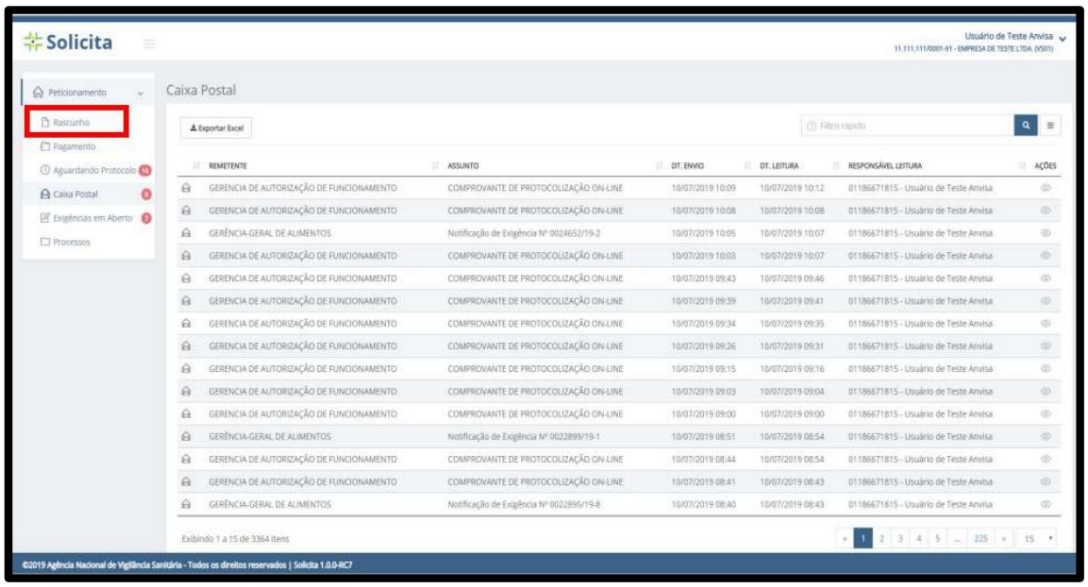
ii. **Register a new LPCO linked to the replacement LI in the Siscomex Single Portal;**

iii. File a secondary petition for a replacement LI in the process of original import.

10. IMPORT PROCESS PROTOCOL AT ANVISA

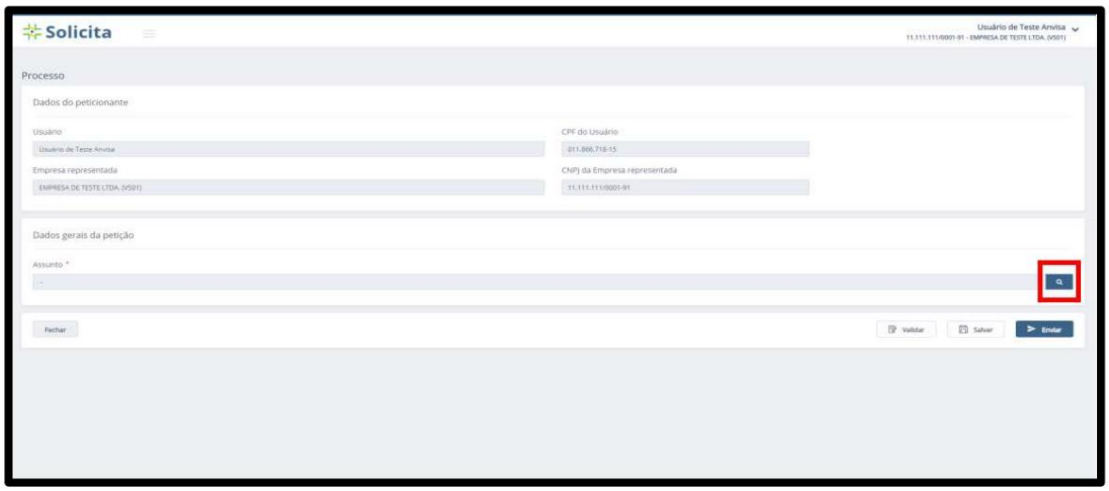
10.1 PRIMARY PETITION

- **Access Solicita through the address solicita.anvisa.gov.br and log in with email and password data;**
- **Click on the “Draft” option on the sidebar of the home screen;**



- **Click on the “New” button and click on “Initial Petition”;**

- **Click on the search button in the “Subject” field;**



- **On the screen that will open, the search can be done directly by the code subject (“Code” field) or selecting the option “Ports, Airports and Borders” for the “Activity/Product Type” field;**

- **When you click on search, a list of all subjects related to Ports, Airports and Borders or the specific subject (to search by code of subject);**
- **Click on the blue arrow in front of the subject description to open the form electronic with the petitioner's data, general petition data, legal basis, and documentation.**

Note: The example with express shipping matters is for educational purposes only. The guidelines in this Manual are exclusive for filing an LI with LPCO.

- **Fill in the "LPCO Number" field and the "Operation License Number" field. Import";**

ATTENTION

It is very important that each LI is linked exclusively to a LPCO and an import process in Solicita. If the protocol is verified of more than one LI, or repeated LPCO in different import processes in the Request, the most recent import process will have its status changed to Petition Closed at Solicita.

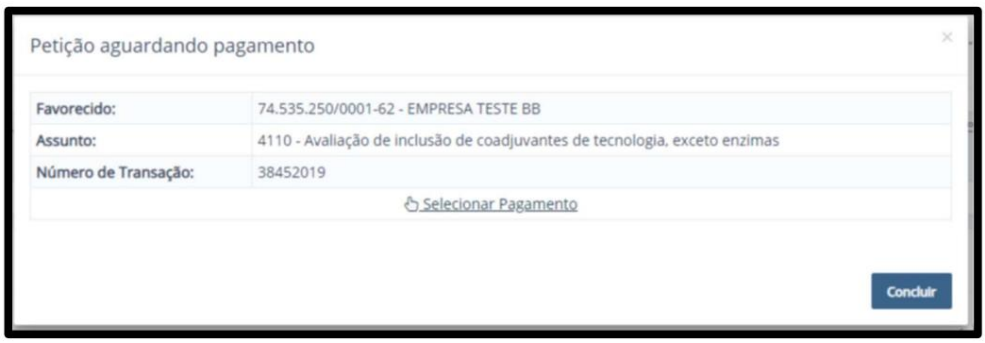
- **If the import is outsourced, of a product regularized by Anvisa, it must be the option "Yes" is selected for the question "The holder of the product regularization with Anvisa is a third party?". In this case, a new question will appear on the screen: "Is it an entity linked to the SUS classified in Art. 23 of Law No. 9.782/1999?". The option "Yes" must be selected if it is an import. by an entity linked to the SUS, as defined in Article 23 of Law No. 9,782/1999.**
  - **For products exempt from regularization, even in the case of import on behalf and order or order, the following must be marked: option "No" to the question "The holder of the regularization of the product with Anvisa is a third party?".**
- **When answering "No" to the question "Is it a public health entity linked to the SUS, framed in art. 23 of Law nº 9782/1999?" the field for insertion of the The third party's CNPJ will be made available. After entering the CNPJ number, the fields related to the corporate name, generating fact, company size will be filled in by the system and the fee amount will be updated accordingly. generator and the size of the company informed.**

ATTENTION If the importer of the product regularized by Anvisa is a third party, the amount of the Health Surveillance Inspection Fee (TFVS) will be calculated based on the size of the CNPJ of the holder of the product regularization in SNVS. If the importer is a public entity that is part of the SUS, classified in Art. 23 of Law No. 9.782/1999, the calculation of the fee will use the size of the CI The exemptions guaranteed by law remain applicable in all cases. Products exempt from regularization are not outsourced imports for the purposes of filling in the LPCO and SOLICITA fields.

- **Private entities linked to the SUS must mark the field "Is a public entity linked to the SUS" as "No", as the fee to be paid must be in accordance with with the CNPJ of the holder of the product regularization.**
- **In the documentation block, there is a list of documents to be attached to the process. The only document listed will be the extract of the Import License, however it will be an optional item that will not need to be attached.**
- **Click on the button** 

and, on the next screen, on the button 

- **If the request requires payment of a fee, a window will be displayed with information about the petition awaiting payment. To proceed, click on "Select payment".**



- **If you choose to make the payment later, the process will be available in the "Payment" tab on the sidebar of the home screen;**
- **When you click on "Select payment", a new screen will open showing the options payment: Generate Bill, which allows printing of the GRU for payment;**

and PagTesouro, which allows online payment via Pix or credit card (Mercado Pago or Picpay).

- **After bank compensation (up to 30 minutes for PagTesouro or up to 48 hours for GRU), the process will be registered and can be consulted in the tab "Processes" from the sidebar of the Solicita home screen.**

ATTENTION

The transaction protocol verification can be found at the link https://consultas.anvisa.gov.br/#/documentos/tecnicos/.

11. PETITIONS WITH MANDATORY PRE-SHIPMENT OF CARGO

For processes of products subject to special control that require authorization pre-shipment, unlike other consent requests, the importer will be responsible for a stage initial with COCIC for the purpose of Authorizing the shipment of goods:

- **The company must petition, as a secondary or tertiary petition, linked to the Import Authorization process, the subject code "70873 - Request for authorization to ship substances and products subject to special control of the Portaria SVS/MS no 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, E and F)".**
- **For the import of products under clinical research and for assistance programs, containing substances subject to Procedures 1 and 1A of RDC 81/2008, a request for boarding authorization will be made to COCIC, as described above. For other imported products intended for clinical research and assistance programs are exempt from pre-boarding.**
- **For reference standards exempt from Import Authorization, the company must file the primary petition requesting boarding authorization with the subject code "Request boarding authorization for standards of reference of controlled products exempt from Import Authorization".**

- **For this step, it is necessary to already have the LI and LPCO registered. The LPCO has a mandatory field "Petition subject code primary". This field must have selected the subject code of the petition that will be used for post-shipment of the goods, for their clearance.**

- **COCIC will express the authorization to board the registered LPCO through of the status "Import authorization issued"**

ATTENTION

The "Primary Petition Subject Code" field does not allow editing after the LPCO record. Wrong subject code protocols even in status of "Boarding authorization issued" will be rejected by code incorrect subject.

- **After the shipping authorization is granted and the cargo is shipped, the importer must complete the Anvisa Request, the process protocol for clearance of the**

merchandise, corresponding to the field informed in the LPCO for the Code primary import subject, which will be sent to PAFME for analysis of the clearance of goods.

- **If it is necessary to register a replacement Import License (LI) due to changes in the information present in the Import Authorization (AI) or in the text of the shipping authorization prior to shipping of the goods, it will be necessary to request a new boarding authorization. This procedure must be carried out through the subject code petition protocol no. 70873. However, for changes that do not affect these documents, it will not be a new boarding authorization is required. Simply proceed with boarding the loading and subsequent protocol of the process for clearance of the goods.**
- **It should be clarified that there is no longer an indication of a deadline for loading the cargo. after the shipping authorization has been granted (import authorization issued). However, the importer must pay attention to the deadline for the final statement in LI which is up to 150 days (60 days that the LI remains "for analysis" + 90 days which remains in automatic requirement), as provided for in Secex Ordinance No. 249 of 2023, since the IMPORT AUTHORIZATION situation ISSUED does not migrate to LI. Therefore, it is up to the importer to plan for ship the cargo in a timely manner for analysis and final conclusion of the claim by Anvisa, approval/rejection, within 150 days of registration of the LI. We suggest that the cargo be shipped and the import process be filed with Anvisa at least 30 days before the deadline of demonstration in LI.**

12. REPORT SHIPMENT OF CARGO

In LPCOs integrated with LI, the "Load" button will be made available to the importer inform the shipment of the cargo.

o When clicking this button, the system will display a modal to enter the data of the load. Attention, this confirmation cannot be undone!

o Information regarding the Bill of Lading document, such as: Mode of transport, Bill of lading number, Date/time of Boarding and Conditions of Carriage, must be provided in the fields specific to the LPCO model. This data must correspond to the information actual shipment of the cargo.

The following must be attached to the LPCO:

ÿ For water, air (non-scheduled flights) and road transport: signed and dated bill of lading proving the start of the loading of the cargo (drafts will not be accepted). In cases of “connections "air cargo" or transhipments or partial boarding, must be informed Date/time of receipt of cargo at origin, which must be attached all knowledge to PUCOMEX.

• Cases of dated and signed bill of lading, but with date after the effective shipment of the cargo, may be accepted, from the LPCO field have the correct and subsequent data the date of signing of the bill of lading.

ÿ For air transport, regular flights: with the evolution of the CCT, the document to be attached to the LPCO must be the extract of the CCT with proof of the actual shipment of the cargo.

If the importer does not know the time of shipment, he must inform 00:00h.

o Discrepancies between the information entered in this field and the attached document, except for that explained in the item above, as well as the absence of information on loading of the cargo, give rise to the summary rejection of the claim.

o For the Ministry of Health, entities linked to the SUS, import of radiopharmaceuticals, medical devices with a shelf life measured in hours and advanced therapy products, this field must be filled in with the draft date or, in cases where the draft is not available, the date of the draft must be informed. invoice. For radiopharmaceuticals and direct unloading of bulk materials, we recommend filling out of the shipping data as being Knowledge “ooooooooo”, and date of boarding as the date of the LPCO protocol. In cases where it is possible to edit the Cargo Shipment field, the date must be updated when the shipment is made loading of the cargo and presenting the valid Bill of Lading. The bill of lading to be attached, in this case it must be identified as draft. Attachments to original or non-negotiable bills of lading will follow the rules general field information and attached documents cited in the first two subitems of this topic (modals).

ÿ In cases of approved LPCO, there is no way to edit the shipment field. cargo. In this case, it is necessary to attach a signed letter to the LPCO by the Legal Representative of the importing company, indicating the effective date of the shipment of the cargo, in addition to the supporting document.

o Bill of lading correction letter: For tax purposes, any correction in the bill of lading must be made by means of a correction letter addressed by the issuer of the bill of lading to the customs authority at the place of unloading, which, if accepted, it will imply correction of the manifest (https://www.gov.br/receitafederal/pt-br/issues/customs-and-foreign-trade/manuals/clearance-of-import/topics-1/import-dispatch/instructional-documents-of-dispatch/bill of lading/letter of correction). Therefore, having need to correct the knowledge of the cargo shipped, should be presented, in addition to the correction letter, the corrected bill of lading and the field of loading the cargo in the updated LPCO.

Still regarding direct unloading of bulk cargo, the following clarifications are in order:

ÿ The bill of lading and the original invoice, due to the specific type of flow, do not are mandatory documents for initial procedural instruction. However, after 05 calendar days, counted from the protocol of the import process in Anvisa, the original Bill of Lading and Invoice must be added

to LPCO/PUCOMEX. If the shipping date may be changed, inform the date of bill of lading.

ÿ The CNPJ field of the storage facility, in this case, must be filled in with the number of the non-bonded warehouse that will receive the DDG cargo.

12.1 CCT (REGULAR FLIGHTS)

Coana Ordinance 127/2023, published on June 27, established the parameters of the Import Cargo and Transit Control System (CCT Import) and made public the implementation schedule of the respective system at customs airports.

The CCT system is available for access by Anvisa. In this way, the Agency already has the profile to evaluate the data on the shipment of cargo subject to health inspection entered by the importer directly into the system.

Based on the implemented evolution, importing companies, in the case of air transport, for regular flights, you must attach the CCT extract in the import process, as proof of the bill of lading on board. In the case of waterway and road transport the physical Knowledge (digitized) or the E-AWB (knowledge of boarding required for export and import customs clearance);

- The CCT extract presented must contain information necessary to prove of the shipment of the cargo, as well as the consignee's information.

The data that will be evaluated in the CCT extract are the same as those in the LPCO field. for cargo shipment information, and must be the same or later than the data on the Bill of lading.

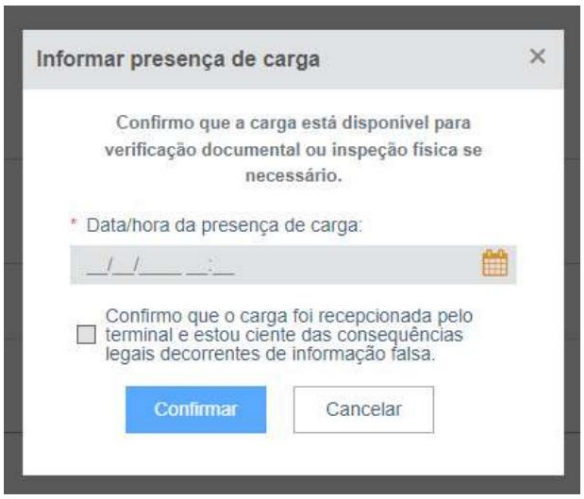
In cases of sending air cargo bills that can be verified in the CCT that the shipping data is different from what is indicated above, the shipping process import may be denied.

13. REPORT PRESENCE OF CARGO

In the LPCO integrated with LI, the “Load” button will be made available to the importer inform that the cargo is available for physical or documentary inspection by the consenting party (If applicable, case). Attention, this confirmation cannot be undone!

o When clicking this button the system will display a modal to enter the data of presence of the load.

o Whenever inspection of the merchandise is requested, the fee will no longer be charged. proof of docking. Anvisa will request that the field be filled in specific information on the presence of cargo, correlating it to the data of the CNPJ of the Customs Warehouse with valid Operating Authorization or Special Authorization, as applicable.



The importer must report the presence of cargo whenever he is aware of it. information.

• If the LPCO has a completed analysis status (approved/rejected), it will not it is necessary to present this information.

• LPCOs in the red parameterization channel must have the information of shipment of the cargo filled by the importer.

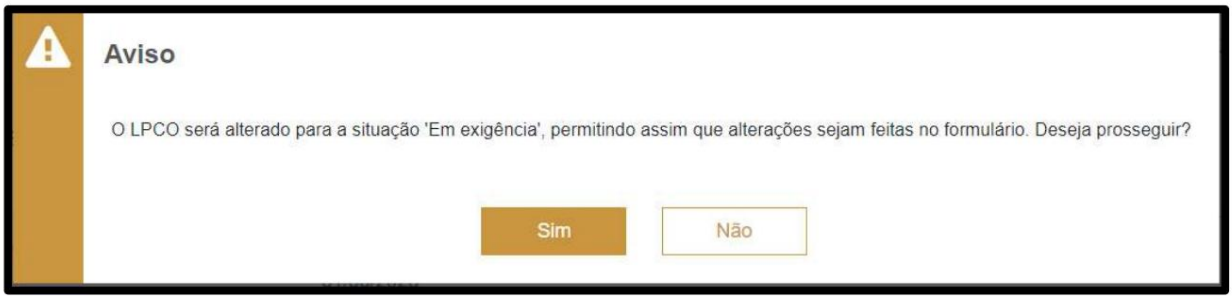
• The consenting server may request information about the presence of cargo, even when LPCO is parameterized in yellow channel.

14. EDITING THE LPCO BEFORE ANVISA ANALYSIS

The LPCO can be changed by the importer before the start of the Anvisa analysis by means of editing the fields:

• **The importer must click on “Change Status” > “Edit LPCO”.**

• **The LPCO status will be changed to “In Demand”**



• **Click “OK” and the fields that can be edited will be made available.**

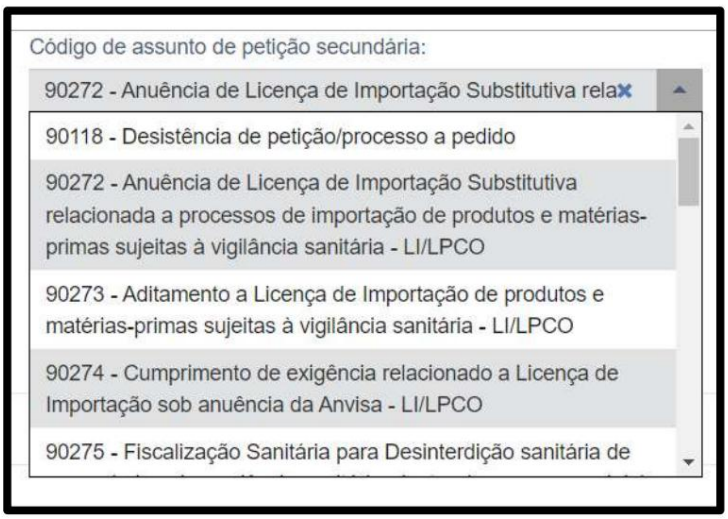
• **Change the relevant information in the LPCO fields.**

• **The importer must include the “Secondary Petition Subject Code” field and inform you. The following subject codes apply:**

  - **90273 – Amendment to the Import License for products and materials raw materials subject to health surveillance - LI/LPCO;**
  - **90428 - Request for prioritization of LI/LPCO analysis**

o 90272 - Approval of Replacement Import License related to import processes of products and raw materials subject to health surveillance - LI/LPCO

901118 - Withdrawal of petition/process on request



Then click on "Respond to requirement".

• When clicking on "Respond to requirement", in the "Respond to compliance with requirement" field, Requirement" the field(s) that were edited in the LPCO must be informed.

- **The LPCO status will be changed to “Requirement Response”. The importer must await a response from Anvisa regarding the request. The form LPCO allows for new editing if necessary.**

ATTENTION

Any changes to the LPCO form, even before the start of the analysis by Anvisa, give rise to the filing of the petition at Solicita – Anvisa. They are applicable to this situation the following secondary petition subjects: Amendment, Analysis Prioritization and Substitute LI and Analysis Withdrawal.

Only after the protocol is filed with Anvisa is it possible for the Agency to analyze the application.

- **Withdrawal of analysis**
  - **The company may withdraw from analyzing the petition before the analysis begins by Anvisa. In this case, you must file the petition with the Request secondary subject code 90118 - Withdrawal of petition/case on request, in addition to following the flow described for secondary petitions. Must justification for withdrawal must be attached to the LPCO. Withdrawal may only be requested if the process has not yet been analyzed by Anvisa and with due protocol at the Agency. The LPCO will remain in the “For Analysis".**

15. PARAMETERIZATION STATUS

After the distribution of the process for analysis by Anvisa, they will be revealed to the importer the parameterization channels in which the processes were classified.

The disclosure of the parameterization channel to the importer will only occur after informing the loading of cargo at LPCO.

Processes classified in the Green Channel will be automatically approved by the system:

ATTENTION

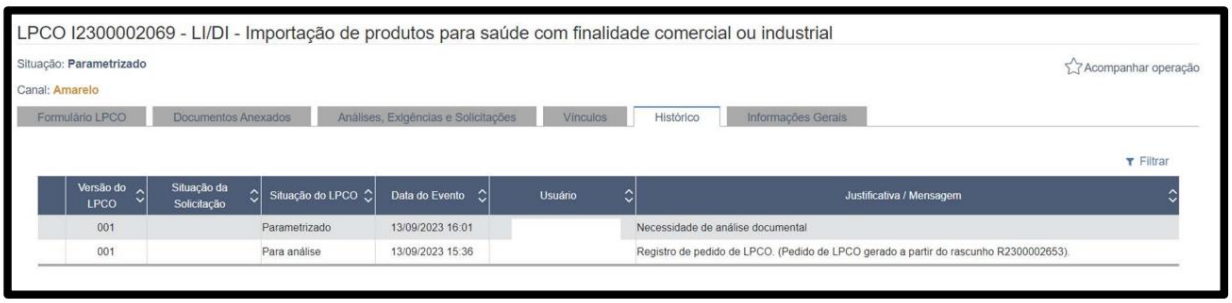
For automatic deferral in the green channel, it is necessary that the shipment of the cargo is reported. In cases where this is not the case, information, the process will have the status "Parameterized" and will not proceed to automatic deferral. It is not necessary to edit the LPCO, but only inform the shipment of the cargo.

ATTENTION

For import processes of finished biological products or biological products in their primary packaging, the need to request the release of a Custody and Responsibility Term after cargo clearance remains, in compliance with RDC 669/2022 and RDC 58/2010.

To release the Custody and Responsibility Term for the aforementioned biological products, complete the secondary petition protocol and present documentation in accordance with art. 7 of RDC 669/2022 and a satisfactory analytical report issued by INCQS (for Procedure 2).

Processes classified in the Yellow Channel will be presented with the following status:



Processes classified in the Red Channel will be presented with the following status:

16. PROTOCOL OF SECONDARY PETITIONS ON THE SINGLE PORTAL

Like primary petitions, secondary petitions must be filed with the Anvisa, through Solicita, and the respective changes must be made on the Single Portal of Foreign Trade.

All modifications will be displayed in the "History" tab, in the "FROM-TO" format.

ATTENTION

The "Under Analysis" status does not allow the importer to edit the LPCO.

16.1 SECONDARY PETITIONS FILED DURING THE ANALYSIS OF THE PLEA

During the analysis of the import process, the import protocol may be required. secondary petitions, such as: Compliance with requirement, Amendment, Release of Term Product Custody and Liability and Substitute LI.

16.1.1 Compliance with requirement

- **For LPCOs that have a requirement issued by Anvisa and that are still no response, when opening the form, there will be a notification box with the highlighted requirement.**

- **The LPCO form will be unlocked for editing.**

ATTENTION

The importer must change the "Secondary Petition Subject Code" field with the specific subject of requirement compliance.

- **After making any changes or attaching documents that have been requested, click on "Change status" >> "Respond to requirement".**

• Enter the response to comply with the requirement and click confirm.

• This step must be carried out by the user.

• The requirement response stage in the LPCO is subsequent to the petition filing secondary requirement compliance in the Solicita system.

• The analysis of compliance with the requirement will only be carried out after receipt of the compliance petition filed in the Solicita system.

• After changing the LPCO, it will have the status “Requirement response”.

16.1.2 Substitute LI

• The importer must edit the LPCO in at least two fields of the form (“LI Number” and “Secondary Petition Subject Code”).

16.1.3 Amendment and Release of Product Custody and Liability Agreement

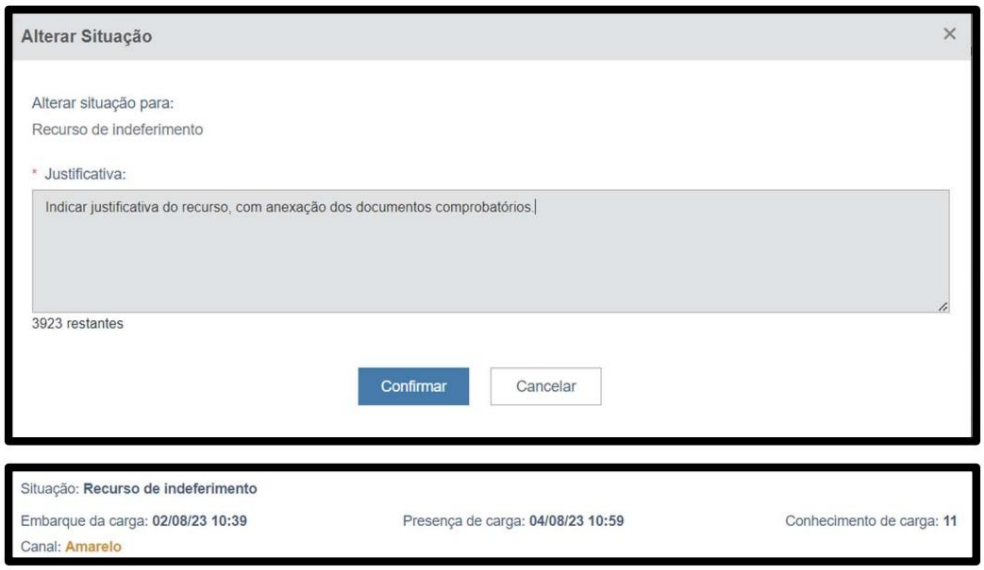
o The importer must edit the LPCO in order to inform the “Subject Code of secondary petition”, attach the applicable documentation.

16.2 SECONDARY PETITIONS AFTER REJECTION OF THE CLAIM

16.2.1 Administrative Appeal

• The importer must access the LPCO, click on “Change status” > “Appeal” of rejection”.

- **The system will open a modal in which the importer must enter the justification for the resource and confirm.**



- **The LPCO status is changed to "Appeal for Rejection".**
- **It will be up to the importer to file the secondary petition for "Appeal" administrative – LI/LPCO" in the Solicita – Anvisa system, adding the applicable documentation supporting the appeal and await technical analysis.**

ATTENTION

The importer must attach to the Application the appeal request, formulated by written, containing the formulation of the request with the exposition of the facts and their fundamentals, under the terms of RDC nº 266/2019!

16.2.2 Addendum and Request for Cargo Release

- **Situations of addition (Example: destination of prohibited cargo) or request for cargo release, with maintenance of the LPCO rejection (Example: irregularity corrected in new import process), editing is not possible do LPCO.**
- **The importer must file the secondary petition for "Addendum" the Import License for products and raw materials subject to surveillance sanitary inspection - LI/LPCO" or one of the subjects related to "Sanitary inspection for the Removal of Interdiction of Goods Under Health Pending" in the Solicita system –**

Anvisa, adding the applicable documentation that supports the lifting of the ban and await technical analysis.

16.3 SECONDARY PETITIONS AFTER APPROVAL OF THE CLAIM

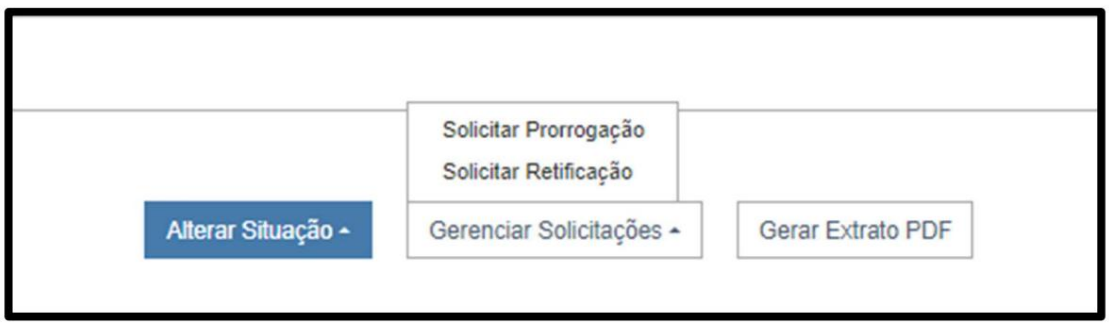
16.3.1 Extension of LPCO and LI term

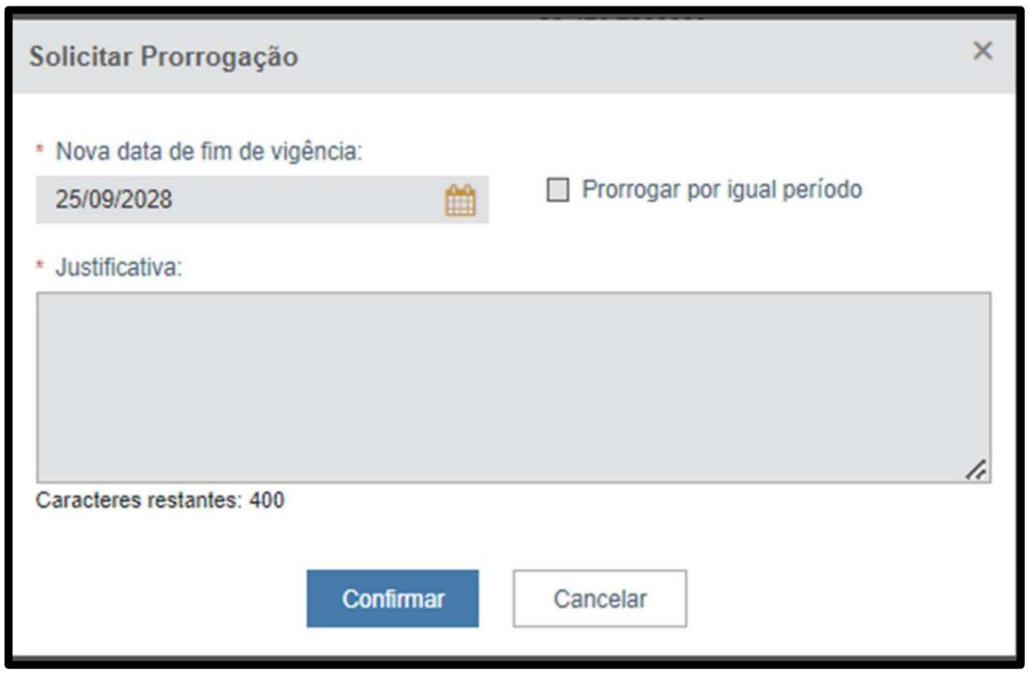
- **As long as the rules of Secex Ordinance No. 23/2011 are respected, it is possible grant an extension of the LI term, at the company's request. In general, as stated in art. 25 of Secex Ordinance no. 23/2011, the term for binding from an LI to an Import Declaration (DI) will be up to 90 (ninety) days, counted from the date following the end of the period referred to in art. 24 (shipment deadline). In the event of there being more than one approval for the LI, the period of 90 days will be counted independently for each consent, being LI is considered expired when the term that expires first has expired. Requests for extension of the validity of the LI for dispatch must be presented, until the due date, with justification, directly to the body whose approval the validity refer to. A single extension of the validity of the LI may be granted for dispatch, the maximum term of which will be identical to the original. This extension of**

This deadline serves to ensure that the company does not lose the LI already registered before customs clearance.

customs and be required to register a new LI.

- **The validity of the Anvisa LPCO is 5 years, non-extendable. Therefore, Request Extension functionality refers to LI and not LPCO. The request for extension must also be made by means of a petition secondary registered in Solicita, and the consenting party's action will take place directly in Siscomex.**
- **The importer must click on Manage Requests > Request Extension > Insert new date and justification.**





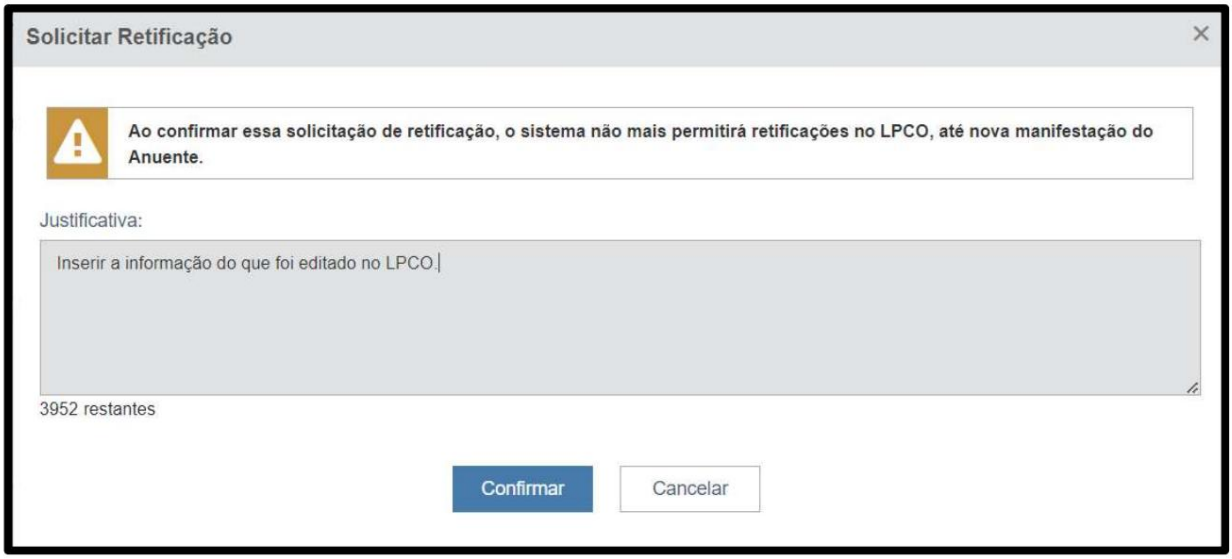
16.3.2 Rectification (for substitute LI, for appeal of deferral, extension of LI term granted, Post-shipment Amendment or other secondary requests)

ÿ The LI Term Extension can only be requested after the LI has been granted.

• On the Single Portal, the importer must request the rectification of the LPCO by clicking in Manage Requests > Request Rectification.

• The LPCO form fields will be available for editing (to change the LI number, new Secondary Petition Subject Code or others fields). After editing the fields, click on the "Request Rectification" button at the end of the page.

- **When requesting the correction, it is up to the importer to provide the justification for the edit.**



- **After rectification of the LPCO, the status is changed to "Rectification: For analysis".**

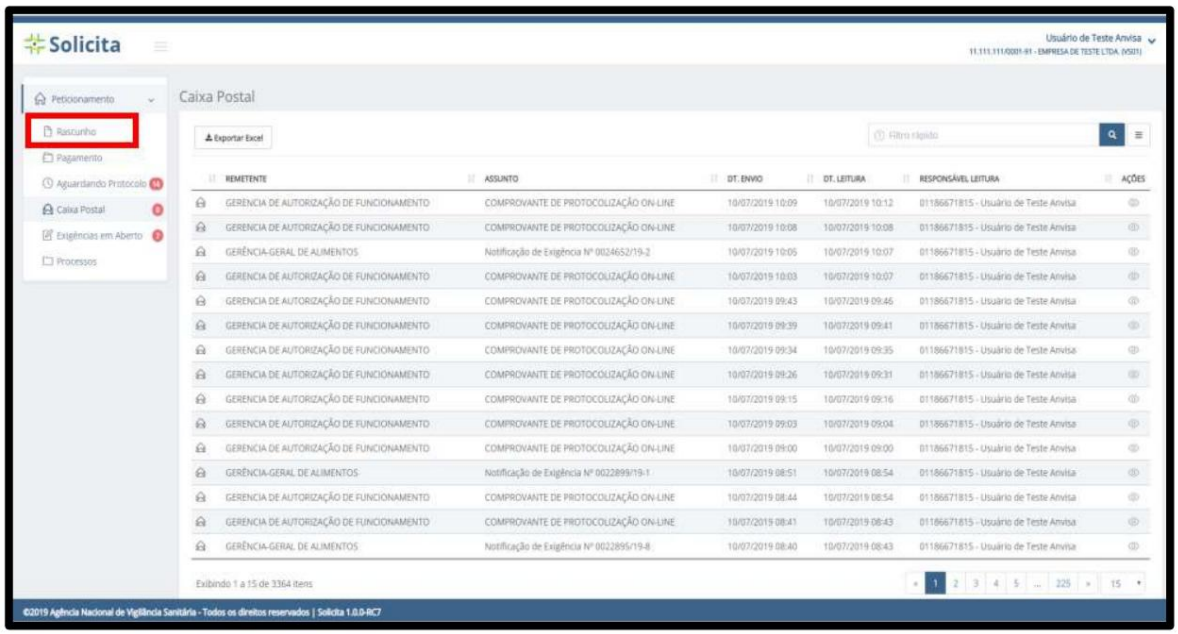
17. PROTOCOL FOR SECONDARY PETITIONS IN SOLICITA - ANVISA

As with the initial analysis, the analysis of the change depends on the protocol of the petition in the Solicita na Anvisa system. For analysis of the changes, the following must be filed: secondary petition with the corresponding subject.

The analysis of secondary petitions will only be carried out after receipt of the petition. registered in Solicita.

Secondary petitions in Solicita are filed as "Petition linked to a existing process", as follows:

- **Access Solicita through the address solicita.anvisa.gov.br and log in with email and password data;**
- **There are two alternatives for creating a secondary petition:**
  - **From the Draft tab.**
    - **ÿ Click on the "Draft" tab on the sidebar of the home screen;**



ÿ Click on the “New” button and click on “Petition linked to a process”

already existing”

ÿ 

ÿ When opening the form, click on the search icon in the “Petition” field.
origin”, to identify the process to which the petition will be linked. The
search for the original process can be carried out using the process number
process, subject code or record.

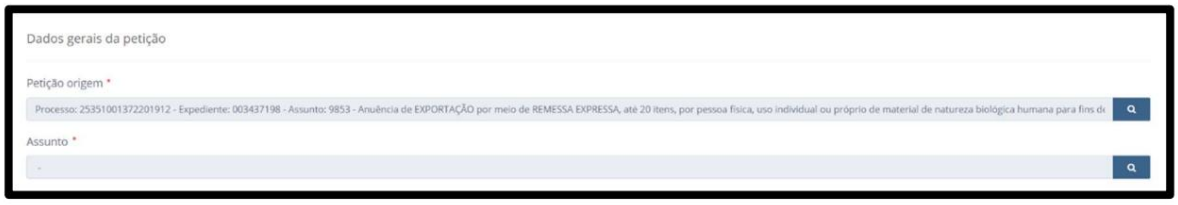
ÿ When you click on search, the list of process(es) will appear, where the
user must click on the blue arrow in front of the subject description to
opening of the electronic form.

o Through the Processes tab.

ÿ Click on the “Processes” tab on the sidebar of the home page and then on folder icon of the process to which you want to link the secondary petition.

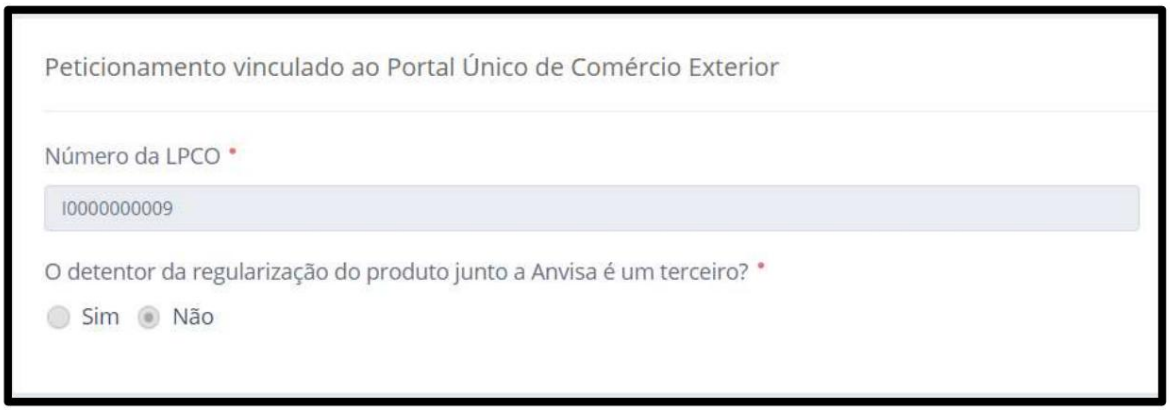
ÿ With this, there will be the option to create the secondary Petition from within the existing process.

ÿ The “Original Petition” field is filled in automatically.



ÿ Click on the search button in the “Subject” field and search for the subject of secondary petition desired.

ÿ **Click on the blue arrow in front of the subject description to open the form.**



ATTENTION

For the replacement LI petition, the “LPCO Number” field will be blocked and the “Import License Number” field will be editable. For other matters of secondary petitions, all fields will be locked for editing.

18. LPCO MODELS

LPCO models are:

- **I00044 – Medical devices**

  the Model applicable to all medical devices, subject to or exempt from regularization at Anvisa/SNVS.

- **I00045 – Cosmetics and hygiene products**

  the Model applicable to all cosmetics and hygiene products, capable or exempt from regularization at Anvisa/SNVS.

- **I00046 – Food**

  the Model applicable to all foods, whether subject to or exempt from regularization at Anvisa/SNVS.

- **I00047 – Sanitizing agents**

  the Model applicable to all sanitizing agents, subject to or exempt from regularization at Anvisa/SNVS.

- **I00048 – Medicines**

  the Model applicable to all medicines, subject to or exempt from regularization at Anvisa/SNVS and advanced therapies.

- **I00049 – Products subject to special control**

  the Model applicable to all substances or medicinal products subject to special control of Ordinance No. 344/1998.

  o Does not apply to medical devices, including those for diagnostic purposes. vitro, which must be linked to LPCO I00044.

- **I00050 – Other goods subject to sanitary intervention**

the Model applicable to: Reference standard; Human biological sample; Miscellaneous products, as per Procedure 5.6 of Chapter XXXIX of Annex of RDC 81/2008; Human cells and tissues;

o Does not apply to reference standards for substances or drugs subject to special control of Ordinance No. 344/1998, which must be linked to the LPCO model I00049.

19. LPCO STATUS APPLICABLE TO ANVISA PROCESSES

For the integration of LPCO into LI, new statuses were made available for LPCO, as follows:

Situation	Application
Import authorization issued	Processes with boarding authorization issued by the competent area of Anvisa.
LI/LPCO granted	LPCO/LI granted
LI granted	Only the LI was granted
Judicially granted	LPCO/LI granted by court order in processes in which Anvisa is a defendant
Under analysis	LPCO under analysis by Anvisa
In demand	LPCO with notice of demand issued.
Under inspection/Physical inspection	LPCO is under inspection by Anvisa
Rejected	LPCO/LI rejected
Appeal for dismissal	Appeal pending Anvisa analysis
Requirement response	LPCO awaits analysis of compliance with requirement by Anvisa
For analysis	LPCO forwarded for analysis by Anvisa
Parameterized	LPCO parameterized in channel oversight.

The only statuses that communicate between LPCO and LI are the completion statuses of analysis, that is, “Approved” and “Rejected”. In the others, the LI will not have its status changed.

In situations where there is some health issue to be fulfilled after the clearance of cargo, such as, for example, discharge of custody and liability terms, return of goods after a fair or event, temporary admission, post-addition deferral already foreseen, among others, the LI will be deferred and the LPCO will be placed in the situation “On demand”. This situation will only change after the importer completes the protocol. secondary petition in Solicita and attach the documentation in LPCO.

20. APPLICATION FOR IMPORT TAX EXEMPTION

The request for a statement from Anvisa for recognition regarding the nature the product is a medical-hospital material, for the purpose of request, by the importer, exemption from import tax, under the terms of article 141 of Decree No. 6,759, of February 5, 2009, must be filed as a secondary petition to process 56

of import, immediately after the initial petition is filed, so that when distributing the import process for analysis, the insertion of the standard text in the opinion of the LPCO and LI regarding such recognition.

Only secondary protocols of this nature will be accepted in processes of import of medical device subject codes. Requests for tax exemption through other methods such as SEI, email or Contact Us.

The procedure to be adopted for editing the LPCO is described in item 15 of this Manual.

21. ANALYSIS PRIORITIZATION CRITERIA

The LPCO "Prioritization Criteria" field should only be selected if the import fits into any of the options described by the aforementioned field with the attachment of the document proving priority. They are:

Priority situations	Importer	Criteria to be met
Secondary petitions for previously analyzed processes, such as compliance with requirements, release of Custody Term, Substitute LI and administrative appeal, as they provide continuity to the analysis of the process and add to the institutional analysis time;	Any company.	• Secondary petition, resulting from a primary petition already analyzed, filed in the Solicita system and amended/ edited in the LPCO. • Secondary petitions with the subjects mentioned in the first column filed prior to the analysis of the primary petition will be summarily rejected. The replacement LI may be filed before the analysis of primary petition, according to the importer's needs, but will not be prioritized because it is an initial demand. • Applies only to finished products. Must fully meet two conditions: • Public or private entity linked to SUS https://
Direct import by the Ministry of Health or entities linked to it SUS, of finished products, to serve public health programs, provided that the link is proven	• Ministry of Health; • Health Departments (State or Municipal); • Public or private entities linked to the SUS; • Private institutions, with or without profit, providing complementary health care within the scope of the Unified Health System.	www.gov.br/saude/pt-br/composicao/ entidades-vinculadas; OR to the • Private institutions complementary to the SUS -

		Present a document proving that the health unit serves the SUS; AND • Present proof of affiliation to one of the programs listed in the MS link - https://www.gov.br/saude/pt-br/acesso-a-informacao/acoes-e-programs
Importation of products that require storage conditions at temperatures below minus 20°C, as well as biological medicines subject to proof of temperature monitoring from their origin to storage by the importer and biological samples	Any company.	• Indicate in the LPCO fields "Transportation conditions" /" Storage conditions" the transport/ storage conditions at a temperature of -20°C, as per product regulation at Anvisa/SNVS; or • Product being a finished biological medicine or in its primary packaging; or • Product being a biological sample.
Importation of products with a shelf life of less than 60 days, food and other perishable products	Any company.	• Present a quality control report, technical sheet or other document, issued by the product manufacturer, indicating the product's expiration date for validation of validity of less than 60 days, counting from the date of the import process protocol at Anvisa.
Import of products by road transport whose dispatch URF is a border enclosure	Any company	• Inform in the LI and in the LPCO a URF dispatch that is mandatory as being border. • The importer may petition for the import process without all the mandatory documents, however, he/she must petition in a single act, within 5 calendar days (and not business days), counted from the protocol of the import process in Anvisa, the completion of the documentation by means of a petition for amendment to the import process. • If there is no attachment of the complementary documentation in the Single Portal with the respective secondary petition for amendment in Solicita/Anvisa, within the period of five calendar days mentioned above,

		the LI and respective LPCO will be rejected. **• These are documents that can be presented later: bill of lading, proof of sterility and report.**
Importing product for research [a] clinical, compassionate use and access and expanded, supply of post-study medications	**Any company**	**• Copy of the Special Communication (CE), Specific Special Communication (CEE) or Document for Importation of Product(s) under investigation from the Clinical Drug Development Dossier (DDCM).**
Importation intended for a specific patient, carried out by an individual or legal entity, whose medical report attests to their health status	**Any company**	**• Present a medical report in the patient's name indicating the need to import the product.**
Import of ready-to-use radiopharmaceuticals	**Any company**	**• Only for non-lyophilized ready-to-use products. • Products classified as radiopharmaceuticals by Anvisa.** **NOTE: Freeze-dried products have a shelf life of 12 months, so they are not prioritized.**
Importation of products at risk of shortage in the market, according to the opinion of the competent technical area of Anvisa	**Any company**	**• Present an opinion from the or competent technical area of Anvisa regarding the market shortage issued by GGFIS, or • Prior statement from Anvisa that such product falls under this priority.**
Importation of specific food products, on the occasion of religious festivals listed in the calendar country official	**Any company**	**• Present a document proving that the event took place (example: folder).**
Import of large-volume cargo that compromises the operation of the customs area, upon formal request from the technical manager of the area, clarifying the reasons	**Any company;** **Direct unloading of bulk cargo**	**• Present a statement from the technical manager of the customs area indicating the reasons for compromising the operation of the area. • In the case of a demand for direct unloading of bulk cargo, a statement from the** technical manager of the customs area **indicating** the reasons operation of the area for compromising the

		technical manager of the customs area for controlling the unloading of the operation, indicating the reasons for compromising the operation of the area and the importer's health license.
Import of radioactive sources or microspheres	Any company	• Inform the product's regularization number as being a radioactive source or microsphere.
Import of products intended for Partnership for Development Productive, as long as the partnership is proven	Any company;	• Present proof of the current PDP for importing the product. Preferably the website address to check the validity of the PDP.
Import for Scientific or Technological Research, Import for Scientific or Technological Research Involving Human Beings, Importation of human biological samples intended for research in general, Importation of substances, plants, medicines and products subject to special control as set out in Ordinance SVS/MS No. 344 of 1998, and its updates, intended for scientific or technological research and research involving human beings	Researchers or Institutions Scientific, Technological and Innovation not accredited by CNPq	• Present the documentation listed in RDC 172/2017.
Import by Certified Company Integrated OAS	Certified companies OEA-Integrated Anvisa	Comply with the requirements of RDC 845/2024.
Importation of Products to address public health emergencies of national/ international importance declared by the Ministry of Health	Ministry of Health Importers or holding product regularization.	- Vaccines and medicines imported by the Ministry of Health, intended to face the public health emergency of national/ international importance published at https://www.gov.br/saude/pt-br/ composicao/svsa/coes; - Diagnostic kits - Disease-specific IVD medical device kits related to the public health emergency of national/ international importance (published at https://www.gov.br/saude/pt-br/ composicao/svsa/coes) in:

		duly regularized with Anvisa, whose import processes are carried out by the Ministry of Health, by importers or holders of product regularization.

ATTENTION

There must be a protocol for the secondary petition with the subject code "90428 - Request for prioritization of LPCO analysis", immediately after the petition is filed primary. Analysis prioritization will be forwarded for distribution when there is a protocol for the specific petition in Solicita.

22. CONSULTING PROCESSES AT ANVISA

Consultation of registered processes can be carried out by the responsible company by filing a petition in Solicita itself, in the "Processes" tab on the home screen. In addition, it is It is possible to carry out a public consultation of the basic information of these requests through the system of Anvisa consultations, available at https://consultas.anvisa.gov.br/#/documentos/tecnicos/.

The status of petitions filed in accordance with the procedures in this Manual will be "Added to the process" from the moment it is filed.

Monitoring of the analysis must be carried out through Siscomex/Portal Único.

We highlight that checking the progress of the process through the LPCO or LI can be carried out by importers or their legal representatives registered with the Federal Revenue Service from Brazil.

22.1 CONSULTATION OF THE IMPORT PROCESS DISTRIBUTION PANEL

Information on the date of distribution of import processes for analysis filed through the Siscomex modality (LI with LPCO) can be obtained through from the Process Analysis Queue Panel – LPCO Import available at: https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoes-analytics/import, according to willing that News published in:

https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2023/anvisa-publica-painel-com-import-process-analysis-queue.

The tool allows monitoring of the distribution of import processes, being possible to view the entry date of each process and the date of its distribution to analysis. This way, it is possible to make a prediction of how many days the filed processes will take wait until they are analyzed.

The panel containing the queues allows you to consult the primary petitions awaiting distribution for analysis and is divided by approval post, which are: the Approval Post Import of Medicines (PAFME); the Food Import Authorization Post, Cosmetics, Sanitizing Products and Others (PAFAL, internally divided into PAFCO); and the Import Consent for Health Products (PAFPS).

In the “post-boarding” tab, the search must be carried out using the secondary petition file. It is important to note that this queue only contains processes that have been boarded. has already been authorized.

Processes that have protocols or priority situations will be displayed in the same queues. However, the processing for priority distribution will be carried out internally by area. In these cases, the order of distribution of the queue will change.

The distribution date shown on the panel refers to the time the process was sent. for analysis. Monitoring of the analysis can be carried out through the Siscomex/Single Foreign Trade Portal system.

It is important to note that after distribution for analysis, the responsible team has a deadline to express themselves, in accordance with RDC 743, of August 10, 2022, which establishes the risk classification and deadlines for responding to requests for public release acts responsibility of Anvisa.

22.2 CONSULTING THE TRANSACTION AT ANVISA

The status of a transaction can be verified in the System Requests, as explained in item 9, or can be consulted at https://consultas.anvisa.gov.br/#/documentos/tecnicos/, entering the transaction data in specific field.

23. CONSULT THE PROGRESS OF LPCO ANALYSES ON THE SINGLE PORTAL

Access the Single Foreign Trade Portal at the address https://portalunico.siscomex.gov.br/portal/, enter with digital certificate and select the module import (imp).

Click on “LPCO” >> “Consult”. Search by LPCO number or any of the filters available and click on Consultar

23.1 NEW LPCO SEARCH CRITERIA

The importer may consult the LPCO using the channels as search criteria “Green”, “Yellow” or “Red”, as well as boarding and presence information. load.

24. SUBJECT CODES

The subject code of a petition to be filed with Anvisa constitutes the combination of a numerical code, linked to a subject descriptor of interest and the respective generating fact of the Inspection Fee recommended by RDC nº 222/2006.

Anvisa provides a system for consulting subject codes, with the values to be paid and freely accessible documentary instructions for interested parties - https://www.gov.br/anvisa/pt-br/sistemas/assuntos-de-peticao.

The list of available subject codes is described below:

24.1 PRIMARY PETITIONS

Mandatory procedural instruction documents and related rules can be consulted at

https://consultas.anvisa.gov.br/#/consultadeassuntos/

Model of LPCO	Code of the Subject	Subject
I00049	90223	Anvisa approval for the import of cannabis-derived products for the care of patients previously registered with Anvisa, whether or not linked to the obligation of judicial compliance, in LI/LPCO
I00050	90261	Anvisa approval for import of standard, material or reference substance, except containing controlled substance, by legal entity, for proficiency testing or Quality Control, in LI/LPCO
I00044	90263	Anvisa approval for the import of medical devices or IVD, by private health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00046	90264	Anvisa approval for the import of food, by public health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00045	90265	Anvisa approval for the import of cosmetics, by public health units, in the finished product stage, for their exclusive use, in LI/ LPCO
I00045ÿ	90266	Anvisa approval for the import of up to 10 items of cosmetics, hygiene products and perfumes, procedure 5.2, by a legal entity for industrial or commercial purposes
I00045ÿ	90267	Anvisa approval for the import of up to 11 to 20 items of cosmetics, hygiene products and perfumes, procedure 5.2, per legal entity for industrial or commercial purposes
I00045ÿ	90268	Anvisa approval for the import of 21 to 30 items of cosmetics, hygiene products and perfumes, procedure 5.2, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00045ÿ	90269	Anvisa approval for the import of 31 to 50 items of cosmetics, hygiene products and perfumes, procedure 5.2, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00045ÿ	90270	Anvisa approval for the import of 51 to 100 items of cosmetics, hygiene products and perfumes, procedure 5.2, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90271	Anvisa approval for import of advanced therapy product intended for expanded access, compassionate use and post-study supply programs, in LI/LPCO

I00048ÿ	90291	Anvisa's Import Authorization for up to 10 items of advanced therapy products, procedure 5.3, per legal entity, for industrial or commercial purposes, in LI/LPCO
I00048	90292	Anvisa approval for importing advanced therapy products under clinical research, in LI/LPCO
I00050	90297	Anvisa approval for the import of up to 20 human biological samples for laboratory diagnostic purposes, related to LI/LPCO
I00050	90298	Anvisa approval for the import of 21 to 50 human biological samples for laboratory diagnostic purposes, related to LI/LPCO
I00047	90301	Anvisa approval for the import of up to 10 items of sanitizing products, procedure 5.4, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00047	90302	Anvisa approval for the import of up to 11 to 20 items of sanitizing products, procedure 5.4, per legal entity for industrial or commercial purposes, in LI/LPCO
I00047	90303	Anvisa approval for the import of 21 to 30 items of sanitizing products, procedure 5.4, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00047	90304	Anvisa approval for the import of 31 to 50 items of sanitizing products, procedure 5.4, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00047	90305	Anvisa approval for the import of 51 to 100 items of sanitizing products, procedure 5.4, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00046	90306	Anvisa approval for the import of up to 10 food items, procedure 5.1, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00046	90307	Anvisa approval for the import of up to 11 to 20 food items, procedure 5.1, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00046	90308	Anvisa approval for the import of 21 to 30 food items, procedure 5.1, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00046	90309	Anvisa approval for the import of 31 to 50 food items, procedure 5.1, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00046	90310	Anvisa approval for the import of 51 to 100 food items, procedure 5.1, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00049	90311	Anvisa Import Authorization for up to 10 items of medicines and substances subject to special control,

		except reference standards, of procedure 1 or 1A, by legal entity for industrial or commercial purposes, in post-shipment LI/ LPCO
I00049	**90312**	**Anvisa Import Authorization, of 11 to 20 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by legal entity for industrial or commercial purposes, in LI/LPCO post-shipment**
I00049	**90313**	**Anvisa Import Authorization, of 21 to 30 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by legal entity for industrial or commercial purposes, in LI/LPCO post-shipment**
I00049	**90314**	**Anvisa Import Authorization, of 31 to 50 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by legal entity for industrial or commercial purposes, in LI/LPCO post-shipment**
I00049	**90315**	**Anvisa Import Authorization, of 51 to 100 items of medicines and substances subject to special control, except reference standards, of procedure 1 or 1A, by legal entity for industrial or commercial purposes, in LI/LPCO post-shipment**
I00048ÿ	**90316**	**Anvisa's authorization to import up to 10 radiopharmaceutical items and raw materials that comprise them, according to procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO**
I00048ÿ	**90317**	**Anvisa's Import Authorization for up to 11 to 20 items of radiopharmaceuticals and raw materials that comprise them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00048ÿ	**90318**	**Anvisa's Import Authorization for up to 21 to 30 items of radiopharmaceuticals and raw materials that comprise them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00048ÿ	**90319**	**Anvisa's Import Authorization for up to 31 to 50 items of radiopharmaceuticals and raw materials that comprise them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00048ÿ	**90320**	**Anvisa's Import Authorization for up to 51 to 100 items of radiopharmaceuticals and raw materials that compose them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00049	**90321**	**Anvisa Authorization for Importation of up to 10 items of medicines and substances that compose them, subject to special control, procedure 3, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00049	**90322**	**Anvisa Import Authorization for 11 to 20 items of medicines and substances that compose them, subject to**

		special control, procedure 3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00049	90323	Anvisa Approval for Importation of 21 to 30 items of medicines and substances that compose them, subject to special control, procedure 3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00049	90324	Anvisa Approval for Importation of 31 to 50 items of medicines and substances that compose them, subject to special control, procedure 3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00049	90325	Anvisa Approval for Importation of 51 to 100 items of medicines and substances that compose them, subject to special control, procedure 3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90326	Anvisa Authorization for Importation of up to 10 items of medical devices, procedure 4, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90327	Anvisa Authorization for Importation of 11 to 20 items of medical devices, procedure 4 per legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90328	Anvisa Authorization for Importation of 21 to 30 items of medical devices, procedure 4 per legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90329	Anvisa Authorization for Importation of 31 to 50 items of medical devices, procedure 4, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90330	Anvisa Authorization for Importation of 51 to 100 items of medical devices, procedure 4 per legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90331	Anvisa approval for the import of up to 10 items of medicines and raw materials that comprise them, from procedure 5.3, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90332	Anvisa Approval for Importation of 11 to 20 items of medicines and raw materials that compose them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90333	Anvisa Approval for Importation of 21 to 30 items of medicines and raw materials that compose them, from procedure 5.3, by legal entity, for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90334	Anvisa Approval for Importation of 31 to 50 items of medicines and raw materials that compose them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90335	Anvisa Authorization for Importation of 51 to 100 items of medicines and raw materials that compose them, from procedure 5.3, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90336	Anvisa Authorization for Importation of up to 10 items of IVD medical devices, including raw materials, of procedure 5.5, by legal entity for industrial or commercial purposes, in LI/LPCO

I00044	90337	Anvisa Authorization for Importation of 11 to 20 items of IVD medical devices, including raw materials, of procedure 5.5, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90338	Anvisa Approval for Import of 21 to 30 items of IVD medical devices, including raw materials, of procedure 5.5, by legal entity for industrial or commercial purposes, in LI/LPCO
I00044	90339	Anvisa Approval for Import of 31 to 50 items of IVD medical devices, including raw materials, of procedure 5.5, by legal entity, for industrial or commercial purposes, in LI/LPCO
I00044	90340	Anvisa Authorization for Importation of 51 to 100 items of IVD medical devices, including raw materials, of procedure 5.5, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048, I00049	90347	Anvisa's approval for the import of raw materials, non-controlled drugs or products containing substances subject to special control under Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), not regularized in the SNVS, for testing purposes, in LI/LPCO
I00048, I00049	90349	Anvisa Approval for Importation of International Donation of Medicines, in LI/LPCO
I00048	90350	Anvisa Authorization for Importation of Medicines under or for Monitoring of Clinical Research, except procedures 1, 1A and 3, in LI/LPCO
I00044	90351	Anvisa Approval for Importation of Medical Devices or IVD, Under Clinical Research, in LI/LPCO
I00048, I00049	90353	Anvisa approval for the import of medicines intended for initial supply and replacement of infirmary, pharmacy or medical kit on board international means of transport, in LI/LPCO
I00044	90354	Anvisa approval for the import of medical devices or IVD, intended for initial supply and replacement of infirmary, pharmacy or medical kit on board international means of transport, in LI/LPCO
I00047	90355	Anvisa approval for the import of sanitizing products intended for initial supply and replacement of infirmary, pharmacy or medical kit on board international means of transport, in LI/LPCO
I00048, I00049	90356	Anvisa approval for the import of medicines, by public health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00044	90358	Anvisa import approval for the return of medical devices or IVD, after the provision of service, repair, repairs or restoration, subject to temporary export, in LI/LPCO
I00044	90361	Anvisa approval for the import of non-regularized medical devices or IVDs intended for fairs or events, in LI/LPCO
I00050	90363	Anvisa Import Authorization for up to 10 items of baby bottles, bottle nipples, pacifiers, teethers, procedure 5.6, by legal entity for industrial or commercial purposes, in LI/LPCO

I00050	**90364**	**Anvisa Import Authorization for 11 to 20 items of baby bottles, bottle nipples, pacifiers, teethers, procedure 5.6, by legal entity for industrial or commercial purposes, in LI/LPCO**
I00050	**90365**	**Anvisa Import Authorization for 21 to 30 items of baby bottles, bottle nipples, pacifiers, teethers, procedure 5.6, by legal entities for industrial or commercial purposes, in LI/LPCO**
I00050	**90366**	**Anvisa Import Authorization for 31 to 50 items of baby bottles, bottle nipples, pacifiers, teethers, procedure 5.6, by legal entities for industrial or commercial purposes, in LI/LPCO**
I00050	**90367**	**Anvisa Import Authorization for 51 to 100 items of baby bottles, bottle nipples, pacifiers, teethers, procedure 5.6, by legal entities for industrial or commercial purposes, in LI/LPCO**
I00049	**90371**	**Anvisa approval for the import of samples and standards of products subject to special control as set out in Ordinance SVS/MS No. 344/1998 (lists C1, C2 and C5), procedure 3, intended for scientific or technological research, in LI/LPCO**
I00048, 90372		**Anvisa approval for the import of medicines intended for expanded access programs, compassionate use,**

I00049		post-study and clinical trial drug supplies, in LI/LPCO
I00048ÿ	90374	Anvisa's Import Authorization for up to 10 items of biological products or raw materials that comprise them, procedure 2, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90375	Anvisa Import Authorization for 11 to 20 items of biological products or raw materials that compose them, from procedure 2C, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90376	Anvisa's Import Authorization for up to 10 items of biological products or raw materials that comprise them, under procedure 2A, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90377	Anvisa Approval for Importation of 11 to 20 items of biological products or raw materials that comprise them, procedure 2A, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90378	Anvisa's Import Authorization for up to 10 items of biological products or raw materials that comprise them, under procedure 2B, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90379	Anvisa Import Authorization for 11 to 20 items of biological products or raw materials that compose them, procedure 2B, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90380	Anvisa's Import Authorization for up to 10 items of biological products or raw materials that comprise them, from procedure 2C, by a legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90381	Anvisa Approval for Importation of 11 to 20 items of biological products or raw materials that comprise them, procedure 2, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90382	Anvisa Approval for Importation of 21 to 30 items of biological products or raw materials that comprise them, procedure 2, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90383	Anvisa Approval for Importation of 31 to 50 items of biological products or raw materials that comprise them, procedure 2, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90384	Anvisa Approval for Importation of 51 to 100 items of biological products or raw materials that comprise them, procedure 2, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90385	Anvisa Approval for Importation of 21 to 30 items of biological products or raw materials that comprise them, procedure 2A, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90386	Anvisa Approval for Import of 31 to 50 items of biological products or raw materials that compose them, procedure 2A, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90387	Anvisa Approval for Importation of 51 to 100 items of biological products or raw materials that compose them, procedure 2A, by legal entity for industrial or commercial purposes, in LI/LPCO

I00048ÿ	90388	Anvisa Approval for Importation of 21 to 30 items of biological products or raw materials that comprise them, from procedure 2B, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90389	Anvisa Approval for Importation of 31 to 50 items of biological products or raw materials that comprise them, from procedure 2B, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90390	Anvisa Approval for Importation of 51 to 100 items of biological products or raw materials that comprise them, from procedure 2B, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90391	Anvisa Approval for Importation of 21 to 30 items of biological products or raw materials that comprise them, from procedure 2C, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90392	Anvisa Approval for Importation of 31 to 50 items of biological products or raw materials that comprise them, from procedure 2C, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90393	Anvisa Import Authorization for 51 to 100 items of biological products or raw materials that compose them, from procedure 2C, by legal entity for industrial or commercial purposes, in LI/LPCO
I00048ÿ	90399	Anvisa approval for importing medicines, except procedures 1, 1A and 3, intended for scientific or technological research, in LI/LPCO
I00050	90400	Anvisa's Import Authorization for up to 20 human biological samples intended for doping control tests, by a laboratory or importing entity not accredited by ABCD, with current accreditation with WADA, in LI/LPCO
I00050	90401	Anvisa Approval for Importation of 21 to 50 human biological samples intended for doping control tests, by a laboratory or importing entity not accredited by ABCD, with current accreditation with WADA, in LI/LPCO
I00044, I00045, I00046, I00047, I00048, I00049, I00050	90402	Anvisa import approval for the entry of goods and products from abroad intended for use in large-scale events in the country, in LI/LPCO
I00050	90404	Anvisa approval for the import of up to 20 items of human biological samples intended for scientific or technological research, in LI/LPCO
I00050	90405	Anvisa approval for the import of 21 to 50 items of human biological samples intended for scientific research

		or technological, in LI/LPCO
I00049	**90406**	**Anvisa approval for the import of samples and standards of products subject to special control of Ordinance 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), of procedures 1 and 1A, imported by drug enforcement agencies**
I00049	**90407**	**Anvisa approval for the import of samples and standards of products subject to special control of Ordinance 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), of procedures 1 and 1A, intended for scientific or technological research**
I00049	**90408**	**Anvisa Approval for Import of standard, material or reference substance, containing substance from procedure 1 or 1A by legal entity, for proficiency testing or Quality Control, in LI/LPCO**
I00049	**90409**	**Anvisa's approval for the import of drug samples under or for monitoring Clinical Research containing a substance from procedure 1 or 1A, in LI/LPCO**
I00049	**90410**	**Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of substances subject to special control, of procedure 1 and 1A, in the finished product stage, without a linked health unit, in LI/LPCO**
I00044	**90413**	**Anvisa Import Authorization for up to 10 items of parts or accessories for medical devices or IVD, procedure 4 or 5.5, per legal entity under the DEA regime, in LI/LPCO**
I00044	**90414**	**Anvisa Import Authorization for 51 to 100 items of parts or accessories for medical devices or IVD, procedure 4 or 5.5, by legal entity under DEA regime, in LI/LPCO**
I00044	**90415**	**Anvisa Import Authorization for 31 to 50 items of parts or accessories for medical devices or IVD, procedure 4 or 5.5, by legal entity under DEA regime, in LI/LPCO**
I00044	**90416**	**Anvisa Import Authorization for 21 to 30 items of parts or accessories for medical devices or IVD, procedure 4 or 5.5, by legal entity under DEA regime, in LI/LPCO**
I00044	**90417**	**Anvisa Import Authorization for 11 to 20 items of parts or accessories for medical devices or IVD, procedure 4 or 5.5, by a legal entity under the DEA regime, in LI/LPCO**
I00044, I00045, I00046, I00047, I00048,	**90418**	**Anvisa approval for the import of goods or products not regularized by ANVISA, by SUS member institutions, linked to the obligation to comply with legal action, except procedure 1 and 1A, in LI/LPCO**

I00049, I00050		
I00049	90423	Anvisa Approval for Import of standard, material or reference substance, containing substance from procedure 3 by legal entity, for proficiency testing or Quality Control, in LI/LPCO
I00049	90424	Anvisa's authorization to import drug samples under or for monitoring Clinical Research or expanded access programs, compassionate use and post-study supply containing substance from procedure 3, in LI/LPCO
I00049	90425	Anvisa's approval for the import of raw materials and products containing substances subject to special control of Ordinance SVS/MS nº 344/1998 (lists A1, A2, A3, B1, B2, C3, D1, F), not regularized in the SNVS, for testing purposes, in LI/LPCO
I00045ÿ 90442		Anvisa approval for import of cosmetic samples, finished or in bulk, not regularized, in LI/LPCO, for: quality control analysis, packaging and labeling, registration, safety and efficacy, product development, market research
I00047	90443	Anvisa approval for importing samples of sanitizing products, finished products or raw materials, not regularized, in LI/LPCO, for: analysis, registration, quality control, proficiency, product development, equipment, market research
I00044	90444	Anvisa approval for import of international donation of medical devices or IVD, in LI/LPCO
I00046	90445	Anvisa approval for import of international food donations, in LI/LPCO
I00045ÿ 90446		Anvisa approval for importing international donations of cosmetics, perfumes, personal hygiene products, in LI/LPCO
I00046	90447	Anvisa approval for the import of food intended for initial supply and replacement of infirmary, pharmacy or medical kit on board international means of transport, in LI/LPCO
I00048, I00049	90448	Anvisa import approval for the return of medicine produced in the national territory and rejected abroad, in LI/LPCO
I00044	90449	Anvisa import approval for the return of a medical device or IVD, produced in the national territory and rejected abroad, in LI/LPCO
I00046	90450	Anvisa Import Consent for the return of food produced in the national territory and rejected in

		abroad, in LI/LPCO
I00044	**90451**	**Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of medical devices or IVD, in the finished product stage, without a linked health unit, in LI/LPCO**
I00046	**90452**	**Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of food, in the finished product stage, without a linked health unit, in LI/LPCO**

I00045	90453	**Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of cosmetics, in the finished product stage, without a linked health unit, in LI/LPCO**

I00046	90455	Anvisa approval for the import of non-regularized food intended for fairs or events, in LI/LPCO
I00045ÿ	90457	Anvisa approval for import of cosmetics, perfumes, and non-regularized personal hygiene products intended for fairs or events, in LI/LPCO
I00044	90458	Anvisa approval for the import of medical devices or IVD intended for scientific or technological research, in LI/LPCO
I00046	90459	Anvisa approval for the import of food intended for scientific or technological research, in LI/LPCO
I00045ÿ	90460	Anvisa approval for the import of cosmetics, perfumes, personal hygiene products intended for scientific or technological research, in LI/LPCO
I00045ÿ	90461	Anvisa import approval for the return of cosmetics, perfumes, personal hygiene products produced in the national territory and rejected abroad, in LI/LPCO
I00044	90462	Anvisa approval for the import of samples of finished medical devices or IVDs, not regularized in the SNVS, for testing, teaching or training purposes, in LI/LPCO

I00046	90463	Anvisa approval for importing samples of food, finished products or raw materials, not regularized, in LI/LPCO, for: analysis for purposes of registration, quality control, packaging, labeling, product development, equipment, market research
I00048; I00049	90464	Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of medicines, except for procedure 1 and 1A, in the finished product stage, without a linked health unit, in LI/LPCO
I00050	90469	Anvisa approval for the import of a maximum of 20 samples of human cells and tissues for therapeutic purposes, in LI/LPCO
I00050	90470	Anvisa Approval for Import of 21 to 50 samples of human cells and tissues for therapeutic purposes, in LI/LPCO
I00049	90488	Anvisa approval for the import of medicines intended for expanded access programs, compassionate use, provision of post-study medicines and clinical trials containing a substance from procedure 1 or 1A, in LI/LPCO
I00046	90496	Anvisa Approval for Importation of food intended for monitoring and evaluation of Clinical Research of medicine, medical device or IVD, in LI/LPCO
I00047	90497	Anvisa approval for import of non-regularized sanitizing agent intended for fairs or events, in LI/LPCO
I00047	90498	Anvisa approval for the import of sanitizing products intended for scientific or technological research, in LI/LPCO
I00045	90499	Anvisa approval for the import of cosmetics intended for initial supply and replacement of infirmary, pharmacy or medical kit on board international means of transport, in LI/LPCO
I00047	90500	Anvisa approval for import of international donation of sanitizing products, in LI/LPCO
I00047	90501	Anvisa approval for import by the Ministry of Health, Secretariats or public entities that are part of the SUS, of sanitizing products, in the finished product stage, without a linked health unit, in LI/LPCO
I00047	90502	Anvisa import approval for the return of sanitizing product produced in the national territory and rejected abroad, in LI/LPCO
I00045	90503	Anvisa Authorization for Importation of cosmetics, hygiene products and perfume, intended for monitoring and evaluation of Clinical Research of medicine, medical device or IVD, in LI/LPCO
I00044	90504	Anvisa Approval for Importation of medical devices or IVD, intended for monitoring and evaluation of Clinical Research of drugs, in LI/LPCO

I00047	90505	Anvisa approval for the import of sanitizing products by public health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00047	90506	Anvisa Approval for Importation of Sanitizing Products, intended for monitoring and evaluation of Clinical Research of medicine, medical device or IVD, in LI/LPCO
I00050	90515	Anvisa approval for the import of up to 10 items of standard, material or reference substance, except containing controlled substance, by legal entity, for commercialization, in LI/LPCO
I00050	90516	Anvisa approval for the import of 11 to 20 items of reference standard, material or substance, except containing controlled substance, by legal entity, for commercialization, in LI/LPCO Anvisa approval for
I00050	90517	the import of 21 to 30 items of reference standard, material or substance, except containing controlled substance, by legal entity, for commercialization, in LI/LPCO Anvisa approval for the import of 31 to
I00050	90518	50 items of reference standard, material or substance, except containing controlled substance, by legal entity, for commercialization, in LI/LPCO Anvisa approval for the import of 51 to 100 items
I00050	90519	of reference standard, material or substance, except containing controlled substance, by legal entity, for commercialization, in LI/LPCO Anvisa approval for the import of up to 10 items of reference standard,
I00049	90520	material or substance, containing controlled substance of procedure 1 and 1A, by legal entity, for commercialization, in LI/LPCO Anvisa approval for the import of 11 to 20 items of standard, material or reference
I00049	90521	substance, containing controlled substance of procedure 1 and 1A, by legal entity, for commercialization, in LI/LPCO Anvisa authorization for import of 21 to 30 items of standard, material or reference substance,
I00049	90522	containing controlled substance of procedure 1 and 1A, by legal entity, for commercialization, in LI/LPCO Anvisa authorization for import of 31 to 50 items of standard, material or reference substance, containing controlled
I00049	90523	substance of procedure 1 and 1A, by legal entity, for commercialization, in LI/LPCO Anvisa authorization for import of 51 to 100 items of standard, material or reference substance, containing controlled substance of
I00049	90524	procedure 1 and 1A, by legal entity, for commercialization, in LI/LPCO Anvisa authorization for import of up to 10 items of standard, material or reference substance, containing controlled substance of procedure 3, by
I00049	90525	legal entity, for commercialization, in LI/LPCO Anvisa authorization for import of 11 to 20 items of standard, material or reference substance Anvisa approval for import of 21 to 30 items of standard, material or
I00049	90526	reference substance, containing controlled substance of procedure 3, by legal entity, for commercialization, in LI/LPCO
I00049	90527	

I00049	90528	Anvisa approval for the import of 31 to 50 items of standard, material or reference substance, containing controlled substance of procedure 3, per legal entity, for commercialization, in LI/LPCO
I00049	90529	Anvisa approval for the import of 51 to 100 items of standard, material or reference substance, containing controlled substance of procedure 3, per legal entity, for commercialization, in LI/LPCO
I00046	90530	Anvisa approval for the import of food, by private health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00045	90531	Anvisa approval for the import of cosmetics, by private health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00048	90532	Anvisa approval for the import of medicines, by private health units, in the finished product stage, for their exclusive use, in LI/LPCO
I00047	90533	Anvisa approval for the import of sanitizing products, by private health units, in the finished product stage, for their exclusive use, in LI/LPCO

SECONDARY PETITIONS

Mandatory procedural instruction documents and related rules can be consulted at

https://consultas.anvisa.gov.br/#/consultadeassuntos/

Code of the Subject	Subject
90118	Withdrawal of petition/import process on request, related to Import License under Anvisa's approval - LI/LPCO
90272	Anvisa import consent, in LI/LPCO Substitute, in LI/LPCO
90273	Amendment to the Anvisa import approval petition/process, in LI/LPCO
90274	Compliance with requirements in Anvisa import approval petition/process, in LI/LPCO

90275	**Health Inspection to verify compliance with health requirements related to the removal of interdiction of products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same municipality**
90276	**Health Inspection to verify compliance with health requirements related to the removal of interdiction of products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same State**
90277	**Health Inspection to verify compliance with health requirements regarding the release of interdiction of products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in Different states**
90283	**Extension of term in LI/LPCO, in Anvisa import approval process**
90284	**Administrative Appeal in Anvisa import approval petition/process, in LI/LPCO**
90286	**Verification of compliance with health requirements related to the Release of the Custody and Liability Term for products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same municipality**

90287	**Verification of compliance with health requirements relating to the Release of the Custody and Liability Term for products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same State**
90288	**Verification of compliance with health requirements relating to the Release of the Custody and Liability Term for products in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in a different State**
90420	**Anvisa import consent, in Substitute LI/LPCO, whose previous LI is exempt from payment of Tax Health Surveillance Inspection**
90428	**Request for prioritization of analysis of the Anvisa import approval process, in LI/LPCO**

90481	**Collection and transportation of samples for laboratory analysis of products subject to control analysis, in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same municipality**
90482	**Collection and transportation of samples for laboratory analysis of products subject to control analysis, in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in a different State**
90483	**Collection and transportation of samples for laboratory analysis of products subject to control analysis, in the Anvisa import approval process, in LI/LPCO, stored outside the customs warehouse, but in the same State**
90489	**Health Inspection to verify compliance with health requirements regarding the removal of interdiction of products in the Anvisa import approval process, in LI/LPCO, stored in the customs warehouse**

90491	**Request for recognition of the nature of the product as a medical-hospital material, for the purpose of exemption from import tax, in the Anvisa import approval process, in LI/LPCO**

25. SUMMARY REJECTION

Summary rejection of the LI/LPCO occurs, for example, when there is a failure to send the items indicated as MANDATORY DOCUMENTS, in the cases of petition protocol with incorrect subject code, as per item II, art. 2 of RDC No. 204/2005 or due to discrepancies in information between the petition and the inspection sanitary as per item 1.3 of Chapter II of the Annex to RDC No. 81/2008.

26. TECHNICAL REQUIREMENT

The technical requirement is a measure that can be used as due diligence procedural when the health authority deems it necessary to request information or additional clarifications on the documentation supporting the filed petitions at Anvisa.

The deadline for compliance with the requirement will be indicated in the text of the requirement formulated, according to paragraph 2 of article 6 of RDC No. 204/2005, being 30 days, non-extendable, counted from the date of registration of the requirement in the computerized approval system import processes and their import licensing.

Once the established deadline has expired, if the petition is not filed, compliance with the requirement, the import process should be rejected for not compliance with the requirements formulated within the established deadline.

If the company fails to comply with the requirements formulated, it will be up to the rejection for not having fully met the requirements formulated, as per paragraph I, of article 7 of RDC No. 204/2005.

We emphasize that additional documents may be requested to those provided for in the RDC. No. 13/2004 and in RDC No. 81/2008, for analysis of the claim and through technical justification, the company must present them when requested (Chapter XXXVII, item 3 of RDC No. 81/2008).

27. INSPECTION OF GOODS

The inspection of goods is a procedure to be carried out at the discretion of the Anvisa in import approval, according to import approval inspection channels provided for in RDC No. 228/2018.

Whenever inspection of the merchandise is requested, proof of payment will no longer be charged.
berthing. Anvisa will request that the specific field be filled in regarding the information
presence of cargo, correlating it with the CNPJ data of the Customs Warehouse.

In the case of in-person physical inspection of the cargo, the Anvisa Office responsible for the
inspection of the customs area where the cargo is stored will schedule the inspection
with the importer or his legal representative. This appointment will be registered in Siscomex
or by other means chosen by the Post.

In the case of remote inspection of the cargo, the approving body will register the proposal in the LPCO/LI
date and time of the remote inspection, as well as the name of the inspector responsible. In this way,
It will be up to the importer to request the faithful depositary to position the cargo and schedule it
of remote inspection. To schedule this, the importer or his/her trustee must enter
in contact with the customs area where the goods to be inspected are located. The
legal representative, with identification document and power of attorney, and the person responsible
customs technician must be present at the time of inspection.

ATTENTION

If the importer does not schedule the inspection, without presenting the due justification, the import process will be rejected, the cargo will be banned and the importer will be fined for health violation, in accordance with the Law n. 6.437/1977.

If a requirement is issued in LPCO that has the status “UNDER INSPECTION”, the importer
You must edit the LPCO, include applicable documentation and edit the subject code field.
of secondary petition.

The warehouse CNPJ must be updated whenever necessary, such as,
for example, in cases of customs transit.

28. TERM OF CUSTODY AND RESPONSIBILITY

Products subject to import approval, upon entry into the country, may
have their exit from the customs area authorized, with reservations, subject to the importer's obligation
to the Custody and Responsibility Term, in the following cases:

- **If the irregularity found in the product is remediable (e.g.: problems with labeling); or**
- **Laboratory tests necessary to prove its nature, identity and quality at these stages of production or manufacturing.**

Requests for release of products under Custody and Responsibility Terms for labeling adequacy must be requested in the initial petition dossier. Only authorized releases under Custody Agreement aiming at adapting labeling to the address of the holder of the product regularization.

The TGR model is available on the Anvisa portal.

After fulfilling the health requirement set by the approving body, the importer must attach proof of compliance with the health requirement in the Single Portal, in the tab "attached documents", petitioning in Requests the petition for cancellation of the TGR.

The agency's statement regarding the Release of the TGR is through the attachment of the Term of Guard with the released stamp on the LCPO of the release request.

If the importer takes more than 90 days to request the release of the TGR, the LPCO that is in "In demand" status is automatically canceled by the system. In this case, the importer must file the petition requesting release of the TGR at Request and attach all applicable documentation to the LPCO. The consenting party will analyze the documentation sent and will attach an opinion regarding the release of the TGR to the LPCO. It will not be It is possible to update the status of the LPCO, which will remain as "Cancelled".

29. INTERDICTION

The Terms of Prohibition of irregular products will be attached to the LI LPCO rejected and banned by Anvisa. The deadline for compliance with demands included in the Interdiction Terms are counted from the date of receipt of the Notification sent to importer via Electronic Letter linked to the rejected and banned import process.

The issuance of a Health Prohibition Term will always be subject to verification of an occurrence classified as a health irregularity, under Law No. 6,437/1977. The Interdiction Term will contain the details of the health irregularity, the period and the type of destination (rejection or destruction).

The importer whose import was not authorized by Anvisa is obliged to return the goods abroad, within 30 days of notification of non-authorization, as per

determined by Law No. 12,715/2012 and updates. The general rule is to return the country of origin of the banned imported good or product, as stated in Chapter XXXII of RDC No. 81/2008. However, there are some situations in which it is possible to proceed with the destruction of the goods, and these situations are assessed on a case-by-case basis by Anvisa.

To request a change in the destination of the banned merchandise, the importer must do so by means of a petition for an addendum, with the respective justification. Requests without due justification will be rejected.

Once the prohibited goods have been disposed of (returned or destroyed), the The importer must submit, by means of an addendum, proof of destination within the deadline

ATTENTION

If the importer does not present proof of destination of the cargo (return or destruction) within the period defined by Anvisa, the importer will be fined for health violation, under Law No. 6,437/1977.

determined by Anvisa. The proof must be attached to the Single Portal, in the tab "Attached documents". Additionally, the importer must request the attachment not requested.

30. DISINTERDICTION

The request for release from interdiction may be motivated by two situations:

- The health irregularity was remedied with a new LI protocol and LPCO approved, where a protocol error was found on the part of the importer; or
- The result of the appeal filed was satisfactory regarding the consent of the LI and LPCOs previously rejected and banned. In cases where there is provision of the appeal or preliminary decision in favor of the importer, is the responsibility of Anvisa proceed with the release of the interdiction of the goods, without the need for the importer file a petition for release from interdiction.

Petitions for disqualification must be made in the same process/LPCO where the Interdiction Term is attached (i.e. in the rejected import process), indicating the substantiated reasons for such request. Petitions for disqualification attached in

other processes/LPCOs, where there is no motivating Interdiction Term, will be rejected and archived.

Petition for release from interdiction attached to the import process or LPCO that does not have linked interdiction will be summarily dismissed and archived.

The Terms of Disinterdiction are attached to the LPCO, linked to the interdicted LI previously, as a result of the analysis of the motivation for the initial interdiction and verification of the remediation of sanitary irregularities.

ATTENTION

Under no circumstances will the removal of interdiction of products be accepted when new LI/LPCO protocol for banned product was carried out, in which verify that the maintenance of the health irregularity, with the intention of circumventing the health inspection.

The appeal instrument is appropriate for situations in which the importer understands that the ban was undue.

31. ADMINISTRATIVE APPEAL

Administrative Appeal is a tool designed to review a decision in administrative process, with the purpose of obtaining the reform or cancellation of the initial decision.

At Anvisa, through specific protocols, administrative resources can be processed through up to three appeal instances.

First instance administrative appeals are petitions filed against decisions issued by Anvisa's Organizational Units. First-degree administrative appeals instance must be addressed (see subject codes) to the authority that made the decision. When they are not retracted in the first instance, administrative appeals are judged by the General Management of Resources, in second instance.

The procedures for filing administrative appeals against Anvisa's decisions are set out in the Collegiate Board Resolution - RDC 266/2019."

The General Management of Resources - GGREC will judge in the second instance all appeals filed against first instance administrative decisions of the units of the Anvisa, while the Collegiate Board – Dicol is responsible for the final judgment.

We recommend reading the Anvisa page about resource flows at the agency - https://www.gov.br/anvisa/pt-br/setorregulado/recursos-administrativos.

The first instance, which begins with the filing of an appeal via petition Requests in the import process of the rejected LI, its judgment is given by the Management-General of Resources. While the second instance, with a specific protocol in last instance, by the Collegiate Board.

The deadline for filing an appeal is thirty days, counting from the first day business day following the date of insertion of the non-consent opinion into the SISCOMEX system.

The appeal petition must be filed with a specific subject code in the Request, linked to the import process whose LI has already been issued by Anvisa. In the event of an appeal against rejection, follow the provisions of item 17.2.1 of this Manual.

All petitions must be accompanied by a written request containing the following data:

- **ÿ administrative body or authority to which it is addressed;**
- **ÿ identification of the interested party or their representative;**
- **ÿ applicant's domicile or place for receiving communications;**
- **ÿ formulation of the request, with an explanation of the facts and their grounds; and**
- **ÿ date and signature of the applicant or his/her representative.**

The administrative appeal shall be addressed to the issuing authority or the adjudicating panel that issued the decision, which, if it does not reconsider within 5 (five) days, will forward the respective appeal to a higher court for assessment and deliberation in the second instance.

Documentary evidence will only be admitted in the context of an appeal. administrative before Anvisa in the following cases:

- ÿ when the evidence referred to in the caput of this article refers to fact or law supervening; or
- ÿ when the evidence referred to in the caput of this article is intended to counter facts or reasons subsequently brought to the record.

At any stage of the proceedings or instance, the appellant may, voluntarily, withdraw the appeal filed. Voluntary withdrawal must be expressed in a manner expressed, by petition with a specific withdrawal subject code linked to the process of import whose LI was "not approved".

The administrative appeal will be received with suspensive effect, except in the cases provided for in the aforementioned resolution and other related rules. In cases of interdicted processes, with deadline for return or destruction, the deadlines are suspended until the decision is made final appeal. All communication regarding the recounting of the term is sent to the importer by means of a notification on the Single Foreign Trade Portal.

The final decision on the administrative appeal must be published within the maximum period ninety days, counting from the date of filing of the appeal.

It is possible to file an appeal against a decision to grant a process import, for example, in cases where the importer wishes to reject the LI/LPCO for the destruction of the cargo. In this case, an appeal petition must be filed. administrative does not request.

32. HEALTH RISK MANAGEMENT

RDC No. 228/2018 establishes how health risk management should be applied to control and inspection activities in the import of goods and products under health surveillance.

It establishes four health inspection channels, according to the risk assessed for each import process:

I. "green, inspection channel that provides for simplified approval, by waiving documentary analysis and inspection of goods and imported products under health surveillance;

II. yellow, inspection channel that provides for documentary analysis of the import process and the possibility of deferral, through exemption from inspection of imported goods and products under surveillance sanitary, in the absence of documentary irregularities;

III. red, inspection channel that provides for document analysis, inspection of imported goods and products under health surveillance and 90

other applicable health procedures provided for in the standard specific; and

IV. gray, inspection channel that involves a procedure of investigation."

The health risk management criteria applied to import approvals are:

I. Product risk class and classification;

II. Purpose of import;

III. Storage and transport conditions;

IV. Compliance and regularity history of companies and products;

V. International epidemiological and health context;

VI. Post-market monitoring of products;

VII. Results of laboratory, tax or control analyses;

VIII. Origin and provenance of the imported product;

IX. Control by random sampling.

The criteria can be used individually or in combination, observing the health risk involved.

Currently, all import processes are subject to Risk Management. RDC, imputing to the analysis flow, different completion times, depending on the channel inspection framed within the process.

33. IMPORT MANUALS (LPCO) PUBLISHED BY ANVISA

- Medical Device Import Manual - https://www.gov.br/anvisa/pt-br/contentcenters/publications/ports-airports-and-borders/guides-and-manuals/medical-device-import-manual.pdf/view;
- Food Import Process Analysis Manual - https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/portos-aeroportos-e-fronteiras/guides-and-manuals/import-process-analysis-manual-of-alimentos_v-02_final.pdf/view;
- Import Manual for Fairs and Events - https://www.gov.br/anvisa/pt-br/contentcenters/publications/ports-airports-and-borders/guides-and-manuals/import-manual-for-fairs-and-events.pdf/view;

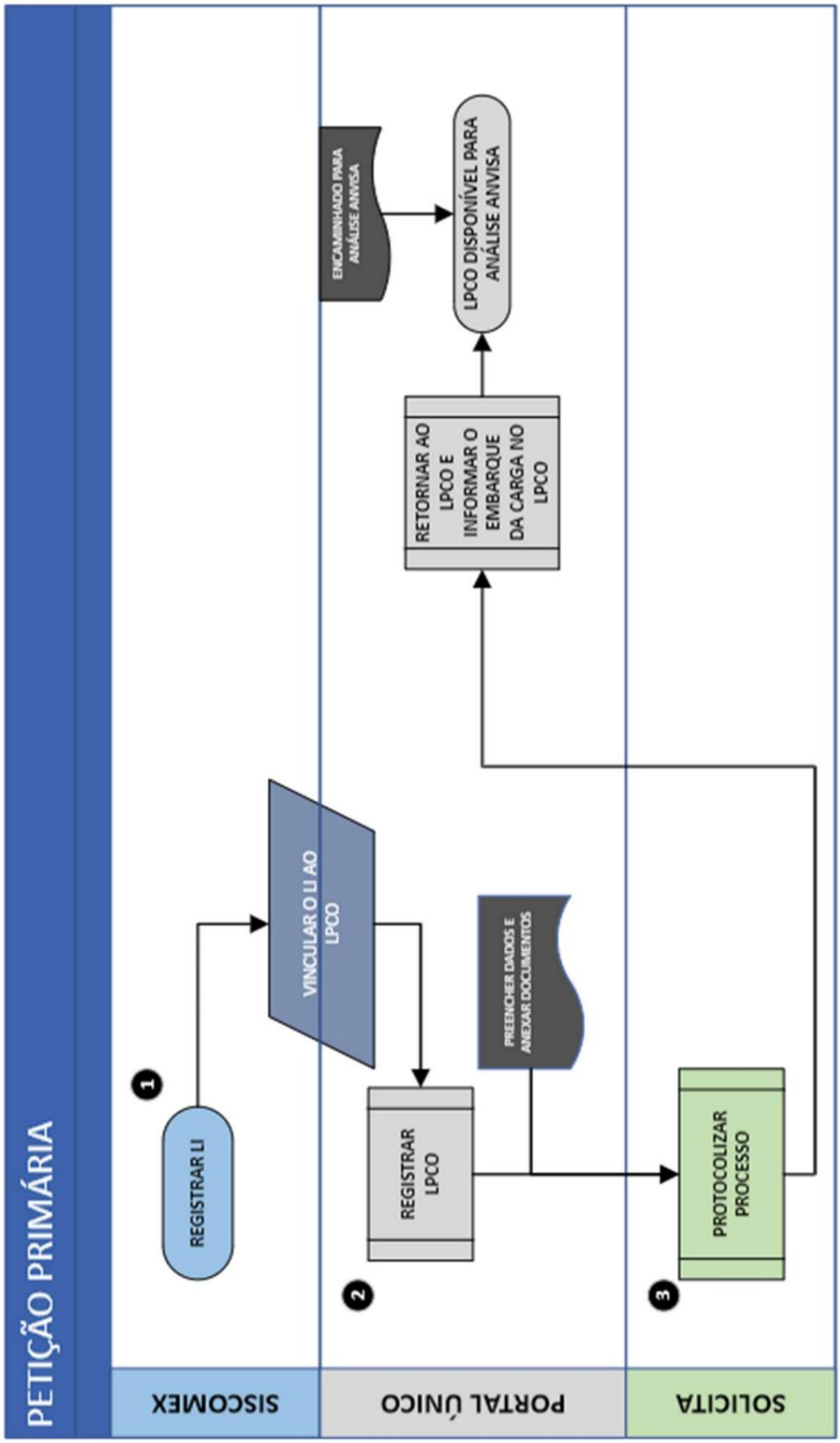
34. SERVICE CHANNELS FOR SOCIETY

Contact with Anvisa is made exclusively through service channels available on the Anvisa website.

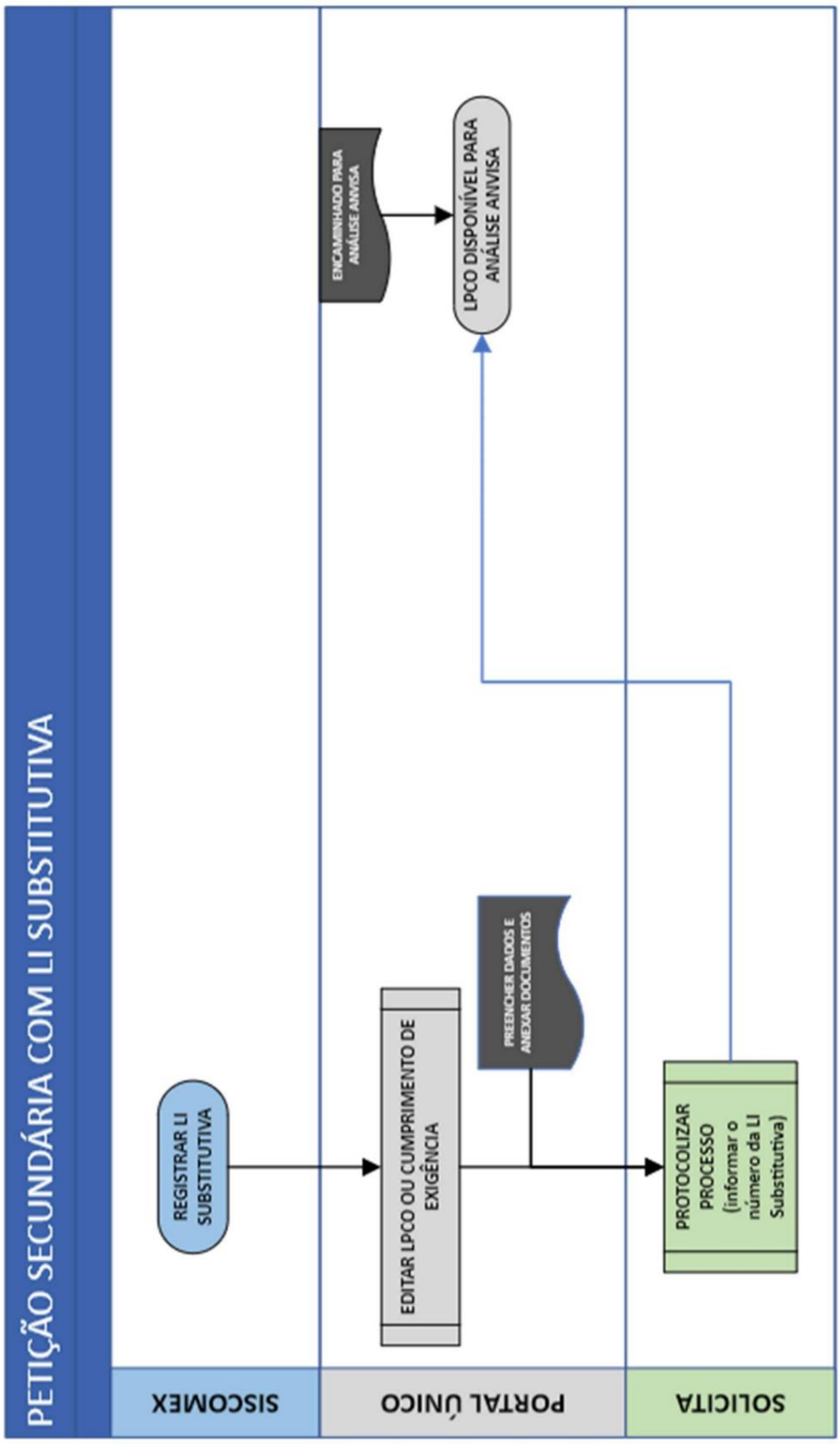
Questions regarding attributes and/or necessary changes in LPCO models should be sent through the contacts mentioned above.

35. ANNEXES

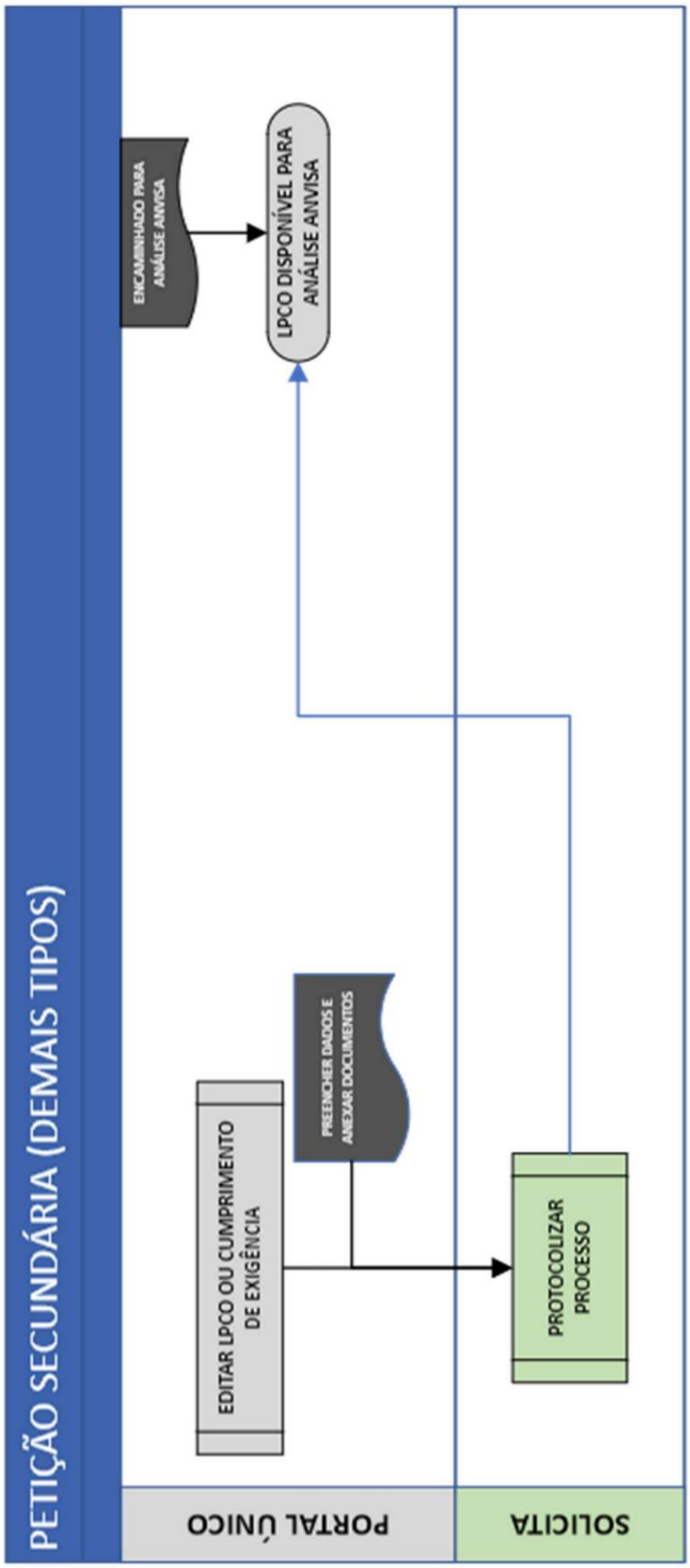
ANNEX I – PROCESS FLOWCHART – PRIMARY PETITION



ANNEX II – PROCESS FLOWCHART – SECONDARY PETITION WITH LI SUBSTITUTIVE



ANNEX III – PROCESS FLOWCHART – SECONDARY PETITION (OTHERS TYPES)



36. REVISION HISTORY

Version	Date		Change
1	10/27/2023	Initial Issue	
1.1	11/03/2023	Item 9.1.5 Fields common to all forms	CNPJ Holder of Regularization – Best field description CNPJ Warehouse – Inclusion of clarification on road transport Carrier's CNPJ – Exclusion of field Product type/purpose – Inclusion of categories SNVS regularization number: – Best field description Product Shelf Life: – Best field description Type of import operation – Update item 4 List of Ordinance SVS/MS nº 344/1998: – Inclusion of list E
		25.1 PRIMARY PETITIONS	Updating the description of the codes subject 90311, 90312, 90313, 90314, 90315, 90406, 90407, 90408, 90409, 90410, 90425.
1.2	06/11/2023	6. GENERAL GUIDELINES	Update of the text on the effective date of the new LPCO models. Changing model numbers LPCO
		19. LPCO MODELS	
		25. SUBJECT CODES	Correction of subject codes
1.3	07/11/2023	11. INFORM PAYMENT OF FEE IN LPCO – PUCOMEX	Changing the information entered in the Attention box
2.0	11/09/2023	Report Fee Payment	The Report Fee Payment functionality was removed from PUCOMEX and the entire Manual was amended.
		9.1.5	Information inserted about Entity linked to SUS, Law 9782/99?

2.1	10/11/2023	24.1 PRIMARY PETITIONS 35. ANNEXES	The model applicable to the code of subject 90223 Update of attachments to exclude the "Inform payment in LPCO" step
2.2	11/14/2023	6. GENERAL GUIDELINES 9.1.5 Fields common to all forms 10.1 PRIMARY PETITION	Update of texts relating to filling in data for outsourced imports of products exempt from regularization at Anvisa.
2.3	11/17/2023	9.1.5 Fields common to all forms	Deleting the Pharmaceutical Form field Information about the IFA registration process has been added Suitability of the Type of Import Operation
2.4	04/12/2023	8 9.1.5 11 12 13 14 15 16.1.2 27	Alert about description of goods in LI. Adjustment and clarification of some items Adaptation of the text on pre-boarding citing the steps in COCIC and PAFME Link citation of technical names of medical devices Subcategory breakdown for kits. Exceptions regarding cargo shipping information Text correction for presence of cargo Indication of applicable subject codes for editing the LPCO Parameterization channel disclosure Adequacy of the replacement LI text Updated text for the Goods Inspection item
2.5		9.1.5 - Fields common to all forms	Update of the "Import operation type*" field Presentation of further clarifications on the INFORM field SHIPPING OF CARGO

		12 - INFORM SHIPPING OF CARGO 15 - STATUS THE PARAMETERIZATION	Inclusion of information on the import of finished biological products or biological products in their primary packaging
2.6	12/22/2023	9.1.5 Fields common to all forms	Inclusion of the Pharmaceutical Form field
2.7	01/25/2024	11. PETITIONS WITH MANDATORY PRE-SHIPMENT OF CARGO 24.1 Primary Petitions	Inclusion of guidance for the Substitute LI protocol for products subject to special control. Inclusion of the list of mandatory instruction documents for the protocol of import petitions for goods and products for all available subject codes Exclusion of subject codes 90471 and 90472, since the laboratory diagnostic purpose is already covered by codes 90297 and 90298. Primary petition subject codes No. 90496; 90497; 90498; 90499; 90500; 90501; 90502; 90503; 90504; 90505 were created, which will be active from 02/01/2024. Deletion of code 90368 Updated description of subject codes for secondary petitions.
		24.2 Secondary Petitions	
2.8	02/16/2024	5. SYSTEM REQUEST 9.1.5 Fields common to all forms 24. SUBJECT CODES	Insertion of the obligation to attach the LPCO extract in the requested protocol Adjustment in the explanatory texts for the fields CNPJ Holder of regularization, Regularization number in SNVS and Type of operation. Review of subject code descriptors to adjust to PUCOMEX.
2.9		24. SUBJECT CODES	Change of description of code 90460; Change of legal basis; Exclusion of code 90352; Inclusion of code 90506.

2.10	02/05/2024	12. Report boarding of load	Updated guidance for the Ministry of Health, entities linked to the SUS, radiopharmaceuticals, medical devices with a shelf life measured in hours and advanced therapy products.
2.11	31/07/2024	9.1.5 Fields common to all forms	Updated information about: CNPJ Holder of regularization, Deadline for Validity
		11. PETITIONS WITH MANDATORY PRE-SHIPMENT OF CARGO	Inclusion of information on shipping deadlines
		12.1 CCT	Inclusion of information regarding
		18. LPCO MODELS	Deletion of LPCO model I00051 – Goods not subject to health intervention
		21. ANALYSIS PRIORITIZATION CRITERIA	Updated description of analysis prioritization criteria
		24.1 PRIMARY PETITIONS	Updated description for subject codes: 90261, 90408, 90423, 90410, 90451, 90452, 90453, 90464, 90501, 90263, 90264, 90265, 90356, 90505, 90424, 90350, 90409 Created subject codes: 90515, 90516, 90517, 90518, 90519, 90520, 90521, 90522, 90523, 90524, 90525, 90526, 90527, 90528, 90529, 90530, 90531, 90532, 90533, 90534 Updated documentation for subject codes: 90216, 90261, 90408, 90423, 90410, 90451, 90452, 90453, 90464, 90501, 90263, 90264, 90265, 90356, 90505
		27. INSPECTION OF GOODS	Information about the warehouse CNPJ has been inserted
2.12	08/23/2024	12. REPORT SHIPMENT OF CARGO 12.1 CCT	Information on these items has been updated.
2.13	30/08/2024	9.1.5 Fields common to all forms	Added item about “LI Highlight”
		9.1.6 Split delivery	Guidelines on split delivery added
		12. INFORM BOARDING OF THE LOAD	Guidelines on radiopharmaceuticals added and about LPCO granted

		28. TERM OF CUSTODY AND RESPONSIBILITY	**Field update**
2.14	**10/09/2024**	**9.1.7 Direct Bulk Unloading**	**Item inclusion**
		9.1.8 NCM reclassification by the Brazilian Federal Revenue Service	**Item inclusion**
2.15	**09/20/2024**	**6. GENERAL GUIDELINES**	**Guidance on importing microspheres**
		9.1.5 Fields common to all the forms - CNPJ Storer:*	**Changed guidance for filling in the case of road transport. Inserted guidance on direct discharge of bulk.**
		21. CRITERIA OF ANALYSIS PRIORITIZATION	**Change of description of the criterion prioritization "Importing sources radioactive" to inclusion the microspheres** **Inclusion of the criterion "Import of Products to address public health emergencies of national/international importance declared by the Ministry of Health"**
2.16		**9.1.5 Fields common to all forms - CNPJ Storer**	**Improved wording on guidance for filling in case of modal road.**
		12.1 REGULAR (FLIGHTS CCT)	**CCT for scheduled flights and Knowledge for non-regulars.**
2.17		**6**	**Clarification on gov.br subscription**
		9	**Insertion of cancelled LPCO in NCM reclassification guidance**