



## INTRODUCTION

In order to safeguard, maintain and improve animal health in the country, imported products intended for animal consumption (complete feed, supplements and formulated additives), in any form or presentation, before entering the country, must be evaluated by the Agriculture and Livestock Service by reviewing their production process monograph, in order to verify compliance with current national regulations.

***All importers of animal feed must communicate the start of activities before the Service, in accordance with the provisions of Article N°7 of the animal feed regulations. You can access this procedure from the SAG online platform <https://cerofilas.sag.gob.cl/> or in person at the SAG office that corresponds to your facilities.***

All information must be submitted in Spanish, English or Portuguese, or originals in another language attaching the legal translation into Spanish or English, the latter if not available in Spanish.

The interested party must pay a fee of **5 UTM + VAT** for each product presented, or process line in the case of food for non-productive species, in accordance with the provisions of Exempt Resolution No. 7113/2016.

### IMPORTANT

- All additives and ingredients of vegetable and mineral origin in their pure state, i.e. not mixed with other additives or ingredients, are excluded from submitting your monograph.
- The need for monograph evaluation in the case of additives or ingredients may be consulted via e-mail.



**For the purposes of this document, the following definitions shall apply:**

**FODDER SPECIES:** those from which livestock products for human consumption are obtained, i.e. ruminants, pigs, poultry (meat or laying hens), meat rabbits, equines, bees, hydro-biological species for consumption, others.

**NON-PRODUCTIVE SPECIES:** those not intended for human consumption, such as dogs, cats, fish and ornamental birds, exotic species and zoological animals.

**PRODUCTION PROCESS MONOGRAPHY:** Corresponds to a technical document written by the manufacturer or person in charge of the production plant and endorsed or presented by the competent health authority of the country of origin, in which the industrial manufacturing process of a product intended for animal feed is described.

Within the monograph should be included:

- Raw Materials: Declare the complete list of ingredients and additives of the product, and their eventual substitutes.
- Products containing ingredients of animal origin must identify the supplier companies (company name and country), in addition to their official number or code issued by the competent health authority of the country of origin, if applicable.
- Nature of raw materials: species, tissue or organ from which it was obtained, or other as determined by the Service, as appropriate.
- Production process diagram: description of the stages and procedures applied in obtaining the finished product, or the process line, as appropriate.
- Physical form of the finished product, this should consider the following background:
  - Guaranteed chemical analysis, or other as determined necessary by the Service.
  - Storage conditions.
  - Shelf life of the product(s). according to the information provided.
  - Indications for use.
  - Precautions and warnings, when applicable.
  - Type of commercial presentation (characteristics of the container and net content).
  - Conditions and procedures for cleanliness of transport, in the case of supplements based on mixtures of ingredients of vegetable origin, with or without additives, authorized for transport and import in bulk.
  - In the case of products obtained in line from non-productive species, specify types and category of products as follows: complete feed, supplement, chewing product.

**MONOGRAPHIC EVALUATION REQUEST FORM:** Depending on the destination of the animal feed input, it will be for slaughter species (1 form per product) or for non-productive species (1 form per process line).



**PROCESS LINE:** The production process to which the product is subjected. Products that share the same manufacturing process, including heat treatment, should be considered the same line.

**Example of process lines:**

- Extruded
- Pelletized Sterilized
- Dehydrated
- Freeze-dried
- Mixed without heat treatment
- Other than above (specify)

**QUALITY ASSURANCE SYSTEM (QAS):** Type of system used (GMP, HACCP, ISO or other). Summary description of the system, according to the points required in Resolution N°5025/2009.

**CERTIFICATE OF FREE SALE (CLV):** The certificate of free sale must indicate the name and address of the producing establishment, trade name(s) of the product(s) and the declaration that the product(s) is (are) freely sold in its national territory. If possible, it should include the official number granted by the competent authority and the list of ingredients.

**The trade names indicated in the CLV must be the same as those under which the products will be marketed in our country.**

It must not be older than two years, except for those certificates that include a period of validity.

Must be original

It must be apostilled (for more information go to [www.apostilla.gob.cl](http://www.apostilla.gob.cl)). If the country of origin is not a member of the Hague Convention, it must be consularized.

An original certificate of free sale must be furnished for each resubmission. Certificates previously submitted to the Service in support of other products will not be considered. This is due to the fact that they are filed as background information for another process.

**STUDIES THAT ENDORSE PRODUCT SHELF LIFE:** These correspond to the studies carried out by factories or laboratories to determine the shelf life of a product, which is the period during which a foodstuff maintains certain characteristics and a level of quality suitable for consumption (preferential consumption).

**PRODUCT TITLE:** Product label. Of origin, it corresponds to the one used for commercialization in the manufacturing country. The national label must comply with the provisions of [Decree N°4/2016](#).



## **BACKGROUND FOR MONOGRAPH EVALUATION FOR FOOD FOR NON-PRODUCTIVE SPECIES**

They should be sent in **PDF format** to **alimentosanimales@sag.gob.cl**.

1. [Application for monographic evaluation for non-productive species](#): **1 application form** is submitted **for the process line**. Products should be grouped according to the process line and packaging if applicable, e.g.: Dry sterilized line, Canned wet sterilized line, Extruded line, etc.
2. Submit a list in Word format with the commercial names of the products submitted for evaluation (**must be the same as those indicated in CLV**).
3. Production process monograph. It must contain the information of all the products of the process line to be presented (Page 3).
4. Quality Assurance System (QAS)
5. Studies that endorse the useful life of the product.
6. Apostilled or consularized certificate of free sale.
7. Original product label
8. Signs to be used in Chile (according to [Decree N°4/2016](#)), in **Spanish** language.



## **BACKGROUND FOR MONOGRAPH EVALUATION FOR FOOD FOR SLAUGHTER SPECIES**

1. [Application for monographic evaluation](#): 1 application for each product.  
You must indicate the same commercial name indicated in CLV.
2. Deliver product composition in Word format.
3. Production Process Monograph (Page 3)
4. Quality Assurance System (QAS)
5. Studies that endorse the useful life of the product.
6. Apostilled or consularized certificate of free sale.
7. Original product label
8. Label to be used in Chile (according to [Decree N°4/2016](#)), in **Spanish** language.



## EVALUATION OF THE BACKGROUND:

Once all the background information has been submitted and the corresponding fee has been paid, the Service must issue a decision within a period of **no more than 60 calendar days**. This period does not include the waiting time for responses from the interested party.

During the evaluation process, the Service may request the submission of additional background information. This request will be made by letter or e-mail.

If within **six months** the interested party does not provide all the information required by the Service, the application will be considered withdrawn, unless the interested party requests in writing an extension of the evaluation. The fee paid will not be refunded.

## APPROVAL OR REJECTION:

If the result of the evaluation of the monograph is satisfactory, the resolution of approval of the monograph is issued.

**For supply species:** This resolution is individual, it authorizes the product according to the name contained in the certificate of free sale and its manufacturing or processing establishment (not the importer, exporter or consignee of the latter).

**For non-productive species:** The authorization is made through a single Resolution of Approval. This will include all the commercial names of the products elaborated in that line and will be valid for two years. After that, the data submitted must be updated.

If the result of the evaluation is negative, the rejection will be made by resolution, which will be notified to the applicant.

Any product approved by resolution of approval shall be included in the **"List of products for animal feed authorized by submission of the following documents of monograph of process"** <https://www.sag.gob.cl/ambitos-de-action/list-of-imported-animal-feed-products-authorized-by-process-monographs-by-direct-approval/registrations>



Date: 

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**REQUEST FOR MONOGRAPHIC EVALUATION OF FOOD SPECIES<sup>1</sup>**

I am requesting the evaluation of the monograph of the production process of the following product with the purpose of importing it to Chile:

Product trade name	Classification <sup>2</sup>	Species	Presentation <sup>3</sup>

<sup>1</sup>Ruminants, Swine, Poultry (meat or laying hens), meat rabbits, Equines, Bees, hydro-biological species for consumption, other productive species

<sup>2</sup> Indicate whether the product is a complete food, supplement, ingredient or formulated additive.

<sup>3</sup>Packaging, bulk (bulk products may enter only if they correspond to vegetable pre-mixes)

Importer's background:

Company name:	RUT:
Address:	
Commune:	
City:	
Region:	
Phone:	
Name of representative before SAG:	
E-mail:	

Manufacturer's Background:

Name of the Processing Plant:	
Address:	
City:	
Country:	No. Official:

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**IMPORTER SIGNATURE<sup>4</sup>**

Importers must make communication of initiation of activities before the SAG, according to Decree 4/2016, Animal Feed Regulation.



Date: 

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**REQUEST FOR MONOGRAPHIC EVALUATION OF NON PRODUCTIVE SPECIES<sup>1</sup>**

I am requesting the evaluation of the process line process monograph of the following establishment and its products with the purpose of importing them to Chile:

Company Name Establishment Producer	Process <sup>line2</sup>	Classification/target species <sup>3</sup>

<sup>1</sup> Non-productive species are those not intended for human consumption, i.e., dogs, cats, ornamental fish and birds, exotic species and zoo animals.

<sup>2</sup> Indicate type of process line:

- Dry products [extruded, pelletized, other].
- Wet products with/without sterilization [canned, pouch or sachet].
- Semi-wet products with/without sterilization
- Other (specify)

<sup>3</sup>In classification/species of destination, specify if it corresponds to a complete feed and/or supplement, ingredient and the species of destination.

Importer's background:

Company name:	RUT:
Address:	
Commune:	
City:	
Region:	
Phone:	
Name of representative before SAG:	
E-mail:	

Manufacturer's Background:

Name of the Processing Plant:	
Address:	
City:	
Country:	No. Official:

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**IMPORTER SIGNATURE<sup>4</sup>**

Importers must make communication of initiation of activities before the SAG, according to Decree 4/2016, Animal Feed Regulation.



## MODIFICATION OF RESOLUTION OF APPROVAL

There are cases in which the modifications made to a product imply a change in the Resolution that approved it, since a modification must be made in some of the paragraphs of said Resolution. This implies that the Resolution must be repealed and replaced by a new one.

The interested party shall pay a fee of 0.5 UTM + VAT for each application submitted, according to Resolution N° 7113/2016, resolvo 1.B.

In the case of food for non-productive species authorized prior to June 2020, a single request for modification of the name or company name may be submitted for all products produced in said process line, notwithstanding the above, the background information must identify all products susceptible to such modification.

The Service will decide within a period of **30** calendar **days** on the request.

### Modification types

- Modification of composition: This modification applies only to approving resolutions for **non-productive species** issued **prior to June 2020** and for **supply species**. In the case of resolutions issued for processing lines of **non-productive species**, authorized after June 2020, it will only be necessary to communicate the change to the Service.
- Modification of product trade name
- Change of target species
- Modification of the company name of the processing plant
- Modification of product shelf life

### Background information to be submitted:

1. Modification request for [supply](#) or [non-productive species](#), as appropriate.
2. Product label with the indicated modification.
3. Background information supporting the shelf life of the product(s) (product stability studies or other).
4. Certificate of free sale of the product(s).
5. Other additional background information supporting the modification.

**When evaluating the modification of a product, the current criteria in terms of sanitary requirements and risk analysis are applied, which is why it is possible that the authorization previously granted may now be denied.**



## Important

It must be taken into account that, when a modification is made, the previous approval resolution is repealed, therefore, it will be eliminated from the **"List of products for animal feed authorized through the presentation of a process monograph"**. As a consequence, the product will not be able to enter Chile as it was approved according to the repealed resolution, therefore, if it is presented in its "version" prior to the modification at any border crossing point, it **will be rejected** for not being approved.

Therefore, importers are advised to carry out this procedure in order to coordinate the product items to be entered in accordance with the above.

**The Service is not responsible for the rejection of consignments generated by mismatches between the modification of the authorization and the importation of a product.**



Date

**REQUEST FOR MODIFICATION OF APPROVAL  
RESOLUTION**

I am requesting your modification of the approval of the production process monograph for the following product:

<b>TRADE NAME (in the case of name modification, indicate the new one)</b>	<b>NO. AND DATE RESOLUTION OF APPROVAL</b>	<b>TYPE OF MODIFICATION<sup>1</sup></b>	<b>COUNTRY OF ORIGIN</b>

<sup>1</sup> Indicate whether it is a modification of the label (trade name), modification of the company name of the Processing Establishment, extension of the species of destination or extension of the shelf life of the product.

Importer's background:

Company name:	RUT:
Address:	
Commune:	
City:	
Region:	
Phone:	
Name of representative before SAG:	
E-mail:	

Manufacturer's background:

Name of the Processing Plant:	
Technical Director:	
E-mail:	
Address	City
Country:	No. Official:

\_\_\_\_\_  
**SIGNATURE AND NAME**

\_\_\_\_\_



Date:

**REQUEST FOR MODIFICATION OF THE RESOLUTION FOR APPROVAL OF  
NON-PRODUCTIVE SPECIES**

I am requesting your modification of the approval of the production process monograph for the following product(s):

TRADE NAME (in the case of a name change, please indicate the new)	NO. AND DATE OF RESOLUTION OF APPROVAL	TYPE OF MODIFICATION <sup>2</sup>	PROCESS LINE <sup>2</sup>	CLASSIFICATION/SPECIES <sup>3</sup>

1 Indicate whether it is a modification of the **label** (trade name), modification of the **company name** of the Processing Establishment, extension of the **species of destination**, extension of the **shelf life** of the product or **updating of** the resolution (without modifications).

2 Indicate type of process line, it should be grouped according to the process line and packaging if applicable, e.g.: Dry sterilized line, Canned wet sterilized line, Extruded line, etc.  
Extruded, pelletized, sterilized, dehydrated, freeze-dried, blended without heat treatment, other than above (please specify)

3 In classification/species of destination, specify whether it corresponds to a complete feed and/or supplement, and the species of destination.

Importer's background:

Company name:	RUT:
Address:	
Commune:	
City:	
Region:	
Phone:	
Name of representative before SAG:	
E-mail:	

Manufacturer's Background:

Name of the Processing Plant:	
Technical Director:	
E-mail:	
Address	City
Country:	No. Official:

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**SIGNATURE AND NAME**

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