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POLICY

Voluntary Public

Date: 5/17/2017

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Brazil

Post: Brasilia

Updated Plant and Label Registration Procedures for Fishery

Report Categories:

Food and Agricultural Import Regulations and Standards - Certification

Approved By:

Clay Hamilton, Agricultural Minister Counselor

Prepared By:

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Report Highlights:

Due to recent changes by Brazil in the procedures to register U.S plants that process fish and fishery products for human consumption, FAS/ Brasilia prepared this comprehensive report with instructions for U.S. exporters to register plants and product labels. FAS/Brasilia updated Annex IV of this report due to recent changes by the Brazilian Ministry of Agriculture.

General Information:

A. Step One – Plant Approval/Registration Process

All fishery plants must send a formal request to the National Oceanic and Atmospheric Administration's (NOAA) Seafood Inspection Program (USDC/SIP) to begin the registration process. After NOAA receives the formal request, it will contact FAS/Brasilia to submit the registration request to include the plant in Brazil's official list. The letter to NOAA must follow the format on [Annex I](#). Please be sure to include the table exactly as shown.

❖ Products Eligible to Export to Brazil

- Fresh and frozen fish;
- Roes and seasoned capelin roes;
- Frozen crustaceous;
- Frozen lobsters.

The United States does not have any agreement to export shrimp and live animals. NOAA and FAS are negotiating a Health certificate for live lobsters.

B. Step Two - New Label Registration Process

The new electronic system designed by the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) and the Department of Animal Products Inspection (DIPOA), can only be used to register new labels. Companies that already have labels registered in the old system do not need to resubmit them.

Once a U.S. plant is registered, a plant representative must submit an email request to FAS/Brasilia (priscila.ming@fas.usda.gov and agbrasilia@usda.gov) with the information listed below, to request access to the system. FAS/Brasilia will then generate and submit a letter to MAPA (system) on behalf of the company.

- Name of the plant:
- Plant number:
- Address (complete address of the plant, including zip code):
- Name of the representative of the plant:
- ID number (driver license or passport):
- Date of birth:
- E-mail address:

Copy of the personal ID (driver license or passport) of the person that will be in charge for the registration process of that specific plant

A letter in Portuguese from the plant authorizing this person to be the legal representative of the plant. Please use the attached template letter in [Annex IV](#).

Note: The new legislation (see [Annex II](#) and [Annex III](#)) gives instructions on how to use the system. According to this new legislation and the new system, FAS/Brasilia can only request access to the system for U.S. representatives of the plants.

FAS/Brasilia will not request access for Brazilian importers, consultants, or traders. The applicant must be in charge of the registration process and for securing all the files. This process is designed to maintain the integrity of confidential plant information. Under this process, MAPA will not request any additional certification information from the competent authority. FAS/Brasilia will not retain any personal identifiable information. If the registration information is lost, all labels will have to be re-registered.

FAS will notify the applicant when the information is submitted to MAPA. Once notified, the applicant can either complete the on-line process themselves or work with FAS/Brasilia by completing the following steps:

1. Once MAPA receives the information from FAS/Brasilia, the system will send a login and password to the U.S. authorized plant representative.
2. After receiving the login and password information, the U.S. plant representative can forward the login information to FAS/Brasilia (priscila.ming@fas.usda.gov and agbrasilvia@usda.gov) who in turn can complete the registration process on behalf of the company.
3. FAS/Brasilia will insert all the information in the system on behalf of U.S. companies.
4. As soon as the system approves the request, the representative indicated in the letter should receive an e-mail from the system. This representative will have the ability to insert the label applications into the system. At this stage, the designated representative can also nominate other representatives, importers, traders and or consultants to have access to the system and their files.

Note: The information from the U.S. plant and their representative will be kept confidential by MAPA. The U.S. company may define who will be the legal representative. After this phase is completed, companies can add as many people as they desire in the system and give them authority to manage the labels. FAS/Brasilia is not responsible if the representative of the company deletes anything in the system. FAS/Brasilia will not retain any personal identifiable information.

Annex I

NOTE: Please send to NOAA, a signed letter on company letterhead adhered to Clay Hamilton (see example below). NOAA will stamp the letter and forward to FAS/Brasilia:

US Department of Agriculture – USDA
 Foreign Agricultural Service - FAS
 Mr. Clay M. Hamilton
 Agricultural Counselor, American Embassy, FAS
 Av. das Nações, lote 3
 70403-900 Brasilia, DF - Brazil

Dear Sir,

We kindly ask you to register the following U.S. fishery plant with the Brazilian Minister of Agriculture:

Número de Controle (Estabelecimento) / Establishment number	Nome empresarial do estabelecimento / Establishment Name	Endereço completo do estabelecimento (cidade/estado) / Address of the Establishment (city/state and zip code) and telephone number	*Tipo de operação/ Type of operation (processing or storage)	**Categoria(s) / Category/ies	***Species	****Forma de obtenção/Ways of Attainment
			(Please check the definition on item *)	(Please check the definition on item **)	<i>Please include fish species</i>	<i>Please choose, Aquiculture, Vessel that manufacture, etc</i>

Note 1: Signed by the company's plant manager or someone responsible for the plant.

Note 2: NOAA will send the signed letter to FAS/Brasilia requesting the plant registration with MAPA.

***TYPE OF OPERATION:**

Slaughter – SL; Processing – PC; Stocking – ST

****CATEGORIES:**

Definitions:

1. **PRODUCTS IN NATURE:** Those which were not subjected to any other conservation process, besides cooling or freezing.
2. **PRODUCTS NOT SUBJECTED TO THERMAL TREATMENT:** Those containing added ingredients and /or additives, which are not the main factors for conserving its microbiologic stability, needing, however, the preservation by cold, without loss of the products in nature.
3. **PRODUCTS SUBJECTED TO THERMIC TREATMENT:** Those that undergo thermal treatment by heat, with the purpose of partial or total loss of the product's characteristics in nature, which may or may not need preservation by cold.
4. **PRODUCTS SUBJECTED TO THERMAL TREATMENT – COOKING:** Those that undergo thermal treatment by heat, low, with the purpose of destroying pathogenic, deteriorative microorganisms, and the inactivation of enzymes, occasionally present in the product, which may or may not need preservation by cold.
5. **PRODUCTS PROCESSED THERMALLY – COMMERCIAL STERILIZATION:** Those that undergo a thermal treatment of higher intensity when compared to cooking, with the purpose of destroying pathogenic, deteriorative microorganisms, and the majority of spores occasionally present in the products.
6. **PRODUCTS WITH ADDED INHIBITORS:** Those with added ingredients and/or additives, which are the main factors for conserving its microbiologic stability, which may or may not need preservation by cold.
7. **PRODUCTS SUBJECTED TO HYDROLYSIS:** Those subjected to a break of the protein chain with the purpose of adding a water molecule to its structure.
8. **PRODUCTS CONSISTING OF DIFFERENT CATEGORIES OF MEAT PRODUCTS WITH OR WITHOUT ADDED INGREDIENTS:** Those obtained from the association of products of different categories, with or without the addition of other ingredients, which may or may not need conservation by cold.

Annex II



MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY

DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS - DIPOA
Esplanada dos Ministérios, Bloco D, Anexo Ala A, 4º Andar, Sala 401, - Bairro Zona Cívico-
Administrativa, Brasília/DF, CEP 70043900
Telephone: (61) 3218-2014/2684 and Fax: - <http://www.agricultura.gov.br>

Official Letter-Circular no. 1/2017/DIPOA-SDA/SDA/MAPA

Brasília, January 16th, 2017

To

SIPOA/SISA/SIFISA Heads

Servants acting in the Federal Inspection Service

Legal responsible individuals of registered (SIF) and listed (ER) establishments

Foreign Health Authorities with view to the legal responsible individuals and export establishments for Brazil

Subject: **Registration of animal origin products. Change to procedures, communicates.**

Dear Sirs,

The DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS - DIPOA/SDA/MAPA communicates that from **18/01/2017** the registration of animal origin products will start to be conducted in a PGA, Agriculture and Cattle Raising Management Platform, system in module **PGA/SIGSIF**. This change will cover all the registrations of animal origin products, whether of a registered (SIF), listed (ER) or foreign (EE) establishment in compliance with the provisions of Decree no. 30.691, of March 9th, 1952, amended by Decree no. 8.681, of February 23rd, 2016.

All the inclusions of applications for the registration of animal origin products in the current system, Federal Inspection Service's Management Information Service – SIGSIF, and those submitted in paper forms (specifically in case of ER), **must be suspended as of that date**.

The applications for the registration of regulated products must be rejected by SIF or by SIPOA/SISA/SIFISA and the establishment must be guided to proceed with new insertion at PGA/SIGSIF.

The applications for the registration of standardized products, those requiring previous approval by DIPOA, and which have been entered at SIGSIF before that date, will be analyzed on a normal basis.

All the application for the registration of animal origin products of foreign establishments (EE) already submitted in paper forms will be analyzed on a normal basis.

As presented above and seeking for the lowest impact as possible in the implementation of the significant amendments communicated above, we hereby emphasize that:

1. In order to obtain the first access, the user must use the link: <http://sistemasweb.agricultura.gov.br/pages/PGA-SIGSIF.html>

2. For non-registered users, **the first access to the system** will be granted/authorized by MAPA upon request by the interested party, and evidence of bond with the establishment. Such bond must be evidenced by presenting the company's documentation indicating the users as being its representatives at PGA/SIGSIF and the user's ID (digitalized copy), if applicable accompanied by a vernacular translation;
3. The access will be granted by the State Managers of PGA/SIGSIF or by the Management Support Division - DSG/DIPOA;
4. The first access must be requested by the company's legal representative (SIF, ER or EE) in the "External Access Control Manager" profile, because the referred first user registered for each establishment will be responsible for releasing the access to the other users to be bonded to that SIF, ER and/or EE;
5. The REGULATED products will be registered in the form of filing by entering the data requested by the PGA/SIGSIF system;
6. The STANDARDIZED products, those without regulation, will be registered upon previous approval by DIPOA;
7. In order to insert the product registration, the search must be started by consulting the **type of establishment (SIF, ER or EE), establishment (corporate name) and standardized product**;
8. For some products with specific attributes, some files must be mandatorily attached so that the registration can be made effective. For example: For organic products, the Certificate of Organic, for products with geographical indication, the designation of Origin, among others. The file name is standard and the company must attach the corresponding file;
9. In the composition tab, the ingredients were classified as ADDITIVES, AROMAS, SINGLE or MIX. If the ingredient is composed of a mixture of at least 2 ingredients, it must be classified as MIX, the ingredients which compose such MIX must be described;
10. Once the unit of weight has been chosen for the ingredients, the system does not allow a change to the unit of weight between the entered ingredients (For example: if it is entered in grams, all the ingredients must be entered in grams, the insertion of liters or kilos will not be allowed). In the composition field, the disposition of the ingredients will be automatically ordered in a descending order of amounts, regardless of the type of ingredient (this system may be different from the order shown on the label);
11. There's a need to bind the entered label to the packages;
12. For the registration of a product with more than one sketch, all the sketches must be attached to a single file so that they are considered for legal purposes.

Yours faithfully,

- Attachments:
- I – Manual for the access to PGA/SIGSIF (SEI no. 1679851).
 - II – Manual for product registration at PGA/SIGSIF (SEI no. 1679866).
 - III – Instructions for the access to PGA/SIGSIF (SEI no. 1679880).
 - IV – Instructions for the product registration at PGA/SIGSIF (SEI no. 1679887).
 - V – Table of regulated products (SEI no. 1679897)



Document electronically signed by **RAFAEL OLIVIERI FILIPPETTI, Director of the Department of Inspection of Animal Origin Products – Deputy**, on 16/01/2017, at 06:16 p.m., official Brazilian time, with the use of a digital certificate issued in the scope of ICP-Brasil, based on art. 10, paragraph 2nd, of Provisional Measure no. 2.200-2, of August 24th, 2001.

Certificate's Serial No. 93885931556632891589631323816293389492



The authenticity of this document can be verified at website http://sistemas.agricultura.gov.br/sei/controlador_externo.php?acao=documento_conferir&id_orgao_acesso_externo=0, by informing the verifying code **1677903** and the CRC code **EE658FB9**.

Esplanada dos Ministérios, Bloco D, Anexo Ala A, 4^o Andar, Sala 401, - Bairro Zona Cívico-Administrativa, Brasília/DF, Telephone: (61) 3218-2014/2684 and Fax:

Annex III

SECRETARY OF AGRICULTURE AND CATTLE RAISING DEFENSE

NORMATIVE INSTRUCTION No. 1, OF JANUARY 11th, 2017

THE SECRETARY OF AGRICULTURE AND CATTLE RAISING DEFENSE, DEPUTY, OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY, in the use of the attributions granted to him by art. 18, subparagraph II, letter "I", and art. 53, both of Attachment I of Decree no. 8.852, of September 20th, 2016, considering the provisions of Law no. 1.283, of December 18th, 1950, in Decree no. 30.691, of March 29th, 1952, and what is contained in Process no. 21000.021334/2016- 62, resolves:

Art. 1st The procedures for the registration, renewal, amendment, audit and cancellation of the registration of animal origin products produced by establishments registered or listed in the Federal Inspection Service - SIF, and by foreign established authorized to export to the country, are established.

Art. 2nd The procedures for the registration, renewal, amendment, audit and cancellation of registration, addressed by this Normative Instruction, must be conducted by the Department of Inspection of Animal Origin Products of the Ministry of Agriculture, Livestock and Supply's Secretary of Agriculture and Cattle Raising Defense – DIPOA/SDA/MAPA

Sole paragraph. DIPOA may designate Federal Fiscal Agriculture and Cattle Raising Auditors who perform inspection activities of animal origin products in the Federal Agriculture, Livestock and Supply Superintendencies to conduct the analysis of registration, renewal, amendment applications and registration audit.

Art. 3rd The procedures for the registration, renewal, amendment and cancellation of registration addressed by this Normative Instruction must be electronically conducted in the computer system available at MAPA's website: www.agricultura.gov.br.

§ 1st The access to the electronic system will be granted upon previous authorization, by means of personal identification.

§ 2nd It is the user's sole responsibility to maintain the confidentiality of the password part of his/her electronic identification, being that it's not accepted, under any circumstances, the allegation of its undue use.

§ 3rd The directions for the use of the computer system are made available at MAPA's website.

Art. 4th The request for accessing the computer system, for national producing establishments, must be performed by its legal representative by means of electronic register.

§ 1st For the purposes of registry, the following documents must be submitted by electronic means:

I – copy of the establishment's by-laws; and

II – copy of the legal representative's personal ID.

§ 2nd The legal representative must authorize the users designated to conduct the activities related to the registration, amendment, renewal and cancellation of registration.

Art. 5th The request for accessing the computer system, for foreign producing establishments, must be performed by its legal representative by means of electronic register.

§ 1st For the purposes of registry, the following documents must be submitted by electronic means, accompanied by vernacular translation:

I – copy of the document issued by the authority of the country of origin indicating the establishment's representative, for the purposes addressed by this Normative Instruction; and

II – copy of the personal ID of the establishment's legal representative.

§ 2nd The representative must authorize the users designated to conduct the activities related to the registration, amendment, renewal and cancellation of registration.

Art. 6th The national producing establishment's legal representative and the foreign producing establishment's representative must maintain the list of its respective system users updated.

Art. 7th The registration application must be conducted by the national or foreign producing establishment, accompanied by the following information and documentary elements in Portuguese language:

I – establishment identification;

II – product identification and characterization data;

III – product composition indicating the ingredients in descending order of amount;

IV – description of the manufacturing process;

V – opinion of the health regulatory body about the use of functional or health property allegations, when such allegations are contained on the label;

VI – thermal processing calculation for canned products, submitted to commercial sterilization for each type of package and product weight;

VII – reliable and legible reproduction of the label, in its original colors, indicating its dimensions and size of the characters of the mandatory information of the label; and

VIII – other documents required by the legislation for granting the registration of specific products.

§ 1st The description of the manufacturing process must be performed on an ordered way and include the purchase or receipt of raw material, processing contemplating the time and temperature of the technological processes used, packaging, storage and preservation of the product, as well as the specifications providing the distinctive characteristics of the product.

§ 2nd The label may present variations in its dimensions, colors and drawings and all the variations must be sent for the purposes of registration.

§ 3rd Non-formulated meat products must have a single registration number whenever they are submitted to the same manufacturing process.

§ 4th Fish in nature must have a single registration number for the several species and presentation forms, whenever it is submitted to the same manufacturing process.

§ 5th The label printed exclusively in foreign language, of products intended for the international trade, must be registered along with its vernacular translation.

§ 6th Compound ingredients must have their components and amounts described.

Art. 8th The registration and amendment of the registration of products not covered by Decree no.

30.691, of March 29th, 1952, or in its complementary acts, must be performed upon previous approval of the information and documents contained in article 7th of this Normative Instruction. Art. 9th The registration and amendment of the registration of products covered by Decree no. 30.691, of March 29th,

1952, or in its complementary acts, must be performed by providing the information and documents contained in article 7th of this Normative Instruction.

Sole paragraph. The list of products provided for in the caput of this article is made available in the computer system addressed by this Normative Instruction.

Art. 10. The products intended for export can be manufactured and labeled according to the requirements of the country they are intended to.

Art. 11. The product registration must be renewed every 10 (ten) years upon request by the establishment before they are expired.

Art. 12. No change to the formulation, manufacturing process or label can be performed without previous update of the registration at DIPOA.

Art. 13. The information contained in the product registration must exactly correspond to the procedures conducted by the establishment.

Art. 14. The number to be assigned to the product registration must be generated by the establishment and automatically controlled by the computer system.

§ 1st Each number corresponds to a registration, being that its reuse is not allowed.

§ 2nd The registration number must be separated by bars from the establishment's registration or control number.

Art. 15. The change to the product sale denomination implies the application of a new registration.

Art. 16. DIPOA must conduct a product registration audit in order to verify the compliance with the legislation and the conformity of the documents and information provided by the establishment.

Art. 17. When non-conformities related to the product registration are found, DIPOA must notify the national producing establishment or the health authority of the country of origin of the foreign producing establishment, specifying the non-conformity and, if applicable, the deadline for its correction.

Sole paragraph. The failure to comply with the measures determined by DIPOA implies the cancellation of the registration.

Art. 18. The cancellation of the registration is automatic in the following situations:

I – if requested by the establishment; and

II – due to the expiration of the registration without application for renewal.

Art. 19. The registration must be cancelled in case of failure comply with the provisions of Law no. 1.283/1950, of Decree no. 30.691/1952, and of the other applicable rules.

Art. 20. The registrations already existing on the date this Normative Instruction is published will remain valid for 10 years from the date it is granted.

Sole paragraph. Any renewal or amendment implies new registration, upon compliance with the procedures established in this Normative Instruction.

Art. 21. DIPOA may request, during the registration process or subsequently, the original of the documents electronically presented by the applicant.

Sole paragraph. The original documents must be preserved for the validity of the product registration.

Art. 22. DIPOA may request additional information or documents in order to subsidize the analysis of the registration application, amendment and audit.

Art. 23. The cancellation of the registration does not impair the application of the fiscal actions and applicable penalties resulting from the violation to the legislation.

Art. 24. This Normative Instruction comes into force on the date it is published.

Art. 25. Ordinance SIPA no. 9, of February 26th, 1986 is revoked.

JORGE CAETANO JUNIOR

DOU 18/01/2017

Annex IV (UPDATED)

LETTER HEAD OF THE COMPANY

PORTUGUESE VERSION

DECLARAÇÃO

**REPRESENTANTE DE ESTABELECIMENTO
ESTRANGEIRO PERANTE A AUTORIDADE
SANITÁRIA DO BRASIL**

Diante da publicação da Instrução Normativa N° 01, de 11 de janeiro de 2017 da Secretaria de Defesa Agropecuária – SDA/MAPA, que estabelece os procedimentos para registro, renovação, alteração, auditoria e cancelamento de registro de produtos de origem animal produzidos por estabelecimentos registrados ou relacionados no Serviço de Inspeção Federal - SIF, e por estabelecimentos estrangeiros habilitados a exportar para o Brasil, vimos por meio deste indicar o (a) senhor (a) _____ *complete name/the same as the document* _____, portador do _____ *description of the document, passport, or driver license* _____ “number* _____, e-mail _____, como representante do estabelecimento estrangeiro _____ *name of the establishment*/must be the same as the Brazil list of approved plants_____, sob número de controle veterinário ____ *plant number* _____, localizado no país Estados Unidos da América, para acesso à Plataforma de Gestão Agropecuária – PGA.

Assinatura e carimbo do representante legal do estabelecimento estrangeiro

LETTER HEAD OF THE COMPANY

ENGLISH VERSION

DECLARATION

REPRESENTATIVE OF A FOREIGN ESTABLISHMENT TO PRESENT TO THE SANITARY AUTHORITY OF BRAZIL

In view of the publication of Normative Instruction No. 01 of January 11, 2017 of the Agricultural Defense Secretariat - SDA / MAPA, which establishes the procedures for registration, renewal, alteration, audit and cancellation of registration of products of animal origin produced by registered establishments or related in the Federal Inspection Service - SIF, and by foreign establishments qualified to export to Brazil, we hereby indicate the _____ * full name/the same as described in the document * _____, bearer of _____ *description of the document, passport, or driver license ** _____ number _____, e-mail _____, as representative of the foreign establishment _____ * establishment name / must be the same as the Brazil list of approved plants * _____, under veterinary control number _*plant number*, located in the country United States of America, for access to the Platform of Agricultural Management - PGA.

Signature and Stamp of the legal representative of the foreign establishment