WORLD TRADE ORGANIZATION

G/LIC/N/3/CHL/9

29 March 2022

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Committee on Import Licensing Original: Spanish

REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES[1]

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES (2022)[2]

CHILE

The following notification, dated 24 March 2022, is being circulated at the request of the delegation of Chile.

Table of contents:

[1] See document G/LIC/3, Annex, for questionnaire.
[2] This notification also concerns 2021.

1 NATIONAL FISHERIES SERVICE (SERNAPESCA)

1.1 Live hydrobiological species

Outline of systems

1. The hydrobiological species authorized for import are those which, in accordance with Article 13 of Supreme Decree No. 430 of 1991 of the Ministry of the Economy, Development and Tourism (MINECON), are included in the list published annually by the Undersecretariat of Fisheries (SSP Resolution No. 3189 of 2019). It should be noted that the list describes the farming conditions and authorized uses for some such species.

Purpose and coverage of licensing

2. It applies to all imports of live hydrobiological species (regular imports or first-time imports), at any stage of development, including their gametes.

3. Only specimens coming from countries that have undergone a health assessment or risk analysis may be imported. The list of assessed and authorized countries of origin is contained in the document entitled "Handbook on procedures for importing live species IMP/MP3" http://www.sernapesca.cl/sites/default/files/imp-mp3_20200723.pdf.

4. The licence is not intended to restrict the quantity or value of imports; rather it seeks to prevent the entry, through the importation of hydrobiological species and their eggs and gametes, of diseases and their causal agents, in particular diseases which are not present in Chilean national territory and diseases covered by a specific surveillance or eradication programme in the country.

5. Laws and regulations under which the licensing is maintained:

- MINECON Law No. 18.892 of 1989: General law on fisheries and aquaculture
- MINECON Supreme Decree No. 72 of 2012: Regulations on certification and other sanitary requirements for the importation of hydrobiological species
- MINECON Supreme Decree No. 730 of 1996: Regulation governing first-time imports of species
- MINECON Resolution No. 3189 of 2019: List of live hydrobiological species authorized for import
- MINECON Resolution No. 1741 of 2013: Classification of high-risk diseases
- Resolution No. 2085 of 2010, establishing, for the purpose of importing hydrobiological species, the diagnostic technique and the organs to be sampled for the detection of infectious salmon anaemia virus
- National Fisheries Service (SERNAPESCA) Resolution No. 65 of 2003 establishing the general health programme for the disinfection of roe

Procedures

6. Not applicable.

7.(a) The live species import application must be submitted to SERNAPESCA at least 72 hours prior to the arrival of the specimens in the country.

(b) Licences cannot be granted immediately.

(c) Not applicable.

(d) Consideration of licence applications is effected in full by a single administrative organ (Chilean National Fisheries and Aquaculture Service (SERNAPESCA)). Background information shall be assessed pursuant to Law No. 19.880 on bases of administrative procedures governing the acts of state administration bodies.

8. None apart from the criteria set out in the regulations. In the event of refusal of an import application, the applicant is always notified, and the reasons for the decision are explained.

Eligibility of importers to apply for licence

9. All natural and legal persons are eligible to apply for import permits.

Documentational and other requirements for application for licence

10. It is necessary to submit the document entitled "*Acta de Internación de Especies Hidrobiológicas*" ("Hydrobiological Species Importation Certificate"), which is available on the SERNAPESCA website: http://www.sernapesca.cl/manuales-publicaciones/control-de-ingresos. It can also be found attached at the end of this questionnaire.

11. The following documents are required upon actual importation:

- Hydrobiological Species Importation Certificate (available at: http://www.sernapesca.cl/manuales-publicaciones/control-de-ingresos)
- Quarantine order (available at: http://www.sernapesca.cl/manuales-publicaciones/control-de-ingresos)
- Invoice from exporter (copy)
- Health certificate issued by the competent health authority of the country of origin (copy)
- CITES certificate (copy, where applicable)
- Air waybill (copy)
- SERNAPESCA report authorizing the quarantine station (applicable to first-time imports of species)
- Authorization granted by the Agriculture and Livestock Service (SAG), in the event that aquatic plants need to be imported

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. There is no period of validity. It is possible to extend the validity of the licence: if the validity of the health certificate granted by the competent health authority of the country of origin expires, the importer can obtain a new certificate with a new effective date.

15. There are no penalties.

16. Licences are not transferable between importers.

17. There are no other conditions.

Other procedural requirements

18. Imported live ornamental species must be quarantined for 15 days in stations previously authorized by SERNAPESCA by means of a resolution.

19. Not applicable.

1.2 Biological or pathological material

Outline of systems

1. To import biological material or pathological material, the interested party must complete a form including all the information required by the office of the National Fisheries Service (SERNAPESCA). This document can be submitted in person to the SERNAPESCA office in the region where the customs clearance of the material is to be carried out (submit two copies), or by email to importaciones@sernapesca.cl.

Purposes and coverage of licensing

2. Importation of biological/pathological materials – (for private use): Any person or firm wishing to import biological or pathological material must have the Service's authorization prior to its arrival.

- Definition of biological material: Material including inactivated tissues of hydrobiological species, cell lines, diagnostic kit (antigen or antibody), culture media or genetic material of microorganisms, used for diagnostic, research or quality control purposes.
- Definition of pathological material: Tissues, not inactivated, extracted from hydrobiological species or strains of pathogenic microorganisms imported for laboratory analysis.

3. It applies to biological/pathological material coming from all countries.

4. The licence is not intended to restrict the quantity or value of imports; rather it seeks to prevent the entry, through such imports, of diseases and their causal agents, in particular diseases which are not present in Chilean national territory and diseases covered by a specific surveillance or eradication programme in the country. However, depending on the type of material to be imported and the assessment carried out by SERNAPESCA, SERNAPESCA may make further requests if deemed necessary.

5. Laws and regulations under which the licensing is maintained:

- Supreme Decree No. 430 of 1991 (Consolidated text of the general law on fisheries and aquaculture). - Ministry of the Economy, Development and Tourism. - National Fisheries and Aquaculture Service (SERNAPESCA) Supreme Decree No. 319 of 2001.
- Approves regulations on measures to protect against, control and eradicate high-risk diseases of hydrobiological species. "The importation into the country of pathological material (for private use) is forbidden, unless authorized by the Service".

Procedures

6. Not applicable.

7.(a) Import applications for biological material must be submitted at least three working days in advance of the arrival of the product and, for pathological material, seven working days in advance.

(b) Licences cannot be granted immediately.

(c) There are no limitations as to the period of the year.

(d) Consideration of licence applications is effected in full by a single administrative organ (Chilean National Fisheries and Aquaculture Service, SERNAPESCA). Background information will be assessed pursuant to Law No. 19.880 on bases of administrative procedures governing the acts of state administration bodies.

8. None

Eligibility of importers to apply for licence

9. All natural and legal persons are eligible to apply for import permits.

Documentational and other requirements for application for licence

10. The interested party must submit a form entitled "*Solicitud para importar material biológico o patológico*" ("Application to import biological or pathological material"). For both biological and pathological material, the importer must submit the following documentation together with the application: Transport documents (copy of air waybill or courier waybill), commercial documents (invoice) and letter signed by the importer stating the specific requirements depending on the material to be imported.

Other documents to be submitted with the application depending on the type of material to be imported (biological or pathological) are listed in point No. 11. The form "application to import biological or pathological material" is attached to the end of this questionnaire.

11. Specific requirements for biological material:

1. Letter signed by the importer describing the characteristics of the material to be imported (the common and scientific name must always be stated for material derived from hydrobiological species) and the destination of the material, and containing a detailed description of its use and final disposal.

2. The following certificates must also be supplied for the biological material listed below:

   (a) Cell lines and culture media: sterility certificate provided by the supplier.
   (b) Genetic material from microorganisms: certificate provided by the supplier certifying that the material is not infectious and is purified RNA/DNA. The documentation must state whether the genetic material is complete or split.
   (c) Diagnostic kit (antigen or antibody): certificate attesting that it relates to non-infectious inactivated material, provided by the supplier.

Specific procedures and requirements for pathological material:

1. The importation into the country of pathological material is forbidden, unless authorized by the Service.
2. In the event of an application to import pathological material, the application must be formally submitted to the Head of the Animal Health Department at the National Directorate of SERNAPESCA, together with a letter signed by the importer that clearly identifies the goods to be imported, the techniques used to identify the strains of pathogenic microorganisms, the purpose of the importation and the biosecurity measures, in particular biocontainment measures, at the destination facilities, during transport and final disposal. Where appropriate, it must also be reported if they are genetically modified organisms.
3. Entry of pathological material shall only be authorized if the biosecurity conditions reported by the importer provide guarantees as to the biocontainment and proper disposal of the material to be imported.
4. Once the background has been assessed, and if the importation is approved, the interested party and regional directorate at the point of entry will be informed.

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. The licence has no period of validity.

15. There are no penalties for the non-utilization of the licence.

16. Licences are not transferable between importers.

17. There are no other conditions.

Other procedural requirements

18. Not applicable.

19. Not applicable.

IMP/MP2/ 20 diciembre 2019

ANEXO 1
SOLICITUD PARA IMPORTAR MATERIAL BIOLÓGICO O PATOLOGICO

Nº aprobación:
Fecha:

IDENTIFICACIÓN DE LA IMPORTACIÓN:

Importador:	
Consignatario:	
Exportador:	
Puerto de embarque:	País:
Agencia de aduanas, embarque o carga:	
N° Guía aérea:	

IDENTIFICACIÓN DE LA MERCANCÍA:

Material biológico ☐ Material patológico ☐	
Descripción de la mercancía (1) :	
Tipo de embalaje:	Cantidad de bultos:
Destino (2) :	
Objetivo de la importación (3) :	
Peso bruto (4):	Peso neto (4):

(1) Indicar, cuando corresponda a muestras de tejido, la especie, origen de cultivo o captura y forma de mantención de las mismas (fijadas, congeladas, frescas, etc.)
(2) En caso de tratarse de un centro de experimentación, deberá identificarse además su Código en el Registro Nacional de Acuicultura.
(3)Detallar si son para análisis microbiológicos, químicos, pruebas organolépticas, etc.
(4) Cuando corresponda

Observaciones [1]:

(1) En caso que la importación la realice de manera directa una persona, se deberá indicar en este espacio identificación del medio de transporte (Nº de vuelo) y nombre y RUT de persona responsable del ingreso.

Funcionario Sernapesca **Firma y timbre**

1.3 Used vessels intended for aquaculture

Outline of systems

1. The procedure applicable to the importation of used vessels intended for aquaculture involves five stages: operation at origin, departure from origin, route, arrival or call at the first port of destination and, finally, entry into operation in national waters. For some of these stages, mitigation measures have been defined according to the type of vessel and its history.

Purposes and coverage of licensing

2. Procedures and requirements applicable to the importation of used vessels intended for aquaculture.

3. It applies to used vessels for use in aquaculture coming from all countries.

4. The licence is not intended to restrict the quantity or value of imports; rather it seeks to prevent the entry of high-risk diseases, both exotic and those covered by a specific health surveillance and control programme (infectious salmon anaemia, caligidosis and piscirickettsiosis), and others that could have a significant impact.

5. The laws and regulations under which the licensing is maintained are as follows:

- General Law No. 18.892 on fisheries and aquaculture.
- MINECON Supreme Decree No. 319/2001 establishing measures to protect against, control and eradicate high-risk diseases of hydrobiological species.

Procedures

6. Not applicable.

7.(a) The application to import used vessels intended for aquaculture must be submitted to the National Directorate of SERNAPESCA at least 20 working days prior to the vessel's departure from the country of origin.

(b) Not applicable.

(c) Not applicable.

(d) Consideration of licence applications is effected in full by a single administrative organ (Chilean National Fisheries and Aquaculture Service (SERNAPESCA)).

8. Not applicable.

Eligibility of importers to apply for licence

9. All natural and legal persons are eligible to apply for import permits.

Documentational and other requirements for application for licence

10. Firms or persons seeking to import used vessels intended for aquaculture must submit a vessel import application (Annex No. 2), available on the website www.sernapesca.cl, to the National Directorate of SERNAPESCA, stating the identification of the vessel, the type of vessel, origin, countries of its last year of operation and their health status, likely departure and arrival dates, port of departure, sailing route from origin to port of destination in Chile and identification of the destination port. The form, "*Solicitud de importación de embarcaciones*" (Vessel import application) is attached to the end of this questionnaire.

11. Together with the vessel import application, complete information must be submitted regarding the design (layout) of the vessel, identifying the areas of direct contact with the fish, their fluids or the waters containing them, as well as a description and maps of the water network systems, and information identifying the location of pumps, filters and other equipment. Vessel import applications must be sent to the following email addresses: acuicultura@sernapesca.cl or impoembarcacion@sernapesca.cl.

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. The licence has no period of validity.

15. There are no penalties for the non-utilization of licences.

16. Licences are not transferable between importers.

17. There are no other conditions.

Other procedural requirements

18. The interested party must also complete certain formalities with the maritime authority prior to importing the vessel.

19. Not applicable.

Anexo Nº 2
Solicitud de importación de embarcaciones

1. Antecedentes del interesado

Nombre o razón social del solicitante:	
Nombre representante legal:	
Dirección:	
Correo electrónico:	
Fono/fax:	

2. Antecedentes de la embarcación

Nombre de la embarcación, señal distintiva y matrícula:	
Destino de la embarcación:	Para el traslado de animales vivos: ☐ Para otros fines[1]:_____
Tipo de embarcación[2]:	Usada ☐ Nueva o recientemente construida ☐

3. Antecedentes de origen, trayecto y destino de embarcación

País y puerto de origen:	
Lugares de operación de los últimos 12 meses [3]:	
Condición sanitaria de los países en que operó[4]:	
Fecha estimada de zarpe:	
Fecha estimada de recalada en Chile:	
Puerto chileno de recalada:	
Trayecto de navegación a Chile[5]:	

1. Indicar uso final; traslado de equipos, alimentos, insumos, personal, etc.
2. En caso de una embarcación nueva, indicar empresa fabricante, astillero, fecha de botadura, fechas y lugares de pruebas de maquinarias y sistemas.
3. Indicar país o países en los que operó.
4. Indicar condición declarada en el país respecto de las Enfermedades de Alto Riesgo.
5. Incluir gráfica visible que incluya origen, destino y puertos de recalada durante el trayecto.

2 CHILEAN NUCLEAR ENERGY COMMISSION (CCHEN)

2.1 Enriched, fissile or radioactive elements or materials, radioactive substances, devices or tools that generate ionizing radiation

Outline of systems

1. Importation of enriched, fissile or radioactive materials and ionizing radiation-generating sources. Supreme Decree No. 323 establishes the conditions and procedures governing the licensing of

civilian entities to carry out activities related to enriched, fissile or radioactive materials and ionizing radiation-generating sources. The importation of radioactive material, nuclear material or radiation generators may not take place without prior authorization granted by the Chilean Nuclear Energy Commission (CCHEN). Supreme Decree No. 133 of the Ministry of Health (Official Journal of 23 August 1984) approves regulations on authorizations for radioactive facilities or ionizing radiation-generating equipment, personnel working in such facilities or operating such equipment and other related activities.

Purposes and coverage of licensing

2. The import licence or authorization issued by the CCHEN covers: importation of radioactive material, importation of nuclear material, importation of equipment containing radioactive material and importation of equipment not containing radioactive material, but which generates radiation.

3. Originating in and coming from all countries. Nuclear material is only imported from countries that have signed an agreement on safeguards with the International Atomic Energy Agency (IAEA).

4. The licensing procedure is not intended to restrict the quantity or value of imports.

5. The laws and regulations under which the licensing is maintained are as follows:

- Law No. 16.319, Law No. 18.302;
- Supreme Decree No. 323 of 1974 of the Ministry of the Economy;
- Supreme Decree No. 133 of 1984 of the Ministry of Health;
- Supreme Decree No. 12 of 1985 of the Ministry of Mining.

Licensing is statutorily required. The legislation clearly states which products are to be subjected to licensing. It is not possible for the Government to abolish the system without legislative approval.

Procedures

6. Not applicable.

7.(a) Applications for a licence must be made 38 days prior to importation. Licences cannot be obtained within a shorter time limit.

(b) A licence cannot be granted immediately.

(c) There are no limitations as to the period of the year during which applications for a licence may be made.

(d) Consideration of licence applications is effected by a single administrative organ.

8. An application for a licence is only refused on the grounds of failure to meet the requirements.

The refusal is based on a reasoned decision, of which the applicant is notified.

If an application is refused, the applicant has a right of appeal pursuant to Law No. 19.880.

Eligibility of importers to apply for licence

9.(a) All authorized persons, firms and institutions are eligible to apply for import licences.

(b) Not applicable.

Documentational and other requirements for application for licence

10. Information required in the application: Identity of exporter, identity of importer, identity of end users and characteristics of the goods.

Documents to be supplied with the application: Transport package certificate, radioactive material certificate, pro forma invoice.

(a) General information:

- Information regarding the owner-operator: name, tax identification number (RUT), address, municipality, telephone numbers, firm's email address, and name, RUT, email address and telephone number of the legal representative.
- Information regarding the recipient-operator: must be the owner-operator, otherwise transfer authorization is required.
- Information regarding the manufacturer or supplier: firm's name, address, telephone number.
- Information regarding the intermediary: firm's name, email address, telephone number (where applicable).
- Indicate facility of use: particle accelerators, irradiation facility, radiotherapy, high radiotoxicity laboratory, gammagraphy and industrial radiography, in accordance with Supreme Decree No. 133, Title 3, Article 7, first paragraph. Research, mining, laboratory, industrial or other.
- Material to be imported: refers to sealed and unsealed radioactive material, nuclear material, and equipment containing radioactive material and generating ionizing radiation.
- Mode of importation: single or annual (put frequency in annual).
- Physical state of radioactive material or nuclear material (solid - liquid - gaseous).

(b) Technical information:

(i) Material:

- Radioactive material:

    - Radioactive material activity certificate (decay table): Verify the make, model and series or code, radionuclide, source activity and date.
    - For used sealed sources, the owner must provide a leak test certificate.

    - Nuclear material:

        - Material certificate (decay table): nuclear material, activity and date.
        - Make, model and series or code, for equipment with shielding of nuclear material or percentage of alloys.
        - Verify the country of origin, which must be under safeguards.
        - Weight of nuclear material (uranium, thorium or plutonium),
        - Equipment: may be equipment containing radioactive material or ionizing radiation-generating equipment.
        - Equipment background, such as the operating manual or other document indicating the characteristics of the equipment, as follows:
        - Equipment containing radioactive material: make, model, series, nominal capacity in Bq or Ci and radioisotope.
        - Radiation generator: make, model, series and rated capacity in mA and kV.
        - For used equipment, the owner must indicate the length of use and report on the state of the equipment.

(ii) Pro forma invoice: These documents may also be called international quotation, purchase order or supplier's quotation. However, they must all contain the same information, and the following must be checked:

- Radionuclide, activity and date of radioactive material or nuclear material.
- Material to be imported: radioactive material - nuclear material - equipment containing radioactive material - ionizing radiation generators
- Physical state of radioactive material or nuclear material (solid - liquid - gaseous).
- Verify manufacturer or supplier information.

(c) Owner-operator: For the importation of any of the materials, the owner-operator must comply with the following:

- Importation of radioactive material: must have an authorized storage facility and authorized associated equipment, where applicable.
- Importation of nuclear material: must have an authorized storage facility and verify that it is under safeguards control.
- Importation of equipment containing radioactive material: must have an authorized storage facility.
- Importation of radiation-generating equipment: depends on the type of facility:

    - Medical area: The owner-operator shall require authorization for the construction of the unit (shielded irradiation room).
    - Industrial area: The owner-operator shall be required to indicate the storage location, which must be in a secure, locked location. (It should be noted that according to the conditions and requirements of the import authorization, the owner-operator must request authorization to operate the equipment within 40 days of receipt. Alternatively, the owner-operator may first apply for construction authorization to assess the calculation report, dose rates, operating conditions, among others, and subsequently apply for operating authorization).

(d) Intermediary: The firm that undertakes the import formalities, but which is not listed as the owner-operator. If the firm transports the material, it must supply transport authorization.

(e) Distributors: The owner-operator firm that imports and subsequently markets the material to one or more operators.

- Must have an authorized storage facility.
- Transfer authorization application. (Optional, it may also apply for transfer authorization once the material is in the authorized facility of the owner-operator).
- Transport authorization.
- List of customers, stating to which firms it will distribute the material.

11. The following documents are required upon actual importation:

- Transport package certificate
- Radioactive material certificate
- Pro forma invoice
- Authorization to transport radioactive material

12. Yes. Fees amount to 2.6 development units (UF).

13. Fees must be paid when the application is submitted. In the event of refusal of the application, the fee will be refunded.

Conditions of licensing

14. For single importation it is valid for a period of three months. For multiple importation it is valid for one year. No type of licence is renewable.

15. There is no penalty for the non-utilization of a licence or a portion of a licence.

16. Licences are not transferable between importers.

17. There are no other conditions attached to the issue of a licence.

Other procedural requirements

18. Not applicable.

19. Not applicable.

3 HEALTH SERVICE

3.1 Food products of any kind

Outline of systems

1. The licence applies to all food entering the country intended for human consumption.

Purposes and coverage of licensing

2. All food and food products intended for human consumption are subject to a control system for importation into Chile.

3. It applies to any third country from which food or food products intended for human consumption are imported.

4. The control system aims to verify compliance with Chilean health regulations to ensure the safety of food and food products intended for human consumption.

5. Laws and decrees under which the licensing is maintained:

- Law No. 18.164/82 of the Ministry of Finance
- Health Code (Decree-Law No. 725/67 of the Ministry of Health)
- Food Health Regulations (Supreme Decree No. 977/96 of the Ministry of Health)
- Manual for imports of food intended for human consumption (Exempt Resolution No. 322/2015, Ministry of Health)

The control system is statutorily required for all food and food products imported into Chile. Regulatory change is subject to legislative amendment.

Procedures

6. Not applicable.

7.(a) Once the product enters customs processing, the National Customs Service indicates that food and food products intended for human consumption require authorization granted by the Ministry of Health through its regional ministerial secretariats.

(b) Yes, in accordance with the epidemiological risk classification for products, described in Ministry of Health Exempt Resolution No. 322/2015.

(c) There are no limitations.

(d) All products are subject to control by the Chilean National Customs Service. Food and food products intended for human consumption, depending on their nature, require authorization from other services besides the Ministry of Health. Products of agricultural and livestock origin require authorization from the Agriculture and Livestock Service (SAG), while products of hydrobiological origin require authorization from the National Fisheries and Aquaculture Service (SERNAPESCA), besides authorization granted by the Ministry of Health.

8. Yes, import refusals are on the basis of a reasoned decision. There is a possibility of appeal pursuant to Book X of the Health Code.

Eligibility of importers to apply for licence

9. All natural and legal persons are eligible to apply for licences.

Documentational and other requirements for application for licence

10. It is necessary to submit an application for a customs destination certificate and a use and disposal certificate, which identify the importer, legal representative, product code, trade name, nature of the product, brand, type of product, product, format, quantity and country of manufacture.

11. The following documents are required upon actual importation:

1. Customs destination certificate.
2. Proof of payment of the Ministry of Health service tariff (Exempt Resolution No. 473/97, updated in 2020).
3. Bovine products must be accompanied by health certificates issued by the competent authorities in the country of origin, as established in Ministry of Health Supreme Decree No. 20 of 2009 and the amendment thereto (Requirements for the importation of bovine products for human use or consumption, according to their official bovine spongiform encephalopathy classification).

The health authority, in application of its legal powers, and considering the international free trade treaties in force and signed on the matter, may request, where appropriate, further background information, such as health certificates, results of analyses carried out in the country of origin, or technical data sheets issued by the product manufacturer. If this additional background information is not available from the importer, the relevant laboratory analyses must be carried out by the Chilean health authority.

12. Ministry of Health service tariffs vary according to the volumes included in each import (point 3.2.1. of Exempt Resolution No. 473/97).

13. There is an associated payment, as described in the previous point. It is not refundable under any circumstances. The aim is to cover the costs related to the activities of the health authority.

Conditions of licensing

14. The authorization is valid for a single import, due to the control system applied by Chile.

15. Not applicable.

16. No, authorizations are for each import as a one-time event.

17. In accordance with the epidemiological risk classification for products, described in Ministry of Health Exempt Resolution No. 322/2015.

Other procedural requirements

18. Not applicable.

19. Not applicable.

3.2 Substances that are toxic or hazardous to health

Outline of systems

1. To import hazardous substances into the country, authorization is required from the regional ministerial health secretariats. First, a customs destination certificate is issued to enable the transfer of the substances from customs to the destination warehouse. Importation is then authorized from the warehouse, i.e. to distribute, sell, dispose of or use the substances, subject to verification of compliance with certain requirements. This is carried out every time regulated hazardous substances are imported.

Purposes and coverage of licensing

2. Customs destination certificate and import or use and disposal authorization, both of which apply to the hazardous substances listed in Ministry of Health Resolution No. 408/16.

3. It is required for any hazardous substance, from any country of origin.

4. The purpose is to comply with the country's existing legal requirements, and for the authority to have a record of the imported substances.

5. Import authorization is established in the Health Code and in Law No. 18.164, which also establishes the customs destination certificate. Resolution No. 408/16 issued by the Ministry of Health establishes the list of hazardous substances concerned by these processes.

Procedures

6. Not applicable.

7.(a) The customs destination certificate must be submitted prior to or at the time of arrival of the substances at the port or airport of entry into the country. The import application must be made once the customs destination certificate has been received. Approximately 90% of customs destination certificates are issued within 24 hours and approximately 90% of import authorizations are issued within three days.

(b) It can be issued on the same day.

(c) The application must be submitted each time a substance enters the country.

(d) Depending on the substances, approval is required from more than one state organ, although these are independent of each other.

8. In the event of refusal, the grounds are established, and the importer has a right to appeal and be granted authorization if they meet the requirements.

Eligibility of importers to apply for licence

9. Any importer of substances is eligible to apply for authorization.

Documentational and other requirements for application for licence

10. The application is made on the digital platform: https://asdigital.minsal.cl/asdigital/index.php#. Requested information: importer's details, details of the destination warehouse of the substances, details of the substance, Chemical Abstract Service (CAS) number, hazard class, format in which the substance arrives, quantity imported.

11. Required documents: commercial invoice, packing list, decision or authorization of the destination warehouse, where applicable, safety data sheets for the imported substances.

12. The fee amount depends on the quantity of the imported substance.

13. To begin the process and obtain the customs destination certificate and import authorization, applications must be paid for in advance.

Conditions of licensing

14. Once authorization has been obtained, the importer can make use of the substances; there is no period of validity. Authorization is obtained each time hazardous substances are imported.

15. Not applicable.

16. Not applicable, as authorization is obtained each time the substance is imported and, once authorization is obtained, the importer can make use of the substance, either by using, selling or distributing it.

17. There are no conditions attached to the issue of the authorization.

Other procedural requirements

18. Not applicable.

19. Not applicable.

4 NATIONAL DIRECTORATE OF STATE BORDERS AND BOUNDARIES (DIFROL)

4.1 Maps, charts and other works showing international boundaries and Chile's borders

Outline of systems

1. The National Directorate of State Borders and Boundaries (DIFROL) is responsible for authorizing the importation of maps, charts and publications concerning or related to international boundaries and Chile's borders. It shall also be responsible for authorizing the publication and circulation of such instruments, following their review.

Purposes and coverage of licensing

2. The authorization applies to any kind of printed matter or documents including maps or charts containing or depicting international boundaries and Chile's border areas. The review shall be restricted to these maps and charts and related texts only.

3. It applies to work coming from all countries.

4. The authorization is not intended to restrict the quantity or value of imports; rather it seeks to ensure that the imported works correctly reflect the international boundaries and border areas of the State.

5. Legislation in force:

- Decree-Law No. 5 of 1968 of the Ministry of Foreign Affairs;
- Decree-Law No. 83 of 1979 of the Ministry of Foreign Affairs;
- Decree No. 566 of 1970 of the Ministry of Foreign Affairs;
- Exempt Resolution No. 108 of 19 November 2020, approving DIFROL's internal organization.

Procedures

6. Not applicable.

7.(a) The import application is made entirely online on DIFROL's website. On occasion, this application has been made by the importer prior to the importation of the product into Chile. The application is generally made when the product or work arrives at customs. The review, however, depends on the complexity of the work.

(b) Not applicable.

(c) Not applicable.

(d) The application must only be submitted to DIFROL.

8. The import authorization or order is not issued if the formal requirements on the website are not met. Subsequent imports or reprints of works that have been checked and corrected may be

circulated, subject to proof from the interested party that the new copies have been duly corrected and that they relate to the same edition.

Eligibility of importers to apply for licence

9. Yes, all natural and legal persons are eligible to apply for authorization.

Documentational and other requirements for application for licence

10. The interested party must submit one or two copies of the work, as required, to DIFROL's Department of Border Studies.

(a) If DIFROL makes any observations during the review, such observations shall be communicated to the interested party in a memorandum and in a cover memo;
(b) Once the work has been corrected in accordance with the memorandum, the interested party shall inform the Department of Border Studies directly so that the corresponding checks can be carried out;
(c) Upon the return of the works containing the observations received, the import order does not need to be resubmitted.

11. The interested party must supply DIFROL with the required information when submitting the online application, although accompanying documents are not required. The written application for review and circulation of the work, together with the work itself, is submitted upon receipt of the import order. However, this is at a later stage, when the work has already entered Chile, but cannot be circulated until it has been reviewed by DIFROL and the corresponding exempt resolution on circulation has been issued.

DIFROL will issue an import order, which will be forwarded to the Customs Supervisory Authority and to the interested party, and which will authorize the withdrawal of the goods from the postal or customs areas, for the sole purpose of their review. Copies not submitted to the Directorate in accordance with the provisions of the following articles to meet the stated objective are kept in the custody of the interested party, under its responsibility, until it is notified of the resolution authorizing the circulation of the work.

12. There are no licensing fees or administrative charges.

13. Not applicable.

Conditions of licensing

14. Once authorization has been granted, subsequent imports or reprints of works that have not been checked may be put into circulation if they relate to the same edition and if their content has not been altered in any way. The interested party shall bring this information to the attention of the National Directorate of State Borders and Boundaries, which will carry out the corresponding checks.

Subsequent imports or reprints of works that have been checked and corrected may be circulated, subject to proof from the interested party that the new copies have been duly corrected and that they relate to the same edition.

In both cases, the National Directorate of State Borders and Boundaries shall issue the resolution authorizing the circulation of the work, with no further formalities other than those indicated in this article.

15. The non-utilization of an import order (i.e. the works remain in customs warehouses), as well as the exempt resolution on circulation, does not carry any kind of penalty; DIFROL has no associated powers to impose penalties.

16. Not applicable.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. Not applicable.

5 AGRICULTURE AND LIVESTOCK SERVICE (SAG)

5.1 Seeds

Outline of systems

1. Seeds entering the country must meet the following requirements (where applicable):

(a) Variety denomination.
(b) Phytosanitary requirements (quarantine weeds, regulated non-quarantine weeds, phytosanitary treatments and others).
(c) Minimum percentage of (physical) purity and germination.
(d) Authorization of the right holder for protected varieties.

Purposes and coverage of licensing

2. This system applies to all seeds.

3. The system applies to all goods imported into the country. There are (quality) requirements that are not applicable to all seeds, only to those imported for the purpose of being sold and that have established minimum germination and purity percentages.

4. This system is not intended to restrict the quantity or value of imports, but to keep records and control the varieties of imported seeds. In addition to keeping a record of and controlling incoming varieties, the system must ensure that incoming seeds comply with the quality standards established for domestic trade.

5. Supreme Decree No. 188 of 1978 on crop seeds establishes the quality requirements for seeds imported into the country. These are minimum percentages of (physical) purity and germination. These requirements will be verified at entry points.

The phytosanitary aspects of importation shall be governed by the general standard that establishes the criteria for quarantine pests in the territory of Chile, the standard establishing regulations for the control of plant species considered as weeds in seed shipments and the specific regulations in place depending on the species and country of origin, which shall prevail over the other aspects considered in the replies contained in this document.

Procedures

6. Not applicable.

7.(a) When importing seeds into our country, the importer or their representative must submit, for processing, a customs destination certificate, in which they must declare accurately and truthfully the product they wish to import, attaching the required documentation in each case. There are two processing procedures:

- Normal (carried out when the cargo has already arrived in the country);
- Advance (carried out before the goods arrive at the port, which makes it possible to remedy possible non-compliance or know in advance the measures to which the shipment will be subject upon arrival). In this case, the goods may be at origin or in transit.

(b) Law No. 18.164 of 1982, on customs destinations and the National Customs Service, grants a period of 72 hours for the Service to rule on the goods presented in the request submitted by the user. This ruling consists mainly of the SAG inspector indicating whether the product falls within the purview of the SAG, and if so, the customs destination certificate is numbered. Once the document has been numbered, and within the aforementioned deadline, documentary verification is carried out, in which the documents accompanying the shipment and indicating its traceability, condition and quality (B/L, consignment note, air waybill, as applicable; packing list, invoice, etc.) are checked to ensure that they tally with one another, along with the certificate, in the case of a regulated product, and its respective requirements (additional declarations, phytosanitary treatments, etc.). There is the option for the importer or their representative to request verification outside business hours, in which case they must submit a request for authorization and bear the consequent higher cost. Missing documents and/or miscellaneous considerations identified by the SAG inspector during the documentary verification are recorded in the observations field of the customs destination certificate. Once the documentary verification is completed, a copy is given to the importer or their representative so that they may subsequently request a phytosanitary inspection.

The SAG inspector carries out the phytosanitary inspection according to the schedule provided by the port administration (an activity coordinated by the port administration and the importer or their representative).

At this stage, the inspector verifies that what is declared in the documents matches the physical aspects (species, variety, batches). In cases where it is necessary to take a sample for laboratory analysis, the SAG inspector must have the authorization of the importer or their representative to extract the sample, which may be explicitly stated in the customs destination certificate or by email.

(c) There are no limitations as to the period of the year during which certificates may be requested or seeds imported.

(d) Applications are considered only by the Agriculture and Livestock Service, when applicable. The Service takes a sample for analysis in official laboratories only in the case of seeds that are not accompanied by a *seed analysis certificate* attesting to compliance with quality and phytosanitary requirements.

8. The application may be refused if the result of the laboratory analysis indicates:

- The presence of quarantine weeds, in which case the import is rejected.
- A germination percentage lower than that established in the standard, in which case the import is rejected.
- A purity percentage lower than that established in the standard, in which case the importer or their representative will have the option of submitting the batch for purification, with the import left pending until a new analysis is carried out. If the batch meets legal minimum requirements, the import is accepted. Otherwise, it is rejected.
- The presence of regulated non-quarantine weeds. In this case, the importer may submit the batch for purification, with the import left pending until a new analysis is carried out. If the batch meets legal minimum requirements, the import is accepted. Otherwise, it is rejected.
- The presence of live quarantine or exotic insects for Chile during the phytosanitary inspection, in which case the import is rejected if the conditions for treatment are not met.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply for seed import licences.

Documentational and other requirements for application for licence

10. The application requires the importer's information in addition to the result of the analysis indicating (when applicable) that the seed complies with the requirements established in the standard.

11. The importer must present the following documents for the importation of seeds:

- Commercial invoice;
- Packing list;
- Authorization of the right holder in the case of seeds considered protected varieties in Chile;
- Seed analysis certificate (when applicable);
- Phytosanitary certificate.

12. Not applicable.

13. The only payment requirement associated with the issue of the licence relates to the proof of payment that the importer or their legal representative must submit to the SAG inspector for the analysis of samples in the appropriate laboratory (when applicable). If the importer or their representative does not pay, the sample will not be sent to the laboratory for analysis.

Conditions of licensing

14. The licence is valid only once. The process must be repeated every time seeds are imported into the country.

15. There is no penalty for the non-utilization of the licence since it is granted at the time of importation.

16. Licences are not transferable between importers.

17. No other conditions are attached to the issue of a licence.

Other procedural requirements

18. Not applicable.

19. Not applicable.

5.2 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

Outline of systems

1. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is a multinational United Nations convention that aims to regulate international trade in wild animal and plant species so that such trade does not represent a risk to the survival of these species.

In the implementation of CITES, each country designates one or more authorities responsible for the administration, management and monitoring of the Convention.

Administrative authorities

The administrative authorities are responsible for granting the permits or certificates required for the importation and exportation of CITES-listed species, and for assessing the legality of specimens to be exported.

In our country, the administrative authorities are:

The Department of the Environment and Maritime Affairs of the Ministry of Foreign Affairs, which plays a coordinating role with the CITES Secretariat and chairs the National CITES Committee.

- SAG: Terrestrial fauna;
- CONAF (National Forest Corporation): Terrestrial flora;
- SERNAPESCA: Hydrobiological fauna.

Scientific authorities

The scientific authorities advise and support the administrative authorities in assessing the risk posed to the species by trade therein. They also approve exports of specimens from the wild.

Purposes and coverage of licensing

2. CITES international trade regulations apply only to species, parts and/or derivatives included in one of the three Appendices or lists of species (Appendices I, II and III).

3. The regulations apply to all countries party to the Convention, of which there are currently 184.

4. The prohibition of international trade (for commercial purposes) applies to certain species that are more endangered. Broadly speaking, this Convention seeks to regulate, rather than prohibit, the transboundary movement of species of conservation concern. These regulations apply to live animal and plant specimens and to all their parts and/or derivatives such as embalmed animals, skins, bones, feathers, skulls, trophies, tissue samples and other biological materials, pharmaceuticals, shoes, handbags and ivory.

5. Chile signed the CITES Convention on 16 September 1974, becoming the eighth country to do so. Subsequently, in 1975, the Government approved it and converted it into a Law of the Republic by means of Decree-Law No. 873 (Official Journal of 28 January 1975) and Supreme Decree No. 141 of the Ministry of Foreign Affairs (Official Journal of 25 March 1975). In our country, the Convention officially entered into force on 1 July 1975.

Subsequently, in November 2016 came the publication of Law No. 20.962 implementing the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the purpose of which is to govern the obligations assumed by Chile as a State party to the Convention.

Procedures

6. The specimen must travel with the relevant permit or certificate.

7.(a) Not applicable.

(b) A licence cannot be granted immediately since this requires the approval of the administrative authority, which must verify background information and, in some cases, consult the scientific authority.

(c) Not applicable.

(d) Not applicable.

8. An application may be denied for various reasons, including:

- When the applicant has been punished and convicted for violating the provisions of Law No. 20.962;
- When the proposed recipient of a live specimen is unable to house and care for it adequately;
- When a scientific authority of the importing State has indicated that the purposes of importation will be detrimental to the survival of the species;
- When an administrative authority of the importing State has detected that the specimen is to be used primarily for commercial purposes;
- When there is a failure to prove legitimate origin.

Eligibility of importers to apply for licence

9. Persons who have been punished and convicted for violating the provisions of Articles 8 and 11 of Law No. 20.962 shall be disqualified from registering any international trade activity involving specimens of the species mentioned in the first paragraph, and the administrative authorities shall be prohibited from issuing any permit or certificate under the terms established by the Convention.

The term of the disqualification shall be one year from the date on which the sentence becomes enforceable.

Documentational and other requirements for application for licence

10. For products classed as terrestrial fauna, the form found on the Agricultural and Livestock Service website (https://www.sag.gob.cl/ambitos-de-accion/convencion-cites) must be submitted.

The information requested includes:

- Background information on the applicant
- Background information on the recipient of the specimens in the destination country
- Background information on the specimens to be shipped abroad
- Background information on the journey

Moreover, the following requirements must be met:

- The SAG (administrative authority) must be able to verify that the specimens will NOT be used for commercial purposes.
- The scientific authority must be satisfied that the purposes of importing such specimens will not be detrimental to the survival of the species, and
- In the case of live specimens, the scientific authority must be satisfied that whoever receives the specimens will be able to house and care for them adequately (through an analysis of the facilities and handling standards)

For products classed as terrestrial flora, the forms available on the CONAF website (https://oficinavirtual.conaf.cl/recursos/cites.php) must be submitted.

For products classed as hydrobiological species, the form available on the following web page must be filled out: http://www.sernapesca.cl/tramites-formularios/formulario-cites, in addition to meeting the requirements set forth in point 1.1 of this questionnaire.

11. The documents to be submitted to the SAG for terrestrial fauna are:

- A permit application form for the importation of specimens of the species listed in Appendix I of CITES.
- A sworn statement before a notary public attesting that the specimens will not be used for commercial purposes.
- A report on the facilities where the live specimens to be imported will be housed.

12. Not applicable.

13. Not applicable.

Conditions of licensing

14. Import permits issued by the various administrative authorities are valid for 6 to 12 months, with the possibility of issuing a new permit in case of expiration.

15. Not applicable.

16. Import permits are not modifiable and must be used by the holder to whom they were granted.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. Not applicable.

5.3 Pesticides

Outline of systems

1. In order to import a pesticide for agricultural use, the product must be previously authorized by the SAG, which also checks all pesticide import requests at ports of entry into our country, applying the standards and procedures set forth in Resolution No. 1.038 of 2003 to verify the identity of the pesticides and their respective chemical compositions.

If the pesticide is not among the products authorized by the SAG, the interested party must request its authorization through a procedure governed by Resolution No. 1.557 of 2014, as amended by Resolutions Nos. 1.400/2015, 1.208/2016 and 5.482/2016.

Pesticides not previously authorized are rejected and ordered to be re-exported or destroyed. The process of requesting authorization takes about 24 months, and it is not possible to keep the cargo at the port during this period.

Purposes and coverage of licensing

2. Only those pesticides for agricultural use authorized by the Agriculture and Livestock Service may enter the country (the list is available at https://www.sag.gob.cl/ambitos-de-accion/evaluacion-y-autorizacion-de-plaguicidas). In the event that the pesticide is not among the products authorized by the SAG, the interested party must request its authorization through a procedure governed by Resolution No. 1.557 of 2014, as amended by Resolutions Nos. 1.400/2015, 1.208/2016 and 5.482/2016. Since 2018, microbial pesticides have been governed by Resolution No. 9.074.

3. The system applies to all goods entering the country, irrespective of their origin.

4. The licence is not intended to restrict the quantity or value of imports.

5. The rules and procedures under which the licensing is maintained are Resolution No. 1.038 of 2003, Resolution No. 1.557 of 2014, as amended by Resolutions Nos. 1.400/2015, 1.208/2016 and 5.482/2016, and, for microbial pesticides, Resolution No. 9074/2018.

Procedures

6. Not applicable.

7.(a) The application must be filed at ports of entry. The Agriculture and Livestock Service will carry out a documentary inspection. Once this has been done, a determination will be made as to whether a physical inspection of the consignment is appropriate. If the consignment is approved, the pesticide may enter the country, provided it is not subject to official sampling. If it is, the consignment must be sampled and held until it has been classified in the analysis results report.

(b) Not applicable.

(c) There are no limitations as to the period of the year during which applications may be submitted.

(d) Licence applications are considered only by the Agriculture and Livestock Service.

8. An application may be refused if the result of the physical analysis differs from the composition indicated in the document "Autorizaciones de Plaguicidas de Uso Agrícola" ("Authorizations of Pesticides for Agricultural Use") in force at the time of sampling, taking into account the tolerances established in Exempt Resolution No. 386 of 1983 or the resolution replacing or modifying it. The interested party may request the relevant Service Office to analyse the first counter sample in its possession in an authorized laboratory different from the first one. If this counter sample yields a result that is within the permitted ranges, the Service will send the second counter sample in its possession to a third authorized laboratory to confirm the previous result.

If, on the other hand, the first counter sample produces a result that confirms the first analysis, the product must be destroyed or re-shipped within a period not exceeding 180 days, with the cost being borne by the interested party or their representative.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply for licences.

Documentational and other requirements for application for licence

10. To request authorization to import a pesticide, the interested party must present the following documentation at the SAG office at the port of entry:

- A customs destination certificate indicating the authorization number issued by the SAG for each pesticide for agricultural use.
- A copy of the pesticide's Safety Data Sheet, in accordance with Law No. 18.164.
- An agricultural product inspection report.
- An original certificate of composition analysis issued by the manufacturer or formulator of the pesticide for each batch of pesticide, which must indicate the manufacturing batch number, active ingredient, concentration, formulation, volume and country of origin.
- An original invoice indicating the volume of the consignment to be imported, amount and c.i.f. or f.o.b. value.
- A cargo manifest, bill of lading or air waybill for the means of transport.

11. The documents required for actual importation are those listed in point 10.

12. Not applicable.

13. In the case of pesticides that have been seized pursuant to a detention order because they are subject to sampling, the costs of sampling and analysis shall be borne by the importer or manufacturer.

Conditions of licensing

14. The licence shall be valid only once.

15. Not applicable.

16. Licences are not transferable between importers.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. Not applicable.

5.4 Genetically modified organisms (GMOs)

Outline of systems

1. The importation of genetically modified propagation material is regulated by Resolution No. 1.523 of 2001, which establishes rules for the entry and introduction into the environment of living modified plant propagation organisms in a confined manner.

Materials entering Chile are classified as follows:

- Materials "with a history" of being released into the country.
- Materials "with no history" of being released into the country.

It should be noted that genetically modified materials "with a history" of being released may be subject to the provisions of Article 9 of Resolution No. 1.523 of 2001, which indicates that biosecurity measures may be partially or totally waived if they have been waived in the country of origin of the modified organism; if the latter has completed periods of biosecurity crop quarantine in Chile and the national background is suitable for adopting such a decision; and provided that the risk analysis allows the adoption of the decision, without prejudice to the possibility of re-establishing biosecurity measures if supervening circumstances so require. The above shall not apply when Chile is a place of origin of the species to which the modified organism belongs.

Within these two classifications (with a history and with no history), the Service has established the following categories:

- Materials without delegated responsibility (SRD).
- Materials with delegated responsibility (CRD).

Purposes and coverage of licensing

2. The licence is intended for living modified plant propagation organisms.

3. The system applies to all goods entering the country, irrespective of their origin.

4. The licence is intended to serve as an authorization procedure for the introduction into the environment of genetically modified propagation material in a confined manner, based on a case-by-case risk analysis process that makes it possible to conclude that the introduction of the material will have no adverse effects on the environment.

5. The laws and regulations under which the licensing is maintained are:

- Exempt Resolution No. 1.523 of 2001, which establishes rules for the entry and introduction into the environment of living modified plant propagation organisms in a confined manner.
- Resolution No. 6.183 of 2018, which establishes standard time frames for the entry and introduction into the environment of living modified plant propagation organisms in a confined manner.
- Resolution No. 3.928 of 2015, which creates a technical committee on genetically modified organisms.
- Information and submission: SAG Agricultural Protection Division (Av. Bulnes 140, piso 3, Santiago) or at the relevant SAG sectoral office.

Procedures

6. Not applicable.

7.(a) Given that the process involves the consideration of a series of prior reports, the authorization procedure for the confined sowing of GMOs takes 45 working days for modified organisms the entry of which is requested for the first time, and 20 working days if entry has previously been requested.

(b) It is not possible for a licence to be granted immediately.

(c) There are no limitations as to the period of the year during which the licence may be requested.

(d) Licence applications are considered only by the Agriculture and Livestock Service.

8. The application may be refused if the SAG determines that the entry of GMOs could pose a risk to the environment.

Eligibility of importers to apply for licence

9. Eligibility is granted to natural or legal persons working in the seed sector, biotechnology developers, research centres and universities that are registered in the GMO Seed Authorization Portal (https://ovvm.sag.gob.cl/empresaadd.asp).

Documentational and other requirements for application for licence

10. To request authorization to import genetically modified propagation material, the user must submit to the SAG:

1. The importation request form generated by the GMO Seed Authorization System.
2. Depending on the characteristics of the material to be imported, the complementary information form will be:

    (a) With no history:

        (i) Importation request form for transgenic plant material for propagation (must be submitted through the GMO Seed Authorization System, available at https://ovvm.sag.gob.cl/empresaadd.asp).
        (ii) C5- Incorporation of maintenance event in the GMO Seed Authorization System (F-PA-VIB-BIO-002).
        (iii) Supplementary information for evaluating the release into the environment of a genetically modified plant without prior authorization (F-PA-VIB-BIO-001).
        (iv) Extract of request for publication in the Official Journal (F-PA-VIB-BIO-004).

        *The forms in points 2, 3 and 4 can be found at https://www.sag.gob.cl/ambitos-de-accion/importacion-de-organismos-vegetales-geneticamente-modificados

    (b) With a history:

        (i) Importation request form for transgenic plant material for propagation (must be submitted through the GMO Seed Authorization System).
        (ii) User guide to generate the importation request form.

        The forms in points 2 and 3 can be found at https://www.sag.gob.cl/ambitos-de-accion/importacion-de-organismos-vegetales-geneticamente-modificados

11. Actual importation requires:

- Paying the evaluation and background check fee.
- In the case of modified material that is being imported for the first time, publishing an extract of the application submitted to the SAG in the Official Journal, subject to the authorization of the SAG.
- Having a history of previous releases in other countries, if new material is to be imported.
- In the case of material developed abroad, identifying the person legally and technically responsible (experienced professional designated by the company who is familiar with the subject).

12. For the evaluation and background check:

- Applications for genetically modified propagation materials without prior authorization: 33.6 standard hours (one standard hour is equivalent to 0.5 monthly tax units (UTM), in accordance with Decree-Law No. 142 of 1990).
- Applications for genetically modified propagation materials authorized in previous cases: 7.8 standard hours (one standard hour is equivalent to 0.5 UTM, in accordance with Decree-Law No. 142 of 1990).

13. There are no additional charges to the one mentioned in point 12.

Conditions of licensing

14. The application makes it possible to obtain:

- A decision issued on a case-by-case basis, authorizing importation until 31 December of the same calendar year. In duly justified cases, it is possible to request an extension of the deadline.
- A decision on release into the environment that establishes the biosecurity measures (pursuant to Resolution No. 1.523/2001) with which the GMO must comply in each case. This decision may be valid for more than one season.

15. Not applicable.

16. Licences are not transferable between importers, given that their issue is based on a case-by-case risk analysis process.

17. The importation of modified plant material for propagation must also comply with the phytosanitary requirements established by the SAG in each case.

Other procedural requirements

18. Not applicable.

19. Not applicable.

6 PUBLIC HEALTH INSTITUTE (ISP)

6.1 Narcotics and psychotropic substances that cause addiction

Outline of systems

1. Imports of narcotic drugs and psychotropic substances are regulated by the 1961 and 1971 United Nations Conventions, respectively. These Conventions establish the need for an annual forecast and an import licence for each international movement.

Based on the above, annual forecasts are provided for in Article 8 of Supreme Decrees Nos. 404/83 and 405/83.

Once the forecasts have been approved, a request is made for the import licence, which in Chile is called the official import certificate, in accordance with Article 10 of Supreme Decrees Nos. 404/83 and 4085/83.

To give effect to the importation, a customs destination certificate must be obtained, and to obtain the full enjoyment of the goods, a use and disposal certificate is required.

Purposes and coverage of licensing

2. Licensing systems apply to all narcotic drugs and psychotropic substances.

3. Applicable to any country that issues export licences for narcotic drugs and psychotropic substances on the basis of a valid and lawfully issued official import certificate.

4. The quantity to be imported is limited to that authorized in the official import certificate, in order to comply with the provisions of the 1961 and 1971 Conventions.

5. The laws and regulations under which the licensing is maintained are:

- Supreme Decree No. 404/83 https://www.bcn.cl/leychile/navegar?idNorma=13057.
- Supreme Decree No. 405/83 https://www.bcn.cl/leychile/navegar?idNorma=13066.

Procedures

6. The quantities that may be imported are determined by the International Narcotics Control Board https://www.incb.org/incb/en/psychotropics/status-of-assessments.html and https://www.incb.org/documents/Psychotropics/assessment/2022/Assesments_-_generated_on_-_14-01-2214_.pdf

7.(a) The time frame is relative. It depends on the evaluation time of the exporting country, which must issue an export licence based on the official import certificate issued by the country. It is not possible to receive goods at a port without an official import certificate.

(b) Although an official import certificate may be issued quickly, it will not have its international counterpart in the form of an export licence from the country of origin, in contravention of the above-mentioned Conventions.

(c) There are no restrictions.

(d) The Public Health Institute alone is responsible for import licences for this type of product.

8. Forecasts may be rejected in the following cases:

(a) Country balance insufficient to meet forecast requirements.
(b) Historical statistics of national and international movements do not justify what is requested in the forecast.
(c) The background information presented does not justify what is requested in the forecast.
(d) Establishment not authorized in Article 8 of Supreme Decrees Nos. 404/83 and 405/83.

The applicant is always aware of the status of their application and the considerations that determine the granting or refusal thereof.

In the event of refusal, the user may submit an appeal for reconsideration to the Director of the Public Health Institute.

Eligibility of importers to apply for licence

9. Only establishments authorized in Article 8 of Supreme Decrees Nos. 404/83 and 405/83.

Documentational and other requirements for application for licence

10. Forecast: no mandatory documentation, but it must include the following elements:

1. Amount requested.
2. Background information supporting the amount requested.

Official import certificate: no mandatory documentation, but it must include the following elements:

1. Authorized import forecast.

   In addition, the following must be indicated in the application:

   (a) Name and address of the establishment or of the legal representative, in the case of a legal entity;
   (b) Identity details of the technical director of the establishment or of the health professional responsible, in the case of medical or scientific research institutions;
   (c) Name and address of the exporter and country of origin of the product;
   (d) Generic name and chemical nomenclature of the drug or product;
   (e) Quantity to be imported;
   (f) Pharmaceutical form, name and nature of the container, in the case of pharmaceutical preparations or specialties; and
   (g) Customs office through which the product is to be imported.

11. Actual importation requires an invoice or purchase order for the product, a transport document or detention letter for the product, a certificate of analysis of origin, a decision authorizing importation for exceptional use, if applicable (for pharmaceutical products without sanitary registration, in accordance with Article 99 of the Health Code, the decision is issued by the Public Health Institute), and an official import certificate for drugs, narcotics or psychotropic substances, if applicable, authorized by the Public Health Institute.

12.- Forecast assessments cost $ 52,371.-
- Applying for an official import certificate costs $ 99,816.-
- A customs destination certificate costs $ 43.519.-
- A use and disposal certificate costs $ 24,658.-13. There are no additional charges to the ones mentioned in point 12.

13. Payment for these services is a condition for the issue of the associated licences. It is non-refundable.

Conditions of licensing

14. The forecast is valid for the calendar year in which it is issued.

Official import certificates are valid for four months.

15. No, there is no penalty.

16. Licences are not transferable between importers.

17. Not applicable.

Other procedural requirements

18. All products to be distributed in the country require prior sanitary registration, as established in the Regulation on Pharmaceutical Products (Supreme Decree No. 3/10).

19. Not applicable.

6.2 Pharmaceutical products, foods for medical use and cosmetics

Outline of systems

1. Pursuant to Supreme Decree No. 3/2010, a pharmaceutical product or drug is any substance intended for human use for the purpose of curing, mitigating, treating, preventing or diagnosing diseases or their symptoms. Pursuant to Supreme Decree No. 239/02, a cosmetic product is any preparation intended to be applied externally to the human body for purposes of beautification, modification of physical appearance or preservation of the normal physical and chemical conditions of the skin and its annexes.

Purposes and coverage of licensing

2. Sanitary registration of the product: One-time registration issued by the Chilean Public Health Institute that guarantees quality, safety and efficacy. Sanitary authorization of establishment: Authorization granted by a health-related entity for the purposes established in a particular decision (storage, distribution, transfer, packaging, etc.). Customs destination certificate: Document allowing products to be moved from the customs area to the authorized sanitary establishment. Use and disposal: Decision allowing the health product to be used, transferred, assigned or sold for any reason.

3. This applies to all countries of origin and provenance of each pharmaceutical and cosmetic product.

4. This procedure is not intended to restrict the quantity or value of imports; its purpose is to certify compliance with current health regulations applicable to pharmaceutical and cosmetic products.

5. Decree having Force of Law (DFL) No. 725 (Health Code) delegates to the Chilean Public Health Institute responsibility for the sanitary control in Chile of pharmaceuticals (Article 96) and cosmetics (Articles 107 and 108), which, in order to be imported and distributed in the country, must first have their sanitary registration authorized by the Chilean Public Health Institute (Article 20 of Supreme Decree No. 3/2010 for pharmaceutical products and Article 4 of Supreme Decree No. 239/02 for cosmetic products).

For importation, the relevant customs destination certificate and certificate of use and disposal must be requested from the Institute, in accordance with Articles 2 and 3 of Law No. 18.164, which introduces amendments to customs legislation. Articles 98 and 99 of Supreme Decree No. 3/2010 on pharmaceutical products and Article 16 of Supreme Decree No. 239/02 on cosmetic products require a customs destination certificate and a certificate of use and disposal for importation and sale in the country.

Circular No. 3779 of 4 December 2015, issued by the Undersecretariat for Public Health, states that the Public Health Institute is in charge of issuing customs destination certificates for pharmaceuticals and cosmetics throughout the national territory.

Procedures

6. The Public Health Institute has provided various instructions for each step required for processing. Links are provided below:

(a) Instructions for registering pharmaceutical products: https://ispch.cl/sites/default/files/prestacion/2012/03/instructivo_requisitos_solicitud_rgistro_ordinario_sro_02_12_2014%20%20INCLUYE%20NORMA%20170%20DE%20BIOTECNOL..pdf
(b) Cosmetic product registration data sheet: https://www.ispch.cl/sites/default/files/prestacion/2009/12/4112001.pdf
(c) Instructions for authorizing establishments: https://ispch.cl/wp-content/uploads/2021/02/Instructivo-Autorizaci%C3%B3n-Lab.-Farmac%C3%A9uticos-Cosm%C3%A9ticos-Droguer%C3%ADa-Dep%C3%B3sitos-Recetario-Est%C3%A9ril-11-02-2021.pdf
(d) Instructions for processing foreign trade operations associated with goods subject to sanitary control by the Public Health Institute: https://www.ispch.cl/wp-content/uploads/2021/01/3007-2020-OP-1.pdf.

7. There are no quantitative limits for the importation of a product or for imports from a given country:

(a) They may be issued prior to arrival in Chile, as long as an invoice and a transport document are provided.

(b) If the invoice and transport document are available, the customs destination certificate can be issued in advance. It must be requested by the importer through the GICONA platform. It should be noted that each process has an associated cost, which can be consulted in the "Services" section of the Public Health Institute's web page.

(c) There are no limitations as to the period of the year during which the licence application may be submitted or the importation may take place.

(d) In this case, licences are considered only by the Public Health Institute.

8. Licences may be refused for incompleteness of background information or non-compliance with health regulations. The importer is informed of the grounds for refusal in the pronouncements made by the Public Health Institute, which can be consulted and appealed through the Lobbying Law platform.

Eligibility of importers to apply for licence

9. Any person may apply for an import licence, as long as the following elements are present: Sanitary registration authorized by the Public Health Institute, sanitary establishment authorized to store and distribute the product, and an account and password for the Public Health Institute's processing platform (GICONA).

(a) Any account holder with an authorized sanitary registration may apply for an import licence.

Documentational and other requirements for application for licence

10. Applications must include the following information: importer, product imported, mode of transport, customs agent and product batch, among other elements.

11. An invoice or purchase order for the product, a transport document or detention letter for the product, a certificate of analysis of origin, a decision authorizing importation for exceptional use, if applicable (for pharmaceutical products without sanitary registration, in accordance with Article 99 of the Health Code, the decision is issued by the Public Health Institute), and an official import certificate for drugs, narcotics or psychotropic substances, if applicable, authorized by the Public Health Institute.

12. Each service has a cost, which can be consulted in the "Services" section of the Public Health Institute's web page (https://www.ispch.cl/productos-y-servicios/prestaciones/)

13. Payment for these services is a condition for the issue of the associated licences. It is non-refundable.

Conditions of licensing

14. The period of validity is subject to the provisions of each decision (sanitary registration and authorization of establishments). The customs destination certificate and the certificate of use and disposal do not have a defined validity.

15. In accordance with Article 3 of Law No. 18.164, the Public Health Institute may establish a security period for the issue of the use and disposal certificate for all imports that require a detailed documentary review. There is no penalty for the non-utilization or partial utilization of the import licence.

16. It is not possible to transfer an import licence from one importer to another, since these licences are subject to prior authorizations for sanitary registration and authorization of establishment. Moreover, it is not possible to sell the products without an authorized use and disposal certificate. The rejection of a use and disposal request leaves the importer with the option of re-exporting the merchandise to the place of origin or destroying it. Notwithstanding the above, the importer may appeal the rejection of a use and disposal request, and have the request authorized, by navigating to "Clarifications on use and disposal decisions (authorized and/or rejected)" on the GICONA platform.

17. The issue of an import licence for pharmaceutical and cosmetic products is subject to other conditions:

(a) For narcotics and psychotropic substances, there is a requirement of prior authorization of the official import certificate by the Public Health Institute. This certificate determines how much of the product can be imported.
(b) For products that are not subject to quantitative restrictions, there may be sanitary restrictions previously established by the Public Health Institute (products the importation of which is prohibited, products subject to an international health alert).

Other procedural requirements

18. Pursuant to Articles 180 and 183 of Supreme Decree No. 3/2010, a series control application is required for biological pharmaceutical products or those determined by the Public Health Institute.

In addition, all imports are subject to what the Public Health Institute has determined previously. When the importation is completed, the importer is required to prepare the corresponding local analysis certificate and submit it to the Public Health Institute.

19. To receive foreign exchange, the importer must obtain an authorized use and disposal certificate, since this document will enable the importer to sell the product in the country.

7 DIRECTORATE-GENERAL OF MOBILIZATION OF THE ARMED FORCES (DGMN)

7.1 Firearms, ammunition, explosives and inflammable or asphyxiating chemical substances and the facilities for their production, storage or deposit

Outline of systems

1. Any natural or legal person wishing to import, bring into the country or export items subject to control must request authorization directly from the Directorate-General or through the supervisory authorities, in accordance with the documents detailed in the regulations supplementing Law No. 17.798.

Purposes and coverage of licensing

2. The licensing systems apply to firearms, including their parts, spare parts, pieces, devices, tools or accessories that may be attached to them, intended for their shooting performance or effectiveness, and any other device, mechanism or tool allowing for the discharge of ammunition, explosive objects, bullets, birdshots, blank bullets and other projectiles, through the expansion of gunpowder gases or any other chemical compound, whatever their calibre, type, size, shape or the use to which they are put.

Tear gas or other gas with physiological effects, understood as any device, mechanism or tool intended to emit, produce or launch gases, smoke or mist, flames, electrical discharges or harmful chemical substances, normally referred to as *artificios* (devices).

Any loaded or unloaded device or projectile with a fuse or spark-producing mechanism or containing explosive, chemical, incendiary, fumigant, lachrymatory, emetic, paralysing or other similar substances.

Cartridges or ammunition used in weapons or devices and their components. Percussion caps, powder or any other chemical element used for the discharge of these projectiles shall be considered a component subject to control.

Explosives and explosive objects such as bombs, grenades and other devices of a similar nature, in addition to their parts and pieces, and chemical substances likely to be used or employed in the manufacture of explosives, and those that serve as the basis for the manufacture of ammunition, projectiles, missiles or rockets, bombs, cartridges and similar items, and, in general, substances or mixtures of substances capable of reacting chemically, with a high level of heat generation in a very short space of time and a considerable increase in volume in relation to their initial state.

Devices and auxiliary items for blasting or explosion, such as: primers, percussion caps, detonators, charges, fuses, detonator cords and other items, whether mechanical, electrical, non-electrical, electronic or of any other type, used to activate (in an instantaneous or delayed manner) an explosive chain, normally referred to as blasting accessories.

Factories, plants, mixer trucks, industries and workshops the purpose of which is to manufacture weapons, explosives or chemical products subject to control, and to condition or repair war materials, weapons or their essential spare parts, projectiles, missiles or rockets, bombs, cartridges and tear gas or other gas with physiological effects or any other device or projectile.

Fireworks and other devices of a similar nature, including their parts and pieces. 3

Facilities used or intended for use as warehouses, arsenals, dumps, tunnels and testing grounds or devices for weapons, explosives, fireworks and other controlled items, whether they are permanent, temporary or mobile constructions, and whether they are located at ground level or underground, and are buried or mobile.

Testing facilities and shooting ranges related to weapons, ammunition and permits granted in accordance with the Law.

Ammunition reloading machines of any type. (l) Spare parts, elements, pieces and accessories of the items subject to control.

3. The system applies to all countries of origin.

4. The procedure is not intended to restrict the quantity or value of imports. Its purpose is to register arms entering the country.

5. The licensing is maintained under Law No. 17.798 on arms control, and Law No. 21.310 amending Law No. 17.798 and its supplementary regulations.

Procedures

6. Not applicable.

7.(a) The application must be submitted at least 20 working days in advance, which is how long it takes for the Directorate-General of Mobilization of the Armed Forces to issue the authorization.

(b) The issue of a licence requires prior registration with the supervisory authority. Thus, a licence cannot be granted immediately if a person is not registered.

(c) Not applicable.

(d) The Directorate-General of Mobilization of the Armed Forces shall serve as the central coordinating authority at the national level for the supervision and monitoring of weapons, explosives, fireworks, chemical products and other items that the Law assigns to the Ministry of National Defence, and in this capacity shall give instructions to the supervisory and advisory authorities to ensure proper compliance with the Law.

The following authorities shall be responsible for implementing and monitoring the Law:

(a) The Armed Forces Garrison Commands,
(b) The highest-ranking authorities of the Chilean Carabineros (Carabiniers) in the jurisdictional area.

The implementing and monitoring authorities shall be appointed by the Minister of National Defence, at the proposal of the Director-General, to whom they shall report directly in performing the functions set forth in the Law, and shall, for such purposes, be known as "supervisory authorities". They shall be appointed pursuant to Supreme Decree (Secretariat General of the President's Office) No. 19 of 2001, issued by the Ministry of National Defence.

The following shall serve as advisory authorities under the terms provided for by law and by this Regulation:

The Army Research and Control Institute, in its capacity as Chile's Ballistic Test Bank, which will provide specialized technical advice to the Directorate-General and the supervisory authorities, either directly or through its regional branches and delegations.

The Director-General may request, through the Minister of National Defence, qualified technical advice from other specialized services of the Armed Forces or from their agencies and staff.

8. Failure to comply with the requirements laid down in the regulations supplementing Law No. 17.798.

Eligibility of importers to apply for licence

9. The registration requirements for importation applicable to private individuals, dealers and dealers on a one-off basis are set forth in the regulations supplementing Law No. 21.310 (https://www.dgmn.cl/leydearmas/wp-content/uploads/2021/06/reglamento_complementario_2007.pdf).

In order to register, dealers, importers, exporters, regular consumers, assemblers, transformers and repairers of controlled items must first submit a registration request to the relevant supervisory authority at their business address and attach the following documents:

(a) Identity details of the applicant and legal establishment of the legal entity and its legal representative.
(b) Request from the legal representative of the company or natural person stating the items to be registered and the quantities to be stored.
(c) Police record for special purposes, of the legal representative and of the partners in the case of a limited liability company, and of the board of directors in the case of a public limited company.
(d) Background information on the storage location, including a detailed description and scale sketch.
(e) Certified photocopy of the current municipal licence or mining concession, in the case of regular users of explosives.
(f) Photocopy of the company's tax identification number (RUT).
(g) For dealers in ammunition, gunpowder, chemical products and fireworks, a document from the local fire department must be provided to certify:

    1. That the facilities comply with fire safety measures.
    2. That there is an internal service equipped to tackle a fire outbreak.
    3. Degree of danger to and from neighbouring buildings, depending on the type of items and quantities requested to be stored by the interested party.

This certificate is not required for dealers who will store weapons only.

For dealers, it will be an indispensable requirement to have storage facilities.

The supervisory authority will issue a report to the Directorate-General giving its approval and will propose maximum storage quantities for each product, in accordance with the request made by the interested party, the merits of the background information and the inspection carried out.

Importers, exporters, manufacturers and repairers, in addition to registering as such, must register as dealers or regular consumers if the products they import or repair are intended for sale on the national or international market or for their own consumption.

Documentational and other requirements for application for licence

10. Any natural or legal person wishing to import, bring into the country or export items subject to control must request authorization directly from the Directorate-General or through the supervisory authorities.

11. The required documentation is detailed below.

(a) Private individuals for own consumption

1. Request by the interested party, whose form will be submitted by the Directorate-General and the supervisory authorities.
2. Photocopy of pro forma invoice with the stamp of the company or individual.
3. Police record for special purposes. Foreigners who do not possess this type of certificate must present a document issued by the relevant Embassy or Consulate, certifying that they are of good character.

In the case of weapons, the Directorate-General must verify that the interested party has a quota to register the weapons to be imported.

(b) Dealers

Any company wishing to import controlled items must be listed in the national registry as an importer, dealer or regular consumer of the items and may not exceed the permitted storage quotas. The requirements are as follows:

1. Request by the interested party, whose form will be submitted by the Directorate-General and the supervisory authorities.
2. Photocopy of pro forma invoice with company stamp.

(c) Dealers on a one-off basis

1. Request by the interested party, whose form will be submitted by the Directorate-General and the supervisory authorities.
2. Letter addressed to the Director-General outlining the basis for importing the product in question.
3. Photocopy of pro forma invoice with company stamp.
4. Police record of the legal representative for special purposes.

The import resolution will be valid for one year from the date of issue.

The Minister of National Defence, through the Director-General, shall grant authorization to those dealers wishing to bring in military weapons as exhibits for the institutions mentioned in Article 3. Subsequently, these weapons must be returned to the manufacturer in the country of origin or handed over to one of the authorized institutions to be held in trust, and may not remain in the dealer's possession.

The Chilean Ballistic Test Bank will provide registered importers with the required characteristics, the number of samples that must undergo laboratory tests in each importation, and the inspection conditions of the controlled products, so that they are aware of the tests to which they will be subjected.

Details of the forms can be found at https://www.dgmn.cl/leydearmas/tramites/autorizacion-para-importar-armas-municiones-o-repuestos/

12. For registration, the applicable duty rate must be paid for each of the items for which the interested party is registering. The same shall apply to registered dealers, importers, exporters, repairers, transformers and assemblers who request an increase in the number of authorized items, namely:

(a) Dealers of controlled products.
(b) Dealers of war material.
(c) Importers of controlled products.
(d) Importers of war material.
(e) Exporters of controlled products.
(f) Exporters of war material.
(g) Manufacturers of controlled products.
(h) Assemblers, repairers and transformers of controlled products.
(i) Regular consumers of controlled products.

13. There are no additional charges to the ones mentioned in point 12.

Conditions of licensing

14. Interested parties requesting annual renewal in the national registry before the expiration date are only required to submit an application specifying the items to be renewed and a current municipal licence or mining concession, as the case may be. For shooting clubs, a document from the Federation will be required, certifying that, on the date of renewal, the club is federated and that the corresponding fee is paid. If the interested party does not renew by the deadline, the registration will be considered expired, and he/she will have to go through all the steps of a new registration in the future.

15. No, there is no penalty.

16. The rights protected by the authorizations granted shall be non-transferable and inalienable, unless the corresponding procedure is carried out in the bodies established by Law No. 17.798. These authorizations shall be suspended, made conditional or lapse in the event of non-compliance with the conditions under which they were granted, without prejudice to the corresponding criminal proceedings.

17. Not applicable.

Other procedural requirements

18. Not applicable.

19. Not applicable.