

FEDERATIVE REPUBLIC OF BRAZIL MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY - MAPA SECRETARIAT OF ANIMAL AND PLANT HEALTH AND INSPECTION - SDA DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS - DIPOA

CIRCULAR LETTER DIPOA/SDA No. 42/2010

Brasilia, 30th November 2010.

From: Director of the Department of Inspection of Animal Origin Products - DIPOA

Ref: Instructions for filling out the REGISTRATION FORM FOR LABELS AND IMPORTED PRODUCTS OF ANIMAL ORIGIN.

In view of the provisions of Normative Instruction No. 22 of the Ministry of Agriculture, Livestock, and Food Supply (MAPA), dated 24th November 2005 (IN 22/05), approving the TECHNICAL REGULATION FOR LABELLING OF PACKED PRODUCTS OF ANIMAL ORIGIN, and considering the need to regulate registration procedures for imported products of animal origin, thus establishing requirements equivalent to those in place for the registration of animal products produced by domestic establishments inspected by the FEDERAL INSPECTION SERVICE - SIF, of the Department of Inspection of Animal Origin Products - DIPOA, this Department has developed guidelines on filling out the REGISTRATION FORM FOR LABELS OF IMPORTED PRODUCTS OF ANIMAL ORIGIN, attached, and additional information on the subject.

After analyzing the comments received in response to Brazilian notification G/SPS/N/BRA/654 about Circular Letter DIPOA/SDA N° 14/2010, the document was reviewed.

The contents of the form changed to comply with IN 22/05.

Only foreign establishments authorized by the DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS – DIPOA - may request registration of their labels and products.

All foreign establishments authorized to export to Brazil should register their products at DIPOA before applying for an Importation License, as established in this document.

As of **1st April 2011** all requests for registration of imported products of animal origin shall comply with the provisions of this instruction in order to be approved.

Establishments that already have registered products will have until **1**st **April 2012** to adjust all registrations. After such date, all registrations will be automatically canceled. Any label not compliant with the current Brazilian legislation should be immediately adjusted.

Labels approved according Circular Letter n° 14/2010 are valid for 10 (ten) years as of the date of approval, not requiring further evaluation.

Approved labels will be valid for 10 (ten) years as of the date of approval; such validity shall be conferred at the time of application for the Importation License - LI. If during such period, there is an amendment to the legislation or if new legislation is put into force that requires adjustments in labels already approved, the labels should be immediately changed and submitted to DIPOA's evaluation.

1 - Documents to be sent for registration of imported products of animal origin:

a) Form: two original copies of the form should be sent to the following address, stating the address to return of the analyzed process:

Departamento de Inspeção de Produtos de Origem Animal Ministério da Agricultura, Pecuária e Abastecimento Esplanada dos Ministérios, Bloco D, Anexo A CEP 70043-900 Brasília – DF Brasil http://www.agricultura.gov.br

b) The Sketches of the Labels of the packaging displayed to final consumers should be attached in their original formats and colors. These labels should include all compulsory information (as per legislation by MAPA and other inspection agencies).

c) Secondary and tertiary packaging that will not be shown to final consumers, used only for storage and transportation purposes, shall not be registered provided the packaged product displays all compulsory information in its labeling and is approved.

Nevertheless, such packaging should display at least:

- Trade name

- Information on the manufacturer (name, registration number of the establishment at the official agency, and address)

- Stamp of the Official Service, if applicable.

- Conservation of the product
- Production and expiry dates.

d) When it is not possible to attach the sketches of the labels in their original size, the actual dimensions of the label to be used should be included.

e) When the compulsory information is displayed on the labeling through the use of adhesive labels (IN 22/05), one should also attach a sketch of the original label/packaging indicating the place to affix the labels.

2 – Filling out instructions:

The REGISTRATION FORM FOR LABELS should be filled out in Portuguese (Spanish will be tolerated).

Each sheet should be filled out as described below:

Field 1.1 – Fill out the veterinary/health control or registration number of the producing establishment, corresponding to the registration number at the AGENCY OF INDUSTRIAL AND HEALTH INSPECTION OF PRODUCTS OF ANIMAL ORIGIN OF THE GOVERNMENT OF THE EXPORTING COUNTRY. Field 1.2. – Fill out the name and address of the agency mentioned in Field 1.1. In case there is an official hallmark (stamp of the official inspection agency) it should be placed on the label;

Field 1.3. – Fill out the sequential number, considering numbering in ascending order, followed by slash and the veterinary/health registration number of the producing establishment at the agency mentioned in Field 1.1. above;

Field 1.4. – Form submission date, to be entered by DIPOA on receipt of said form;

Field 1.5. - Enter the corporate name of producer, which should be the same contained on the label;

Field 1.6 - Enter the full address of the producing establishment (city, state and country), including telephone, fax, email and/or website;

Field 3.1.1 - Applies in case of application for product registration.

Field 3.1.2. - Applies in case of a change in the product manufacturing process and/or change in the composition of a product already registered, in which case the initial registration number is maintained;

Field 3.1.3. - Applies only to change to the sketch of the label, in which case the initial registration number is maintained;

Field 3.1.4. - Applies to companies wishing to request cancellation of product registration;

Field 4.1. - Enter product name in a manner that is clear and understandable for consumers;

Field 4.2 - Enter product brand name;

Field 5.1.1. - Applies to labels printed on paper or plastic;

Field 5.1.2. - Applies when product identification is made through an adhesive label and not a traditional label, containing all information about the product and its origin;

Adhesive labels should be waterproof, indelible and inviolable;

Field 5.1.3. - Applies when label drawings and wording are printed directly on the recipient;

Field 5.1.4. - Applies to products in wooden packaging;

Field 5.1.5. – Applies to products in packaging whose label is printed directly on the container through lithography;

Field 5.1.6 – Please indicate any other type not listed in the form;

Fields 5.2.1 to 5.2.5 - Self-explanatory.

Field 6.1. - Indicate product weight or volume. For bottled liquids, also indicate the drained net weight. For products whose weights vary, the label should

comply with specific Brazilian legislation and, as appropriate, packaging weight should be stated on the label.

Field 6.2. - Such information should be shown on the label, as per specific Brazilian legislation.

Field 7 – The place where the producing establishment is located should be considered.

Field 8 – Self-explanatory.

Field 9.1 – As per item 1.1.

Field 9.2 - As per item 1.3.

Field 10.1 - Product ingredients should be stated in descending order of initial weight or volume, including additives and corresponding INS number. The percentages of the ingredients must totalize 100%.

When a combination of ingredients and/or additives is used in the formulation of the product for which registration is being requested, a description of each of the components as well as their percentages should be presented.

Ingredients' percentages should total 100%;

Field 11 – Enter an orderly description of the product manufacturing process, from obtaining or receiving raw material, until processing and shipping final products to the Brazilian market.

Inform process and product parameters that are references for checking final product quality (time, temperature, humidity, etc.).

Field 12 - Describe how primary, secondary or other packaging is carried out along the production flow.

Field 13 - Describe how and where the product is stored, specifying the temperature in case refrigeration is required;

Field 14 - Describe in detail QUALITY CONTROL procedures used by industry during all stages of the industrialization process;

Field 15 – Describe all steps and care taken to transport products to their final destination;

Field 16 - Inform where importer's information should be placed in the label.

The information on the importer (company name, number at the National Companies Registry - Ministry of Finance of Brazil - CNPJ/MF and address, telephone, etc.) should be included on the label to be exposed to the consumer.

Field 17 - Attach, if necessary or requested, control records, graphs (for example, control of the sterilization process for canned products), technical specifications of products, technical and scientific literature subsidizing the submission, etc.;

Field 18 – The place where the producing establishment is located should be considered.

Field 19 - Self-explanatory.

FORM TO BE USED BY THE VETERINARY/HEALTH AUTHORITY IN CHARGE OF HEALTH AND HYGIENE CONTROL ONLY

Field 2 – The competent health authority should check whether the establishment complies with all the items.

Field 3 - This field is reserved for further explanations by the Representative of the Veterinary/Health Service.

Field 4 – The place where the producing establishment is located should be considered.

Field 5 - Self-explanatory.

3 - Sketch of Label

1. The labels should be compliant with Instruction 22/05 and the legislation of other inspection agencies.

2. Companies should prefer the use of labels printed with the compulsory information in Portuguese.

3. In accordance with item 3.4 of the regulation approved by MAPA's Instruction No. 22/05, "the labeling of products of animal origin should only be carried out in processing establishments authorized by the competent authority in the country of origin for preparation or fractioning. When labeling is not written in the language of the destination country, an additional label should be affixed containing the mandatory information in the appropriate language with characters of appropriate size, clear and visible. This label can be placed either in the origin or destination. In the latter case, it should be placed before marketing."

The additional label mentioned is the label previously approved by DIPOA in the process of registration of imported products, directing also the sketch of the label/original packaging, indicating the location where the labels will be fixed.

4. As provided for by IN 22/05, the trade name should be in the label's main panel in highlight, with characters that are uniform in color and body, and without the interleaving drawings or other wording.

5. Expressions such as traditional, original, special, premium, more ..., best quality, healthy, etc., will not be accepted without due justification for evaluation by DIPOA, and when accepted the label should contain text explaining such differential.

4 - Evaluation by DIPOA

After analysis of the form and sketch, the Divisions/CGI/DIPOA shall issue an opinion as per the standard form attached, and the label may be: **1. Not Approved**: In this case all the sheets should be stamped with the term Not Approved or Failed by the Division.

2. Approved with Restriction: The label may be used only after restrictions are resolved.

3. Approved.

After the analysis of the request, the FFA in charge of evaluation shall stamp the labels affixed with the model stamp below:

DIPOA/SDA/MAPA
□ Not Approved
□ Approved
□ Approved with restriction
Brasília,//

The option corresponding to the result of the evaluation should be ticked, stamped and signed.

Upon request of the Importation License – LI - the importer/company should also submit the label approved and stamped as described above.

This document and its annexes should be circulated to all involved (importing companies, authorized foreign companies, embassies of countries exporting to Brazil, SIPOAS/SISAS/SIFISAS, VIGIAGRO).

This Circular Letter revokes Circular 125/1998 DCI/DIPOA and Circular Letter DIPOA/SDA n° 14/10.

Annex I - REGISTRATION FORM TO BE SENT TO EVALUATION. Annex II - FORM TO BE USED BY DIPOA ONLY Annex III - MINIMUM MANDATORY INFORMATION FOR THE LABEL

Yours,



	FEDERATIVE REPUBLIC OF BRAZIL MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY - MAPA				
	SECRETARIAT OF ANIMAL AND PLANT HEALTH AND INSPECTION - SDA				
	DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS - DIPOA REGISTRATION FORM FOR LABELS OF IMPORTED PRODUCTS OF ANIMAL ORIGIN				
1 – I	DENTIFICATION				
1.1 - No. of veterinary/health control of producing establishment in the country of origin:					
1.2 - Name and	address of the central agency in charge of the veterinary/health control of producing establishment:				
1.3 - Number of	product registration in the Ministry of Agriculture of Brazil:///////.				
1.4 Date of subr	nission to DIPOA:////				
1.5 – Corporate	name (name) of producing establishment:				
1.6 - Address of	f producing establishment:				
	PPLICATION				
	n Director of DIPOA,				
	ed company, through its legal representative and its technical manager, requests from this Department the Ind in item 3 of this sheet.				
P					
	YPE OF REQUEST				
3.1 - Request: 3.1.1 □ REGISTR.	ATION 3.1.2 D CHANGE IN COMPOSITION/MANUFACTURING PROCESS				
3.1.3 □ CHANGE	IN THE LABEL 3.1.4 CANCELATION				
	RODUCT IDENTIFICATION				
4.1 Product N	lame (Trade name) – original and in Portuguese:				
4.2 - Brand:					
4.2 - Diana.					
5 - 0	CHARACTERISTICS OF LABEL AND PACKAGING				
5.1 - Label:					
5.1.1 PRINTED 5.1.2 ADHESIV	5.1.3 □ RELIEF PRINTING 5.1.5 □ LITHOGRAPHY E LABEL 5.1.4 □ HEAT PRINTING 5.1.6 □ OTHER ()				
5.2 – Packaging:					
5.2.1 🗆 CAN	5.2.2 □ PAPER 5.2.3 □ PLASTIC 5.2.4 □ NATURAL PACKAGING 5.2.5 □ OTHER ()				
	QUANTITY AND FORM OF IDENTIFICATION				
6.1 - Quantity of	product packed and the unit of measure used:				
6. 2 - Manufacti	uring or packaging date and shelf life (place and manner of statement):				
7 - P	LACE AND DATE				
<u> 8 -</u> A	UTHENTICATION				

Signature and stamp of the legal representative of Signature and stamp of the technical manager of producing producing establishment establishment (*) Sequential number, followed by a slash and the number of official registration of the establishment at the Veterinary Inspection Service or Health Inspection Service. The registration number must be indicated on the label and on the international health certificate of products exported to Brazil. Model as per Circular Letter DIPOA No. 42/2010



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9 - IDENTIFICATION

9.1 - No. of veterinary/health control of producing establishment:

9.2 - Number of product registration at the Ministry of Agriculture of Brazil:(*)

10 - COMPOSITION

10.1 - Ingredients	KG OR L	PERCENTAGE (%)
TOTAL		100%

11 - MANUFACTURING PROCESS

Description:



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11 - MANUFACTURING PROCESS (cont.) Description:

12 - PACKAGING SYSTEM

Description:

13 - STORAGE

Description:

14 - QUALITY CONTROL / PRODUCT CONSERVATION

Description:



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15 – PRODUCT TRANSPORTATION

Description:

16 - IMPORTER INFORMATION

Please indicate the place and manner of affixing the information on the importer :

17 - DOCUMENTS ATTACHED

Please list:

18 - PLACE AND DATE

19 - AUTHENTICATION				
Signature and stamp of the legal representative of the	Signature and stamp of the technical manager of the producing			
producing establishment	establishment			



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REGISTRATION FORM FOR LABELS / IMPORTED PRODUCTS OF ANIMAL ORIGIN

FORM TO BE USED BY THE VETERINARY/HEALTH AUTHORITY IN CHARGE OF HEALTH AND HYGIENE CONTROL ONLY

1 - IDENTIFICATION

1. 1. - Corporate name of producing establishment:

1. 2. No. of veterinary/health control of producing establishment:

2 - CERTIFICATION OF VETERINARY / HEALTH AUTHORITY

I, the undersigned, certify that:

1. The company implements the quality control methods informed in an appropriate manner;

2. The facilities, equipment and production flow are appropriate and approved for the development of the product;

3. The company implements the manufacturing process and meets the product composition as described;

4. The establishment has the qualification required to manufacture and export the product to the Brazilian market.

3. COMMENTS

4. PLACE AND DATE

5. AUTHENTICATION

Full name of Veterinary/Health Service official in charge of producing establishment

Signature and Stamp of Veterinary/Health Service official in charge of producing establishment



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FORM TO BE USED BY DIPOA ONLY

1 - IDENTIFICATION

1.1 – No. of veterinary / health control of the producing establishment:					
1.3 - Number of product registration at the Ministry of Agriculture of Brazil:/					
1.4 - Date of submission to DIPOA:////					
1.5 – Corporate name (trade name) of producing establishme	nt:				
1.6 - Address of producing establishment:					
2 – TYPE OF REQUEST 2.1 - Request:					
	HANGE IN MANUFACTURING PROCESS / COMPOSITION				
3 - PRODUCT IDENTIFICATION					
3.1 Product Name (trade name)::					
24 B 1					
3.2 - Brand:					
4 - CHARACTERISTICS OF THE LABEL AND I	PACKING				
4.1 - Label:					
4.1.1 □ PRINTED 4.1.3 □ RELIEF PRINT 4.1.2 □ ADHESIVE LABEL 4.1.4 □ HEAT PRINTIN					
5.2 - Packaging					
5.2.1 CAN 5.2.2 PAPER 5.2.3 PLASTIC	5.2.4 D NATURAL PACKAGING	5.2.5 🗆 OTHER			
5 - QUANTITY / FORM OF IDENTIFICATION 5.1 - Quantity of product packed and the unit of measure used:					
6 - CONSIDERATION OF REQUEST FOR LABB	EL REGISTRATION				
Dear Sir/Madam Head of Division, we propose the label is		NOT APPROVED.			
Notes on restrictions *:					
* Restrictions should be resolved before the making and use 7 - PLACE AND DATE OF ANALYSIS OF REQU					
7 - FLACE AND DATE OF ANALISIS OF REQU	JES1				
BRASÍLIA, DF, BRAZIL,/////					
8 - AUTHENTICATION					
	Approved **				
	Approved with restrictions **				
	Not approved, as explained in Box 6 above.				
	** Valid for 10 (ten) years.				
	BRASILIA, DF, BRAZIL/////				
Signature and stamp of Veterinarian FFA of DIPOA	Signature and stamp of Head of Division /	CGI / DIPOA			

Model as per Circular Letter No. 42/10 DIPOA.

Minimum mandatory information for the LABEL TO BE AFFIXED TO THE ORIGINAL PACKAGING, FOR IDENTIFICATION IN PORTUGUESE OF IMPORTED GOODS TO BE MARKETED IN BRAZIL, as per IN 22/05.

1. Product name in Portuguese

2. Ingredients: (in descending order of initial amounts in the formula, including additives used, if any)

3. Produced by (corporate name of product manufacturer)

Location of the producing establishment (city, state and country)

4. Est. Number (health control number at the Veterinary/Health Service for Inspection of Products of Animal Origin. The official stamp or hallmark (inspection stamp) of the agency in charge of health control of the product may be placed on this label).

5. Batch identification

6. Manufacturing date (day / month / year)

7. Expiry date (day / month / year)

8. Net content

9. Registration at the Ministry of Agriculture SIF/DIPOA under No. 0000/000 (sequential number - 4 digits, slash, followed by the health control number of the establishment) for each product.

(name of the nationality adjective of the country of origin) Industry

Note: Additional information on product conservation, storage and use can be displayed on the label; in addition, it should comply with the requirements of other inspection agencies.