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US Market Accessibility
Introduction Guide for Food Labeling

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US Market Accessibility - Introduction Guide for Food Labeling

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Introduction

Presentation

Labels are a fundamental element especially for all goods intended for direct consumption: labels are the real identity card of the product and are the primary means of information for the consumer. For this reason, every country has precise rules so that the indications on labels follow a certain order, not misleading and not incomplete.
In the USA, food products and their labeling rules are regulated by the FDA (Food and Drug Administration).
Just recently, after more than 20 years from the latest legislation, the institution has decided to modify its labeling regulations introducing some important changes. The change of rules was necessary because the old nutritional labels, in force since 1994, have not helped to the decrease of the obesity rate in the United States.
The new rules also extend to goods imported from third countries, therefore it is good that any agricultural-food company interested in exporting its products in the USA territory inquire about it and apply to the FDA regulations.
This short guide, certainly not exhaustive, wants to give an indication of all the procedures that a European exporter of agricultural-food products in USA must necessarily know and apply. In addition to the indications for a correct labeling, it will be mentioned also the registration procedures with the FDA and the indication of the voluntary content on the product packaging; finally, some notes on USDA labeling will be provided (valid for red and white meat and eggs).

Sources

Images and labeling guide

- https://bit.ly/3f4xWpH
- https://bit.ly/2X3CHtw

Allergens

- https://bit.ly/30eOkzN
- https://bit.ly/30f7GVF

Claims

- USDA:
  - Label Claims for Conventional Foods and Dietary Supplements (https://bit.ly/2X4KpU7)
  - Nutrient Content Claims Notification for Foods and Dietary Supplements Containing Linoleic Acid (https://bit.ly/2DcP1AI)
- https://bit.ly/2X3CHtw

Additives

- https://bit.ly/3hVDVii

New requirements provided by the USA legislation

Reference legislation

The legislation of the importation of food products into the USA is managed and regulated by Federal Government departments and connected agencies:

Department of Agriculture (USDA)[1]: department responsible for the development and implementation of federal government US policies related to livestock, agriculture and food which includes:

- **Food Safety and Inspection Service (FSIS)**[2];
- **Animal and Plant Health Inspection Service (APHIS)**[3];

Department of Health and Human Services (HHS)[4]: department that heads the protection of the health of American citizens which includes:

Food and Drug Administration (FDA)[5], agency responsible of the regulations and supervision of food safety, dietary supplements, medications, vaccines and medical -biological products. It is the most important reference regarding the exportations of food products;

Department of Homeland Security (DHS)[6]: department responsible for internal security.

For alcoholic and malt drinks (beer), the Department of Treasury deals through Alcohol and Tobacco Tax and Trade Bureau (TTB) of the procedures for the importation of these products: http://www.ttb.gov.

Classifications and customs tariffs are published in the Harmonized Tariff Schedule of the United States (HTS) under the responsibility of the United States International Trade Commission (Office of Tariff Affairs and Trade Agreements).

In the United States the list of calls and alerts is available at the following website: http://www.fda.gov/Safety/Recalls.

The first report to the FDA may come with the food inspection, on indication of the manufacturing companies, on alarms sent by the health system and on the advice of the Center for Disease Prevention and Control (CDC). If the FDA considers necessary to alert consumers based on the classic reporting, it provides the divulgation of the reports through the media or other means of communication.

Subsequently the reports are subject to checks and, only if they are confirmed and the alert is classified based on the health severity, goods are withdrawn, according to a procedure that can be consulted in **FDA 10: Product Recalls** at the following link: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm.

The publications of the alerts take place weekly; it

[1] See http://www.usda.gov.
[2] See http://www.fsis.usda.gov.
[3] See http://www.aphis.usda.gov.
[4] See http://www.hhs.gov.
[5] See http://www.fda.gov.
[6] See http://www.dhs.gov.

is possible do the registration on internet for receive updated information and for receive any online reports.

Procedure

FDA registration to obtain the "FDA number"

Registering the company with the Food and Drug Administration (FDA) is mandatory by USA law. Without the FDA registration number is impossible to export food products into the United States. The information needed to proceed to the FDA registration are:

- Business name
- Company address
- Warehouse address
- Responsible person
- Telephone / Fax number
- Type of processing performed on the food products
- Address of the warehouse where the food products to be exported into United States are stored
- List of all food product categories stored in the warehouse mentioned before
- Warehouse features: controlled temperature, cold room, temperature environment etc.

Please note: at the end of the registration, it is released the **FDA number** that will be for business relevance; it will be indicated in the import practice in the USA and must be attached in the United States import customs practice used by the customs declarant for the customs clearance of food at the American customs.
You need to have an FDA number even for ship food samples.
If the company has multiple warehouses and if the products to be exported into the America are stored in more than one warehouse, you must ask for an FDA registration for each of the warehouses where the products are stored. The same applies for the plants of production.

Designation of the FDA Agent (mandatory by law) The FDA requires the name of a representative agent of the Italian company in the United States (natural person or legal) that has its domicile / headquarters in the United States. It is an administrative contact person with no powers. It is not a commercial or legal figure, it is only the one that connect the FDA, Food and Drug Administration, to the Italian manufacturer, a company that the FDA can contact for any communication without having any language problems, time zone or cost for abroad calls.

Preparation of the Food Safety Plan [HARPC]

Since September 2016, a series of FDA regulations relating to the safety of food preparations have been into effect. The legislation goes with the name of FSMA (Food Safety Modernization Act). The Food Safety Plan for FSMA, summarized in the HARPC manual has the objective on identifying risks (the procurement of raw materials, food production processes, storage and transport of finished products) with also a special attention to the implementation of appropriate corrective and proactive actions to prevent contamination.
The basic elements for the preparation of Food Safety HARPC plan are:

- the **risk analysis** for all the procedures of food processing[7];
- the development, implementation, monitor the effectiveness of preventive **controls**;
- development of a detailed written **plan** that describe: how risks will be controlled,
- preventive controls put in place, program and methodology for monitoring the controls efficiency;
- **verification** of the control efficiency, with written records of verification processes, like for example:
  - adoption of sanitary procedures in the contact points of the food surface; hygiene guarantee of tools and equipment;
  - staff training;
  - environmental monitoring program (for pathogenic controls);
  - food allergen control program;
  - keep record activities;
  - supplier verification activities;
- the update of the HARCP plan is at least every three years; more often, however, if new product lines are added or if machinery is changed or are adopted new product lines for the production.

Please note: FSMA is also American importers' responsibility, since they now have an obligation to certify the products and producers from which they import are precisely in accordance with the FSMA.

FCE registration for long-life conservation canned foods with low acidity

For food specialties such as tuna in oil, peeled tomatoes, preserves, canned or long-life conservation products, **FCE** (**Food Canning Establishment**) **registration** is required at the FDA.
In addition to the FCE registration, it is also necessary to obtain a **prior import authorization** (**SID procedure**). The authorization procedure examines the sterilization process of the product and shows to the customers that the product has been registered with the FDA.
The FDA rules regarding the certification FCE registration and SID process filing are complicate and contain numerous exemptions for various products depending on the processing method and other factors.
Please pay attention that the FDA inspectors can stop the import of food for weeks, requesting further information from the producers and sending samples in the laboratory.

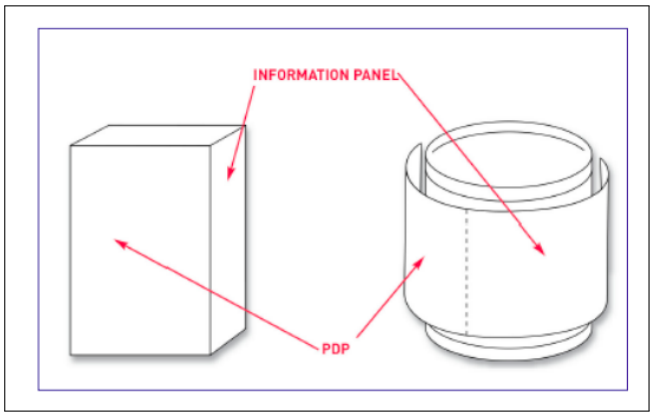
Request for import permits in the United States

Some products require an import permit and health certificates issued by the ASL. Before proceeding with the export, it must be carefully checked if or not import permits are required so it is possible to request them on time.

[7] Examples of risks identified in the HARPC manual: physical and radiological, biological, chemical, natural toxins, pesticides, drug residues, decomposition hazards, parasites, allergens, food additives and unapproved dyes; hazards / risks present in nature and / or unintentionally introduced into the food chain; hazard / risks intentionally introduced (including also the ones followed by terrorism acts).

Labeling

Revision of the Labels for the USA



Food labels to be exported into the United States must comply with FDA regulations. These are very precise rules that concern both the content of the label and its shape.

- **PDP** (**Principal Display Panel**): main side, the side most exposed to the consumer at the time of purchase. The information that are always mandatory on the PDP are:
  - **name of the food**: evident, parallel to the packaging and not misleading
  - **net quantity**: expressed in solid or liquid measurements, both in metric units and in American sizes (pounds, ounces, gallons etc). Expressed at a specific point and with a precise character size. If the packaging is multipack indicate number e weight of the individual packs;
- **Information Panel**, side to the right of the PDP, containing:
  - **Name and address of the manufacturer, packer or distributor**:
    - if the name is not of the manufacturer add "*manufactured for*" or "*distributed by*";
    - street address, city, country and postal code;
  - **List of ingredients**:
    - they must be indicated with their common or usual name, in weight descending order;
    - water is considered an ingredient and always had to be indicated; spices and flavors can be indicated with their own common name or just with their category;
    - the ingredients of the ingredients must be indicated between parentheses next to the name;
    - the indication of the allergenic contents must be at the end with the word "contains" followed by the list, in characters not inferior of those of the ingredients;

INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE [VITAMIN B_1], RIBOFLAVIN [VITAMIN B_2], FOLIC ACID), WATER, VEGETABLE OIL (SOYBEAN OIL, PALM OIL AND PALM KERNEL OIL WITH TBHQ AND CITRIC ACID FOR FRESHNESS), EGGS, LEAVENING (BAKING SODA, SODIUM ALUMINUM PHOSPHATE, MONOCALCIUM PHOSPHATE), SUGAR, CONTAINS TWO PERCENT OR LESS OF SALT, CALCIUM CARBONATE, WHEY, SOY LECITHIN, VITAMIN A PALMITATE, NIACINAMIDE, REDUCED IRON, YELLOW #5, PYRIDOXINE HYDROCHLORIDE (VITAMIN B_6), THIAMIN HYDROCHLORIDE (VITAMIN B_1), RIBOFLAVIN (VITAMIN B_2), YELLOW #6, VITAMIN B_{12}.

CONTAINS WHEAT, EGG, MILK AND SOY INGREDIENTS.

- **Nutrition Facts** (nutrition label):

- it is mandatory except in particular cases (e.g. spices, instant coffee, small packs);
- it is always included in a box, where there is indicated only the nutritional information;
- the values are obtained from calculations and laboratory analyzes (it is preferable the laboratories that use the AOAC method, or equivalent);
- percentage values can be found in C.F.R. 21, 101.9 (c);
- the size of the characters and the lines are reported in the C.F.R. 21, 101.9 (d); there is a horizontal format if the vertical does not fit with the packaging; in case of multi-component pack it is possible to use multiple single tables or one joint table;
- the "Proposed rule" denies the new *Nutrition Facts* (image below);

List of differences and multiple significant changes introduced with the new rules:

- the **Serving Sizes** change (and consequently the Serving Sizes change for Container); daily **quantities** change, and also the percentages of each ingredient in the value tables nutritional must be updated;
- it is mandatory a **double column nutritional table** for those food specialties that can also be consumed integrally (not only in portions);
- *Calories notation* is eliminated by *Fat*;
- Vitamins A and C notation are eliminated;
- it is mandatory to indicate Potassium and Vitamin D;
- the most significant changes, however, is the obligation to clearly indicate the "**Added Sugar**" and the new definition of the "**Dietary Fiber**". The FDA is about to issue further rules relating these two elements.

The new labels change size and position of texts and borders.

Please note: Although already in force since last January 1, companies that invoice less than 10 million dollars per year from the sale of food products have until January 01, 2021 to comply.

Please note: The expiration of the products is not mandatory. It can be indicated by the company voluntarily.

For a correct labeling it must be taken in consideration the following areas:

- Nutritional values
- Ingredients
- Allergens
- Dyes
- Preservatives
- Assertions made on the label ("Claim"):

  - natural: everything which nothing artificial or synthetic has been added;
  - fresh: the food has not been under processing;
  - organic: for finished unprocessed or processed agricultural products or in ingredients derived from these products;

- Main label elements.

Allergens

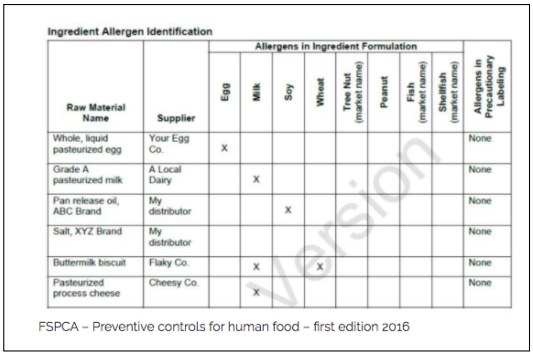
Foods that can create allergies or intolerances with reference to US law. They must be indicated at the bottom of the labeling with the word "*Contains*":

- Wheat
- Crustaceans and products based on crustacean
- Eggs and products based on egg
- Fish and products based on fish
- Peanuts and products based on peanut
- Soy and products based on soy
- Milk and products based on milk
- Nuts (almonds, hazelnuts, walnuts, cashew nuts, pecans, Brazil nuts, pistachios, macadamia nuts + coconuts and pine nuts, chestnuts).


INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE [VITAMIN B_1], RIBOFLAVIN [VITAMIN B_2], FOLIC ACID), WATER, VEGETABLE OIL (SOYBEAN OIL, PALM OIL AND PALM KERNEL OIL WITH TBHQ AND CITRIC ACID FOR FRESHNESS), EGGS, LEAVENING (BAKING SODA, SODIUM ALUMINUM PHOSPHATE, MONOCALCIUM PHOSPHATE), SUGAR, CONTAINS TWO PERCENT OR LESS OF SALT, CALCIUM CARBONATE, WHEY, SOY LECITHIN, VITAMIN A PALMITATE, NIACINAMIDE, REDUCED IRON, YELLOW #5, PYRIDOXINE HYDROCHLORIDE (VITAMIN B_6), THIAMIN HYDROCHLORIDE (VITAMIN B_1), RIBOFLAVIN (VITAMIN B_2), YELLOW #6, VITAMIN B_{12}.

CONTAINS WHEAT, EGG, MILK AND SOY INGREDIENTS.

To manage the allergen danger, to the Food Safety Plan is good implement it with the **Allergen Preventive Control**.
The first step is to analyze the risk of allergens for each production line starting with the **ingredient allergen identification** (identification of allergens on each of the raw materials used).


Ingredient Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Product Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Whole, liquid pasteurized egg	Your Egg Co.	X								None
Grade A pasteurized milk	A Local Dairy		X							None
Pan release oil, ABC Brand	My distributor			X						None
Salt, XYZ Brand	My distributor									None
Buttermilk biscuit	Flaky Co.		X		X					None
Pasteurized process cheese	Cheesy Co.		X							None

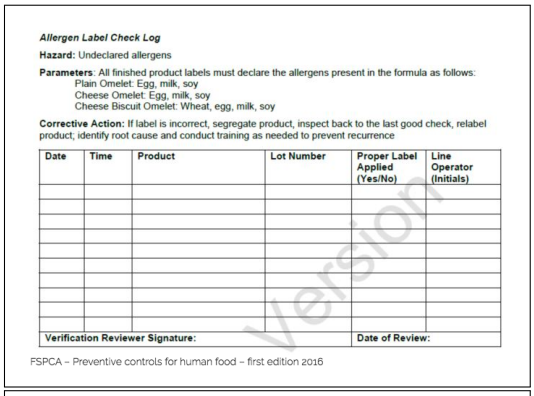
FSPCA – Preventive controls for human food – first edition 2016

The second step is to check the possibility of contamination during the different processing phases. The allergenic risk analysis must therefore be done for each of the processing phases.
Where from the analysis mentioned emerges the need for control, the following aspects must be indicated:

- the risk;
- the used evaluation criterion;

- the monitoring system that must be adopted to minimize the risk;
- corrective actions;
- verification activity;
- the recordings that need to be made.

In addition, an **Allergen Label Check Log** (in order to check the correctness of the labels, as regards the allergen declaration) and the **Allergen Run Order record** (for the correctness of the production plan application).
Finally, all basic principles of the good standards processing (such as staff training, staff clothing, product storage, etc.) remain valid and appropriate in the USA market.



Allergen Label Check Log

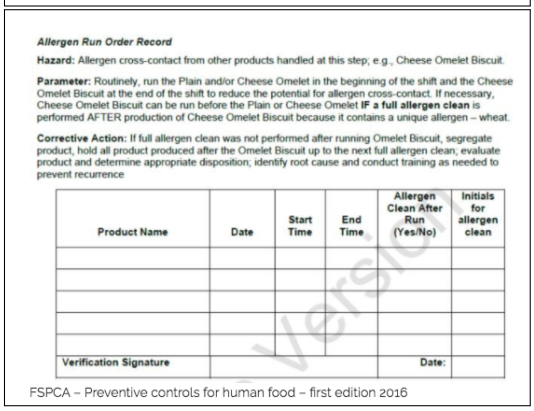
Hazard: Undeclared allergens

Parameters: All finished product labels must declare the allergens present in the formula as follows:
Plain Omelet: Egg, milk, soy
Cheese Omelet: Egg, milk, soy
Cheese Biscuit Omelet: Wheat, egg, milk, soy

Corrective Action: If label is incorrect, segregate product, inspect back to the last good check, relabel product; identify root cause and conduct training as needed to prevent recurrence

Date	Time	Product	Lot Number	Proper Label Applied (Yes/No)	Line Operator (Initials)
Verification Reviewer Signature:				Date of Review:	

FSPCA – Preventive controls for human food – first edition 2016



Allergen Run Order Record

Hazard: Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit.

Parameter: Routinely, run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact. If necessary, Cheese Omelet Biscuit can be run before the Plain or Cheese Omelet **IF a full allergen clean** is performed AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

Corrective Action: If full allergen clean was not performed after running Omelet Biscuit, segregate product, hold all product produced after the Omelet Biscuit up to the next full allergen clean; evaluate product and determine appropriate disposition; identify root cause and conduct training as needed to prevent recurrence

Product Name	Date	Start Time	End Time	Allergen Clean After Run (Yes/No)	Initials for allergen clean
Verification Signature				Date:	

FSPCA – Preventive controls for human food – first edition 2016

Claims

The term **claim** means the nutritional or health indications applied on the packaging of food products for advertising purposes, which exalt or describe particular characteristics capable of inspire the interest of the final consumer. Among those that can be used on food supplement labels are three categories of claims that are defined by the FDA:

- **health claims**;
- **nutrient content claims**;
- **structure function claims**.

Health Claims

They describe a **relationship between a food substance and a reduced risk of a disease or of a health-related condition**. There are three ways the FDA supervise health claims determining which ones can be used in labeling:

- the 1990 **Nutrition Labeling and Education Act** (**NLEA**) provides that the FDA issues regulations authorizing health claims for foods and food supplements after examining and evaluating scientific evidence; NLEA provides the use of health claims in the labeling that characterize a relationship between a food, a food component or a dietary ingredient and the risk of a disease, only if the indications meet certain criteria and are authorized by an FDA regulation. The FDA authorizes these types of health claims based on a large review of the scientific literature, using the significant standard scientific agreement for determine if the substance / disease relationship it's well established;
- the 1997 **Food and Drug Administration Modernization Act** (**FDAMA**) provides health claims based on an authoritative statement from the National Academy of Sciences or from a scientific body of the government of the States United responsible for public health protection or nutritional research;

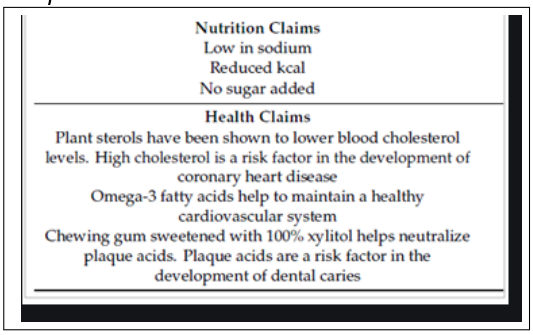
provides a second way to authorize the use of a health claim on the food labeling. Under the FDAMA, a new health claim can be authorized by submitting a notification to the FDA of an indication based on an "authoritative statement" from some scientific bodies of the United States government or the National Academy of Sciences. The FDA has published a guide on how a company can file such notification and make use of authoritative indications based on statements. FDAMA does not include food supplements in the arrangements relating to health claims based on authoritative statements;

- **Qualified Health Claims** (**QHCs**) are supported by scientific evidence, but do not meet the "significant scientific agreement" standards required for an indication on authorized health. To ensure that these claims are not misleading, must be accompanied by a statement of non-responsibility or by another qualified language to accurately communicate to consumers the level of scientific evidence supporting the request.
  Food manufacturers can submit a petition to the agency for evaluate the faculty to exercise the discretionary power over the application of a qualified health claim. The FDA does not "approve" petitions of qualified health claims. For a QHC petition with credible scientific evidence, the FDA issues a discretion letter that includes a specific request language that reflects the support level of the scientific evidence and the details of all the discretion factors of the application according to which the FDA will not oppose to the use of the QHC.

Nutrient Content Claims

The **Nutrition Labeling and Education Act** (NLEA) of 1990 allows the use of indications on the label that characterize the level of a nutrient in a food (the nutrient content claims) if they have been authorized by the FDA and are made in accordance with FDA authorization regulations. The statements on nutrient content claims describe the level of a nutrient in the product, using terms like “free”, “high” and “low”, or comparing the level of a nutrient in a food with one of another food, using terms like “plus”, “reduced” and “light”. An accurate quantitative description (for example 200 mg of sodium) which does not "characterize" the level of nutrients, can be used for describe the amount of a present nutrient.
Most regulations on the request for nutritional content claim only applies to those nutrients that have an established daily value.

Example of Nutrition Claims and Health Claims



The requirements governing the use of nutrient content claims help to ensure that descriptive terms, such as *“high”* or *“low”*, are used consistently for all types of food and are significant for consumers. The percentual indications for food supplements are another category of claims on nutritional content. These statements are used to describe the percentual level of an ingredient dietary in a food supplement and may refer to dietary ingredients for which there is no daily value established, as long as the indication is

accompanied by a declaration based on the amount of the dietary ingredient per serving.

Structure Function Claims

The **Nutritional Supplements Health and Education Act** of 1994 (DSHEA) established some special regulatory requirements and procedures for the use of structure function claims and two types of indications on the labeling of food supplements, general well-being indications and relative indications to a nutrient deficiency disease.
Statements about structure / function can describe the role of a nutritional or dietary ingredient intended to influence normal structure or function of the human body, for example "calcium builds strong bones". In addition, they can characterize the way which a nutrient or a dietary ingredient acts for maintain the structure or function, for example "the fiber maintains intestinal regularity" or "antioxidants maintain cell integrity". The general indications on well-being describe the general well-being resulting from the consumption of a nutrient or a dietary ingredient. The statements about nutrient deficiency disease describe a good thing related to a nutrient deficiency disease (such as vitamin C and scurvy), but such statements are only allowed if indicate how much the disease is spread into the United States. These three types of statements are not pre-approved by the FDA, but the manufacturer must have the proof that the request is truthful and not misleading and must present one notification with the text of the request to the FDA under and no later than 30 days after the marketing of the dietary supplement with the complaint.

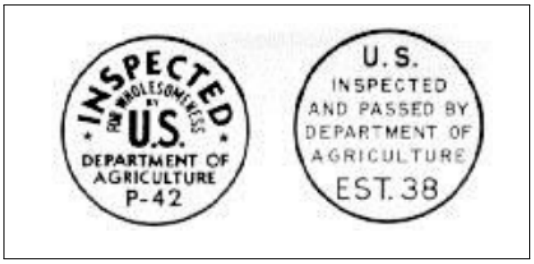
U.S.D.A. labels

For export food products such as meats, eggs, poultry in the USA it is necessary to contact the U.S. Department of Agriculture authorities (USDA):

APHIS / USDA (Animal and Plant Health Inspection Service / United States Department of Agriculture): defines the "country risk" in relation to the health status regarding animal pathologies;

FSIS / USDA (Food Safety and Inspection Service / United States Department of Agriculture): defines food safety standards.

The consignor country must have an agreement with these agencies for export this kind of products into the USA.



In addition to the standards described for generic labels for the exportation of food products into USA territory, the inspection stamp must be present and mandatory on the label PdP.
The following should also be indicated:

- **Safe Handling Statement**: requested for products that need it for maintain health conditions (for example *Keep refrigerated*, *Keep frozen*, etc.);
- **Safe Handling Instructions**: requested for raw or partially cooked food (not classified as *Ready To Eat*).

Please note: All indications of nutrition facts, claims nutritional, ingredient list and expiration date are the same as products regulated by the FDA.
Meat and poultry must be subject to specific inspections by the local veterinary service before to be

admitted to the United States. Will be examined the inspection systems adopted abroad to verify that follow the same requirements of those used in the United States; this verification it is performed by FSIS which also checks the samples of the goods imported at the moment of their admission into the country. Another thing that will be checked, at the port of entry into the United States, is the presence of adequate labeling, any of damages caused by transport and in general the condition of the goods. However, all products that can be exported must come from factories and slaughterhouses registered on the list of USDA approved establishments. These requests of registrations must be accompanied by the confirmation certificate from the official veterinarian indicating the preparation of standard sanitization procedures (SSOP), *Hazard Analysis and Critical Control Points* (HACCP) and the compliance of standards USDA-FSIS for salmonella. After it will proceed at the ministerial inspection of the factory.

Additives

Food coloring additives require US FDA approval. Shape and the approval time depend on the characteristics of the additive colorant. For the most part of these the best way to obtain the approval is through the Color Batch Certification program expected by the FDA for the approval of each batch. For obtain the certification of different batches of additive colorants, manufacturers must provide the FDA with a representative sample of each batch of additive together with the required documentation. There FDA analyzes the additive colorant sample for verify that it meets the specific requests. According to United States legislation all additives are described in CFR 21, 170, listing the 32 categories of additives (against 26 in EU) and adopting a different nomenclature from the EU.