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Panama

Food and Agricultural Import Regulations and Standards -Narrative

2017 FAIRS Narrative Report for Panama

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Report Highlights:

The U.S.-Panama Trade Promotion Agreement entered into force on October 31, 2012, and established simplified requirements for the importation of U.S. food and feed products. Amendments to this bilateral agreement have facilitated U.S. beef, beef products and pet food exports to Panama. Consumers continue to perceive U.S. food products as high quality, wholesome and reliable, which has resulted in a continuous growth in demand. Panama imports 60% of all its agricultural product needs from the United States.

Section I. Food Laws:

Acronyms used in this document:

GOP: Government of Panama

TPA: U.S. - Panama Trade Promotion Agreement

AUPSA: Panamanian Food Safety Authority

MIDA: Ministry of Agricultural Development of Panama OIE: International Organization for Animal Health

BSE: Bovine Spongiform Encephalopathy

MINSA: Ministry of Health of Panama USDA: U.S. Department of Agriculture FSIS: Food Safety Inspection Service

APHIS: Animal and Plant Health Inspection Service

NOAA: National Oceanic and Atmospheric Administration

Panama has adhered to the terms of the bilateral agreement with the United States regarding certain sanitary and phytosanitary measures and technical standards affecting trade in agricultural products, which is an integral part of the TPA, by publishing the following regulations:

- Law Decree 11 of 22 February 2006, published 24 February 2006, which created the Food Safety Authority, AUPSA, responsible for SPS and certain measures related to the importation of food and feed products.
- MIDA Resolution No. 60 of 24 March 2006, published 8 February 2007, by which Panama grants equivalence recognition to the U.S. sanitary and phytosanitary systems for meats, poultry, dairy and other products for human and animal consumption. Also contains provisions related to certification requirements for U.S. agricultural exports to Panama.
- MIDA Resolution No. DAL-216-ADM of 23 August 2006, published 8 February 2007, by which Panama adopts OIE consistent measures related to BSE for U.S. bovine products.
- MINSA Resolution No. 070-A of 24 March 2006, published 12 February 2007, by which Panama grants equivalence recognition to the U.S. sanitary and phytosanitary systems for meats, poultry, dairy and other products for human and animal consumption. Also contains provisions related to certification requirements for U.S. agricultural exports to Panama.
- MIDA Resolution No. DAL-30-ADM of 2 June 2006, published 27 February 2007, by which Panama recognizes U.S. beef grading and cuts nomenclature systems as equivalent.
- MIDA Resolution No. DAL-274-ADM of 20 November 2006, published 27 February 2007, by which Panama accepts U.S. measures related to Newcastle disease and Avian Influenza as consistent with directives from the OIE, and permits the importation of U.S. poultry and poultry products into Panama. Also contains provisions related to certification requirements for U.S. poultry products.
- Panama's Food Safety Authority (AUPSA) Scientific and Technical Council of Food Safety Resolution No. 001, of 22 February 2007 published 27 February 2007, and corrected 1 March 2007, by which it recognizes the equivalence of the U.S. sanitary and phytosanitary systems for the importation of meats, poultry, dairy and other products, and contains provisions related to certification requirements. Establishes alternatives to product registration.
- AUPSA's Scientific and Technical Council of Food Safety Resolution No. 002 of February 28, 2007, published March 1, 2007, by which Panama grandfathers MIDA's Resolution DAL-216-

- ADM, and MIDA Resolution No. DAL-274-ADM on BSE and avian diseases.
- AUPSA's Scientific and Technical Council of Food Safety Resolution No. 002 of May 17, 2013, by which it modifies the Resolution No. 001 of February 22, 2007 that recognizes the equivalence of the U.S. sanitary and phytosanitary systems for the importation of meats, poultry, dairy and other products, and contains provisions related to certification requirements. With this amendment of the Annex of the Resolution 001, henceforth there is no need to use the Bovine Export Verification Program for U.S. Beef and Beef products exports to Panama.
- AUPSA's Scientific and Technical Council of Food Safety Resolution No. 002 of February 10, 2015, by which it modifies the Resolution No. 001 of February 22, 2007 that recognizes the equivalence of the U.S. sanitary and phytosanitary systems for the importation of meats, poultry, dairy and other products, and contains provisions related to certification requirements. With this amendment of the Annex of the Resolution 001, henceforth simplifies exports to Panama of U.S. Pet Food containing animal origin ingredients.
- Executive Decree No. 65 of June 9, 1997 establishes the mandatory Hazard Analysis Critical Control Point or HACCP for all beef, dairy and fishery plants for Panama.

Complete text of these regulations may be accessed by date of publication at this hyperlink of the Official Gazette of Panama.

Besides the above mentioned laws and regulations, the U.S.-Panama Trade Promotion Agreement (TPA) which entered into force on October 31, 2012, has several chapters that established new applicable regulations for U.S. food products exported to Panama such as the chapters on Market Access, Sanitary and Phytosanitary Measures, Technical Barriers to Trade, Rules of Origin, and Intellectual Property Rights among others. The complete text of the TPA can be accessed through this hyperlink of the U.S. Trade Representative website.

Section II. Labeling Requirements:

The label can be in English. There is no requirement for labels to be in Spanish (Article 36 of Law 45 of October 31, 2007), except for medicines, agricultural chemicals, toxic products, and food products that require specific instructions or warnings because of risks to human health, such as health enhancers.

Article 36 of Law 45 of October 31, 2007 defines labeling requirement as follows:

"It is the responsibility of suppliers to consumers:

1- To inform consumers in a clear and truthful manner, of the characteristics of products or services offered, such as their nature, composition, contents, weight, origin, date of expiration, toxicity, precautions, price and any other condition, all of which will be printed on the label of the container or on the shelves where products are offered to consumers."

Expiration date and country of origin of the product are the most important details that local inspectors look for in labels of imported food products. The Authority for Consumers Protection and Defense of Competition (ACODECO) routinely inspects supermarkets and smaller stores (mom & pop's), checking expiration dates on food products. Results are published in newspapers to warn consumers. Weight checks are done mostly on rice and pulses sold in supermarkets. ACODECO and MINSA are empowered to confiscate expired products and to fine stores that offer them to consumers.

For dietary products containing Aspartame or Acesulfame K, an individual label in Spanish must state that the product contains Phenylalanine, according to the Executive Decree No. 423 of June 12, 1993 and MINSA Resolution No. 11 of July 12, 1994.

Other Specific Labeling Requirements:

Poultry products: The <u>Technical Regulation DGNTI-COPANIT No. 33-480-2007</u> of the Ministry of Commerce and Industry of Panama, General Directorate of Standards and Industrial Technology, establishes on its article 7.1.2. That the label must include:

- The statement "keep refrigerated or frozen" according to the case.
- Expiration date for the fresh-refrigerated or frozen product:
- · Half-life with the legend: "Consume before" or "Consume preferably before"
- Half-life for the fresh-refrigerated product: not exceeding 0 to 7 degrees Celsius for a maximum of ten (10) days.
- Half-life for the frozen product: at a temperature between 0 and -18 degrees Celsius for a maximum of one (1) year.
- Date of production.

Milled rice: All milled rice sold in Panama, according to the <u>Technical Regulation DGNTI-COPANIT</u>
No. 75 of 2002, must be labeled that it contains "no less than 95 percent of long grain rice" for Special Rice or "no less than 95 percent of medium grain rice" for Premier Rice.

Dietary supplements and vitamins: If a product says in the label that it has any type of therapeutic or health improvement purpose, it needs to get a certified authorization of the Department of Pharmacy and Drugs of the Ministry of Health of Panama, before it can be registered with AUPSA. All the documentation in English must be accompanied with a Spanish translation for the process at MINSA.

Baby food: Since April 2014, all baby food products, such as infant formula, complementary food (fruit and vegetable juices, puree), baby bottles and pacifiers need to have additional stickers over the product labels in Spanish and uppercase font that states, "Mother's milk is the best food for infants." Panama issued the Executive Decree 513 of May 14, 2013, and Executive Decree 1457 of October 30, 2012, Regulating Law No. 50 of November 23, 1995, which protects and promotes breastfeeding. The new regulation is applicable for locally produced and imported products.

Section III. Packaging and Container Regulations:

Panama requires that all products are packaged with "food grade materials". There are technical regulations issued for specific products (section VI of this report), which has packaging materials requirements.

According to Article 54 of Law Decree 11 of February 22, 2006, all processed food products for retail, bottled or packaged in some form with given name and brand, must be registered at the Panamanian Food Safety Authority (AUPSA), prior to importation. This means that all food products intended for retail as a final product for direct consumption must be registered prior to importation, sale or trade. Excluded from the above are raw materials such as fresh meats (which are not packed and ready for retail), fresh vegetables and fresh fruits, grains in bulk loads or in bags, dairy product in bulk loads or in bags for further processing, ingredients and additives for the process of a final food product.

For bottled water there is a specific returnable plastic bottle regulation, according to MINSA Resolution No. 181 of August 10, 2001.

Section IV. Food Additives Regulations:

Panama adheres to the Codex Alimentarius Standards in regards to food additives as established by Codex Standard 192-1995 and other Codex Standards for specific categories of food products.

There are some specific food additive regulations:

- Technical Regulation DGNTI-COPANIT (Panama) 08-241-1998 concerns Deli products (hams, sausages).
- It is forbidden to use additives in frozen calamari, per Codex Stan 191-1995.
- For cooking oil and cooking fat/greases/butter, the food coloring, antioxidants, emulsifiers, thickeners, stabilizers and flavors must comply with the Codex Alimentarius standard.
- For beverages in powder mixes, it is forbidden to have cyclamate as an additive, as established in Technical Regulation DGNTI-COPANIT (Panama) 26-399-1999 and in MINSA Decree No. 56 of October 18, 1971.
- All food products must be free of glycerol, sorbitol or propylene glycol, as established on Panama's Executive Decree No. 386 of November 30, 2006.

If a food additive is going to be exported to Panama for the food processing industry, it must be brought in through AUPSA's import procedures as described in section IX of this report and with its specific Technical Regulations.

Section V. Pesticides and Other Contaminants:

MINSA Executive Decree No. 467, from November 7, 2007, published in Official Gazette No. 25932 of December 4, 2007, dictates the maximum limits of pesticide residues and other contaminants in fruits and vegetables for internal consumption as well as for exports. This rule adopts maximum levels applied by the CODEX, the EPA, and the EU, whichever is the lowest. It establishes that the Ministry of Health will collect samples from warehouses and supermarkets, while the Ministry of Agricultural Development will collect samples at farms. No frequency for sampling is established, and cost of analysis is charged to distributors and importers.

Panama has a residue laboratory to analyze food products for pesticides and other contaminants. Random samples are taken from imported food products to be tested at this lab, which uses USDA and/or EPA tolerances for pesticides, and has been reviewed by private consultants to improve procedures and effectiveness (activity supported by FAS). In addition, they are applying for ISO certification.

Section VI. Other Regulations and Requirements:

Technical Regulations, Standards and Conformity Assessments

The General Directorate of Industrial Norms and Technology (DGNTI) through its Commission of Technical Standards (COPANIT), an agency of the Ministry of Commerce and Industries, oversees quality standards and certification for all products. It participates in the preparation, adoption and adjustment of norms for industry, commerce and services. This agency is also the point of contact in Panama for the Codex Alimentarius. It is also the Panamanian registering authority for participation in ISO program.

The General Directorate of Standards and Industrial Technology (DGNTI) leads in conducting conformity assessments but is joined by a number of other public and private organizations. In Panama, several organizations conduct conformity assessments on a regular basis. These organizations include the Central Laboratory of Health from the Ministry of Health (MINSA), the University of Panama, the Technological University of Panama, the National Secretariat of Science and Technology (SENACYT), the Ministry of Agricultural Development (MIDA), the Consumer Protection Authority and Defense of Competition, and the Agricultural Marketing Institute (IMA).

Law 23 requires that the Panamanian Commission for Industrial and Technical Standards (COPANIT) and the General Directorate of Standards and Industrial Technology (DGNTI) publish all agreements, technical regulations, norms and procedures.

They operate a primary Metrology Lab, duly equipped to offer services such as calibration to weights, and solution to measuring problems.

List of food products for which they have issued a Technical Regulation:

- Cereals, Wheat flour
- Ethylic alcohol for alcoholic beverages
- Rum (local)
- Fruit and Vegetable juices
- Fruit nectars
- Tomato juice
- Orange juice concentrate
- Orange juice
- Milk and Dairy Products
- Vegetable oils
- Animal fats
- Sugar
- Table salt
- Onions
- Poultry products
- Additives
- Colors
- Fish, frozen
- Fishmeal
- Beef and products
- Eggs and egg products

Complete information (in Spanish language) may be accessed at the Ministry of Commerce and Industry website for <u>Technical Regulations</u>.

Facility and Product Registration Requirements

All U.S. federally inspected establishments for meats and poultry are eligible to export to Panama. The list of these can be found at: http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpi-directory/

Panama does not have food facility registration requirements for the United States as was agreed in the United States – Panama Agreement regarding certain sanitary and phytosanitary measures and technical standards affecting trade in agricultural products, of December 20, 2006.

The Panamanian Food Protection Authority (AUPSA) is the agency created to oversee all aspects of food importation. In compliance with the bilateral SPS agreement, they receive requests for food and feed products sanitary registration and provide answers within 24 hours. This procedure can be made online and there are no fees for this service. The submission of documentation as indicated in this section may be through AUPSA's website: www.aupsa.gob.pa which is user friendly but, is in the Spanish language only.

According to Article 54 of Law Decree 11 of February 22, 2006, all processed food products for retail, bottled or packaged with given name and brand, must be registered at the Panamanian Food Safety Authority (AUPSA), prior to importation. This means that all food products intended for retail as a final product for direct consumption should be registered before import, sale or trade. i.e. alcohol beverages, snacks, canned food, among others.

Excluded from the above are raw materials such as fresh meats (which are not packed and ready for retail, used for food service or food processing), fresh vegetables and fresh fruits, grains in bulk loads or in bags, dairy product in bulk loads or in bags for further processing, ingredients and additives for the process of a final food product.

For food product registration, importers or the exporters must send the following information:

- Product Name
- Name and address of the product manufacturer, packager, or distributor, as specified on the label.
- Product description as stated on the label.
- Product ingredients (in descending order by weight) as stated on the label.
- For U.S. food products either:
 - a. A Certificate of Free Sale of the product, or any other certificate issued by any U.S. federal or state or local authority within the last 12 months, such as a Sanitary Certificate issued by your State authority (Agriculture or Health), in which certifies that the product is fit for human consumption and complies with the Sanitary regulations in your State. A list of States authorities can be found at: http://www.nasda.org/6467.aspx
 - A Supplier or Manufacturer's Declaration (if the product is for international sales only, not sold in the United States), on company letterhead, stating that the product is fit for human consumption.

6. Bar code scanned of the product.

In addition, so AUPSA may corroborate the above information, it is necessary to send the legible scanned copy of all labels. The originals of such documents shall be presented at the AUPSA's Registry office, within a period of 30 working days.

Food product registration shall remain in effect as long as the information provided remains unchanged.

Other Certification and Testing Requirements

The certifications that must accompany shipments are:

- For meats and poultry: a FSIS Export Certificate of Wholesomeness (FSIS form 9060-5)
- For fresh vegetables and fresh fruits, grains in bulk loads or in bags: an APHIS Phytosanitary Certificate (PPQ Form 577)
- For seafood and fishery products: a NOAA's Health Certificate for fishery products.
- d. For dairy products, other processed products, ingredients and additives for the process of a final food product: A Certificate of Free Sale of the product, or any other certificate issued by any U.S. federal or state or local authority within the last 12 months, such as a Sanitary Certificate issued by your State authority (Agriculture or Health), in which certifies that the product is fit for human consumption and complies with the Sanitary regulations in your State. Also, for dairy products the USDA/AMS Sanitary Certificate for Exports or, the USDA/APHIS Export Certificate for Animal Products (VS Form 16-4) can be used.
- For shell eggs for human consumption: USDA/AMS Disease Free Certification Statements for Panama, and USDA/AMS Fresh Shell eggs Grading Certificate for consumption (AMS Form PY-210S)
- For Pet Food: an USDA/APHIS Export Certificate for Animal Products (VS Form 16-4) with the additional statements mentioned on Section VII, paragraph c of this report.

The Inspection, Testing and Sampling requirements are:

- A computer-based importation/verification system of AUPSA, known as SISNIA, is used at the
 ports of entry in Panama. The SISNIA system allows for the inspectors to see when the load will
 arrive, and what kind of tests (microbiological, entomological, chemical, MRL, etc.) must be
 done. The software also allows the general public to learn about the import sanitary
 requirements, how much food has been imported and by whom. http://www.aupsa.gob.pa
- 2. At the ports of entry, shipments clearance is based on documents and physical inspections.
- Customs inspectors also verify the shipment, especially the Customs Declaration Form and the payment of duties, if applicable.
- Frozen and Refrigerated food products, for physical inspection, are not opened at the ports of entry because of lack of cold storage facilities.
- Since the ports of entry, especially the docks, don't have refrigerated facilities, the AUPSA inspectors execute the physical inspection process in the importers' cold storage facilities or at the processing plant, to preserve the cold chain of the food product.
- For sampling, a whole box of product is taken from the load for further organoleptic, microbiological and toxic residues testing.
- A laboratory analysis order is issued for the sample to be tested and a certified GOP laboratory is selected for the testing purposes (i.e., LCRSP, LADIV, LSV, IEA or other).

- The analysis parameter(s) to be tested for any specific sample is also randomly selected by the SISNIA, through bio-statistics software.
- Panama has zero tolerance policy towards e. coli and salmonella spp. in cooked products; raw products could have a certain number of positive samples, and if this occurs, the inspectors send a warning to the importer.
- 10. When a foreign processing plant or establishment (including but not limited to the United States) is exporting to Panama for the first time, it is subjected to sampling of five consecutive loads/shipments (starting sampling), then a reduced sampling protocol follows for every 11 loads and then on every 22 loads.
- If a MRL analysis yields a positive result or if there is a microbiological finding, five consecutive loads will be sampled.

Section VII. Other Specific Standards: Vitamin and Minerals enrichment requirements

As per MINSA Resolution No. 5705 of October 28, 1996, Panama forbids adding potassium bromate to wheat flour, adopting CODEX Standard 152-1985-91. The resolution specifies that it is for wheat flour only, and not for products made of wheat flour such as cookies, crackers, etc., which are not affected by the regulation.

- All wheat flour must be fortified with iron according to the Executive Decree No. 80 of March 24, 2003.
- a. All table salt for human consumption must contain iodine according to the Executive Decree No. 127 of August 31, 1998. Panama's Food Safety Authority (AUPSA) issued Resolution No. 048-AG-2016 on August 2, 2016, disabling the Sanitary Registration for all imported noniodized salt for human consumption.

AUPSA's resolution is based on the Executive Decree No. 20 of March 2, 2001, which establishes that all the salt that is processed, produced, imported or sold, for human consumption inside of Panama must contain an amount of iodine between 20 to 60 mg/Kg (20 to 60 ppm).

Import Requirements for U.S. Beef and Beef products to Panama

Import requirements for U.S. beef and beef products for human consumption, adopted by AUPSA's Scientific and Technical Council of Food Safety Resolution No. 002 of May 17, 2013, by which it modifies the Resolution No. 001, of February 22, 2007, recognizes the equivalence of the U.S. sanitary and phytosanitary systems for the importation of meats, poultry, dairy and other products, and contains provisions related to certification requirements. With this amendment of the Annex of the Resolution No. 001, the use the Bovine Export Verification Program for U.S. Beef and Beef products exported to Panama is no longer required since Panama recognizes the equivalence of sanitary and phytosanitary systems and other related regulatory systems of the United States.

In accordance with the above in the mentioned resolutions, beef meat and meat products for human consumption originating from the United States must be accompanied by an Export Certificate of Wholesomeness issued by USDA FSIS with no additional certification statements. Article 5 of the Agreement establishes that all products containing, by weight, more than 3 percent of meat have to be accompanied by an FSIS Export Certificate of Wholesomeness.

The previous resolution was modified by AUPSA, after a re-negotiation with the GOP because Panama and the United States have the same BSE Risk Status (Negligible risk) recognized by OIE as of May 2013.

The export requirements for U.S. meats and poultry to Panama can be found in English at the following link: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Panama

In addition to the above, each shipment must be accompanied by the following documents:

- Copy of the Import Notification Form, filled in the web site of the <u>Panamanian Food Safety</u> Authority
- Copy of the commercial invoice of the product.
- Customs pre-declaration.

Import Requirements for U.S. Pet Food to Panama

In June 2014, pet food certification requirements were simplified following an exchange of letters between USTR and the Panamanian Ministries of Agriculture, Health, and Commerce. This agreement entered into force through AUPSA's Scientific and Technical Council of Food Safety Resolution No. 002 of February 10, 2015, by which it modified Resolution No. 001 of February 22, 2007 that recognizes the equivalence of the U.S. sanitary and phytosanitary systems for the importation of meats, poultry, dairy and other products, and contains provisions related to certification requirements. With the amendment of the Annex of the Resolution 001, U.S. pet food exports to Panama containing animal origin ingredients were greatly simplified.

The revised additional certification statements on USDA APHIS export certificates that accompany U.S. shipments of pet food containing animal origin ingredients to Panama are:

- The products may be freely sold in the United States as pet food.
- Dry, semi-moist, and dehydrated pet food products were subjected during processing to a heat temperature designed to ensure the destruction of pathogenic agents harmful to animals.
- Canned pet food products have been treated in hermetically sealed containers with an F0 of 3.0 or more.
- 4. The product has been hygienically handled and packed in clean containers made of impermeable, hermetic, and strong materials that are sufficient to protect the product from environmental contamination and safeguard commercial sterility obtained during thermal processing.

Specific Import Requirement for Table Stock Potatoes:

AUPSA requires an additional certification under the Phytosanitary Export Certificate (issued by the Animal and Plant Health Inspection Service (APHIS)) for sprout inhibitor applications on shipments of U.S. table stock potatoes. In order to meet this requirement, APHIS recommends that shippers provide a "Packer Affidavit" stating that a sprout inhibitor application on shipments of U.S. table stock potatoes has been given as part of the shipping documentation.

Potatoes must be free of the following pests and must be stated in the Additional Declarations line of the Phytosanitary Export Certificate: Ditylenchus destructor, Ditylenchus dispaci, Phthorimaea operculella, Pratylenchus penetrans and Tylenchorhynchus claytoni. Also it needs to be produced in a free area of potato purple top (except for potatoes from State of Washington) or apply anti sprout fumigation. Per AUPSA's Resolution AUPSA-DINAN-028-2015.

Specific Import Requirement for Onions:

On July 8, 2016, Panama notified to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee the Notification G/TBT/N/PAN/86 regarding the technical regulation DGNTI-COPANIT 52-2016, establishing the new quality requirements for fresh onions.

This technical regulation includes a restriction that the onions must be sold within 120 days of its harvest, even if the product is refrigerated. The regulation also includes specific packaging and labeling materials, among other requirements for sampling and testing by the Panamanian Food Safety Authority (AUPSA).

Import Requirement for Third-Country Food Products Coming from the United States

Third-country food products coming from the United States to Panama are considered by AUPSA as a re-exported or transshipped product. Therefore, the shipment must be accompanied by the photocopy of the sanitary or phytosanitary certificates from the countries of origin. This requirement also applies for sanitary registration of the third-country food products. The special regulations for U.S. food product registration are not applicable.

For the importation of rice (Oryza sativa L.) milled, packaged or re-packaged for human consumption and /or for processing originating in Asia, coming from the United States of America, the shipment must be accompanied by a phytosanitary export or re-export certificate, issued by USDA-APHIS with the following additional declarations:

- The rice has undergone a process of inspection and sampling, and during the storage period in the United States of America, the grains were not exposed to the risk of pest infestation or infection or pollutants.
- The rice comes free of live insects of any kind, as well as other biologicals, chemicals and physical contaminants, including soils.
- The phytosanitary export or re-export certificate must include an additional statement certifying that the rice free of Trogoderma granarium.

Import Requirement for Commercial Samples of Food Products, for Personal Consumption, Food Aid Donations and Special Events:

In accordance with import requirements published on Resolution AUPSA-DINAN-055-2016, for commercial samples of food products, for personal consumption, food aid donations and special events (such as gastronomic exhibitions, tastings and embassy events), food products can only be imported if they have been processed and pre-packaged to minimize the potential health and/or phytosanitary risks, and only non-processed foods from eligible countries recognized by AUPSA can be imported. Food products for commercial samples, personal consumption, special events and donations do not require sanitary registration of the product in AUPSA.

The following documentation must be presented at the port of entry in Panama (terrestrial border, airports and maritime ports):

- 1. Import Prior Notification Form with the signature of approval by AUPSA.
- If the importers are out of the country at the time of application, an e-mail can be sent to normas@aupsa.gob.pa with the Import Prior Notification Form scanned requesting the authorization for the importation. Form in Spanish is attached
- Sanitary or Phytosanitary Export Certification notarized. Also, a Free Sale Certificate or a
 Sanitary Certificate issued by the state authority (Agriculture or Health), in which certifies that
 the product is fit for human consumption and complies with the Sanitary regulations in your
 State. A list of states authorities can be found at: http://www.nasda.org/6467.aspx
- Payment of \$2.00 for verification of commercial samples of food products, and for personal
 consumption. The payment must be made through National Bank of Panama, Checking Account
 No. 010000104031. A National Bank of Panama is located at the Tocumen International Airport.

The following are exempt to request the above authorization, based on article 3 of Resolution AUPSA-DINAN-021-2014:

- 13 Gums, resins and other vegetable saps and extracts
- 15 Animal or vegetable fats and oils
- 17 Sugars and sugar confectionery
- 18 Cocoa or its preparations
- 19 Preparations of cereals, flour, etc.
- 20 Preparations of Vegetables, fruit plants
- 22 Drinks, spirits and vinegar
- 25 Mineral products
- 28, 30, 32, 34 additives used for food processing
- 29 Organic Chemicals
- 33 Essential Oils and Resinoids
- 35 Starches and starch products

The maximum allowable amounts authorized for importing food products for commercial samples and personal consumption (if a greater amount is required, the importer shall request the Import Prior Notification Form authorization for the importation from AUPSA):

- Commercial samples: up to 5 kilograms or its equivalent in volume by product.
- Personal consumption: up to 20 kilograms or its equivalent in volume, in total per person.
- Dietary Supplements for personal consumption: up to 3 kilograms or its equivalent in volume, in total per person.

If the above requirements and documentation that accompany food products (in case an AUPSA's Import Prior Notification Form authorization is needed) are fulfilled, the inspection procedure is immediate and on-site.

Import requirement for shell eggs for human consumption:

For clarification purposes, packing material represents shell egg cartons (6-egg, 12-egg, 18-egg, etc.); packaging material represents loose pack shipping containers (i.e. 15, 24, or 30-Dozen Cases):

- All shell eggs must originate from the United States.
- Flocks must be participating in the National Poultry Improvement Plan (NPIP) administered by APHIS / USDA.
- Product must be in compliance with the Food and Drug Administration's (FDA) regulations for the prevention of salmonella in shelled eggs during production, storage, and transport.
- Product must be processed and packed under USDA supervision in shell egg facilities utilizing either USDA's voluntary resident or temporary grading service.
- The shell eggs must be graded and certified as U.S. Grade A or better, as outlined in the United States Standards, Grades, and Weight Classes for Shell Eggs. Regardless of the grade, certification must be determined by either online or stationary lot grading.
- All packing and packaging material must be new, showing no evidence of previous use.
- All packing and packaging material must contain the Statement of Identity (EGGS). The "Keep Refrigerated" statement or similar terminology must appear on individual packing material.
 Packing material must contain the Safe Handling Statement, as well.
- The Country Code (US) must be stamped on individual packing material. Alternatively, each egg
 can be individually stamped with the Country Code (US) when packaging material is utilized.
- All packing material must contain the Packing Date (Batch Date). This date represents the
 consecutive day of the year in which the product was processed (i.e. 001 = January 01). All
 packing material must contain a valid legal line (corporate or producer/packer); U.S. grade, size,
 and quantity of product; official plant number, and duration of quality.
- All packaging material must contain the Packing Date (Batch Date). This date represents the
 consecutive day of the year in which the product was processed (i.e. 001 = January 01). All
 packaging material must contain the name, address, city, state, and zip code of the
 producer/packer; U.S. grade, size, and quantity of the product; official plant number; duration of
 quality, and the flock identification number. Alternatively, the flock identification number can
 be recorded on the Form PY-75 for each load that is produced.
- The USDA Graded for Export Stamp with the applicable certificate number must be stamped on individual packaging.
- The duration of quality cannot exceed 45 days, including the date of processing. The following
 prefixes must be used in conjunction with the duration of quality: Best Before, or EXP. If the
 prefix, EXP is used with duration of quality that exceeds 30 days including packing date, the
 following disclaimer will be printed in the remarks section of the Shell Egg Grading Certificate:
 "The expiration date declared on the product is the responsibility of the applicant."
- All shipment of fresh shell eggs, in shell (shell), for human consumption, must be stored and transported at a maximum of 7.2 degrees Celsius ambient temperature.
- The containers and / or thermos-refrigerated vehicles must be sealed (locked, strapping) and sealed so that these labels can be removed only by the Panamanian Food Safety Authority, upon arrival to the country.
- The shell eggs for human consumption shipments must be accompanied with a USDA/AMS Disease Free Certification Statement for Panama and a USDA/AMS Fresh Shelled Eggs Grading Certificate for Consumption (AMS Form PY-210S).

Import Requirements for Processed Foods Intended for Human Consumption, Direct Use, Transformation or Further Processing: According to Resolution AUPSA-DINAN-002-2012 of January 16, 2012, importers must inform AUPSA electronically, through the Import Notification Form, in a minimum of 48 hours prior to the arrival of products to the point of entry, and no more than 60 days prior to the arrival.

Upon arrival of a shipment to the point of entry into the country, the departure should be supported with the following documentation:

- Import notification form.
- b. Certificate issued by the official authority of the country of origin, according to the type of food. For processed foods, which are packaged with a trademark, a copy of the Certificate of Free Sale and/or Safety or equivalent must be submitted, stating that the food is fit for human consumption. For foods of plant origin, give their degree of processing (malting, roasting, drying oven, milled, parboiled, others) which do not require any form of phytosanitary control, including raw materials, a Health Certificate or equivalent should be presented.
 - c) Product's certificate of origin
 - d) Copy of the product's commercial invoice
 - e) Pre-customs or customs declaration.

Section VIII. Copyright and/or Trademark Laws:

On April 23, 2013 the Ministry of Commerce and Industry of Panama through the General Directorate of Industrial Property Registration, registered at the Bulletin No. 297 of 2013 (attached in Spanish) a total of 112 Geographical Indications (GIs), Designations of Origin (DO) and Indications of Origin from the European Union, including but not limited to dairy products, such as "Provolone Valpadana", "Fontina", "Gorgonzola" and "Parmigiano Reggiano", among other products.

The Panamanian Copyright Law (Law 64 of October 10, 2012) is based on the World Intellectual Property Organization (WIPO) model. It modernizes copyright protection in Panama, provides for payment of royalties, facilitates the prosecution of copyright violators, and makes copyright infringement a felony. The Copyright Office is drafting improvements to the Copyright Law to implement the new WIPO treaties, to raise penalties for infractions and to enhance border measures.

The Industrial Property Law (Law 61 of October 5, 2012) provides 20 years of patent protection from the date of filing. This Law also provides trademark protection, simplifies the process of registering trademarks and makes them renewable for ten-year periods. It grants ex-officio authority to government agencies to conduct investigations and to seize materials suspected of being counterfeited. The Trademark Registration Office has undertaken significant modernization with a searchable computerized database of registered trademarks that is open to the public and is remotely accessible to customs officials, among others. This facilitates the inspection and investigation process considerably.

The legal framework for the protection of intellectual property rights (IPR) in Panama has improved significantly over the past decade. The government passed an Anti-Monopoly Law in 1996 mandating the creation of commercial courts to hear anti-trust, patent, trademark, and copyright cases exclusively. Two district courts and one superior tribunal began to operate in June 1997 and have been adjudicating intellectual property disputes. In January 2003, the GOP designated an IPR-specific prosecutor with national authority, which has consolidated and simplified prosecution of those cases.

This Industrial Property Law of 2012 establishes on the Panamanian Legal system the Geographical Indications, Designations of Origin, and Indications of Origin. However, IPR implementing regulations or applications, and protection of Regulation of use are pending, specifically regarding compound terms that include generic terms and specific geographic indications, because the GOP is still undergoing internal consultations.

The TPA provides for improved standards for the protection and enforcement of a broad range of intellectual property rights, which are consistent with U.S. standards of protection and enforcement and with emerging international standards. Such improvements include state-of-the-art protections for digital products such as U.S. software, music, text and videos; stronger protection for U.S. patents, trademarks and test data, including an electronic system for the registration and maintenance of trademarks; and further deterrence of piracy and counterfeiting. Panama is a member of the World Intellectual Property Organization (WIPO), the Geneva Phonograms Convention, the Brussels Satellite Convention, the Universal Copyright Convention, the Bern Convention for the Protection of Literary and Artistic Works, the Paris Convention for the Protection of Industrial Property, and the International Convention for the Protection of Plant Varieties. In addition, Panama was one of the first countries to ratify the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty, although the GOP has yet to introduce implementing legislation to put these treaties fully into force in Panama and to establish new offenses, such as those needed for internet-based copyright violations and to enhance border measures.

Under the TPA, Panama would be obligated to ratify or accede to the Patent Cooperation Treaty, the Convention Relating to the Distribution of Program-Carrying Signals Transmitted by Satellite, and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure by the date the TPA enters into force. Panama accede the International Convention for the Protection of New Varieties of Plants on November 22, 2012; and the Trademark Law Treaty, which entered into force on September 7, 2012.

Panama's legal system provides for a trademark protection regime, which includes a simplified process of trademark registration, and the ability to renew a trademark for 10-year periods.

All the copyrights and/or Trademarks must be registered at the <u>General Directorate for Industrial</u>
<u>Property Registration</u> of the Ministry of Commerce and Industry of Panama. A Panamanian Attorney must submit the registration documents, with a Power of Attorney of the applicant.

Section IX. Import Procedures:

Panama's food and feed trade moves through the Balboa port in the Pacific and the Atlantic ports of Manzanillo, Cristobal, Colon Container Terminal and Evergreen (these three ports are located at Colon city) which are managed by transnational companies. The Tocumen International Airport handles the bulk of Panama's air cargo.

With AUPSA's Resolution No. 031-AG-2015 and No. 032-AG-2015 of May 25, 2015 establishing new requirements for the Registration of Importers into their Data Base and the minimum time to make the Prior Notification for Imports (60 days); an Importer or User can be registered at AUPSA's Imports

Notifications System, known as SISNIA, only if it has an Operations Certificate and has an storage or warehouse facility for the imported products. Translated Resolutions attached.

Food Products and Animal Feed

Panamanian regulations allow companies and individuals to import directly with no intervention from agents or distributors. However, it is preferable to work with a customs agent (broker) or an "imports expediter" that has experience in importing food products.

<u>Step 1:</u> All processed food products for retail, bottled or packaged in some form with given name and brand, must be registered at the Panamanian Food Safety Authority (AUPSA), prior to importation, as explained in section VI paragraph b of this report.

Step 2: All importers must submit to AUPSA an Import Prior Notification form at least 48 hours ahead when the shipment will arrive to Panama. SISNIA is the online system of AUPSA where importers can upload the requested information. In order to upload the information the importer must submit to AUPSA the necessary documentation to prove they are legally established.

<u>Step 3:</u> At the Port of Entry in Panama, the importer shall present these documents, which are going to be checked for compliance:

- Copy of Import Notification form, submitted on Internet at the AUPSA web site: http://www.aupsa.gob.pa/notificaciones/. The notification must be submitted, at a minimum of 48 hours prior to the arrival of the product at a port of entry.
- 2. If the Certificate of Free Sale of the product, or any other certificate issued by any U.S. federal or state authority, or a Supplier / Manufacturer's Declaration [1], was not submitted at the moment of the Food Product Registration [2], then a copy of any of the above certificates must be presented at the Port of Entry in Panama.
- Packing List of products.
- Certificate of Origin (where appropriate [3])
- Copy of commercial invoice of the product.
- Pre-Customs Declaration

<u>Step 4:</u> AUPSA conducts inspection, testing and sampling on imported food products, mainly in fresh or refrigerated food products, looking for contaminants, for example: live regulated pests, E. coli, Salmonella, heavy metals and Listeria. See section VI paragraph c of this report for more details.

<u>Step 5:</u> If the shipment is cleared, it is released to be imported. If is not cleared, due to findings of any contaminants, AUPSA will notify the importer about which mitigation measure will be applied or if the shipment must be rejected for importation into Panama.

AUPSA has been accepting during the last 3 years, in accordance with the U.S. - Panama SPS/TBT Equivalence
Agreement signed on December, 2006, the Supplier or Manufacturer Declaration when the product is not freely sold in the
U.S. territory, meaning that is produced for International Sales only. If the food product is fively sold inside the U.S.
territory, then any U.S. federal, state or local competent authority should issue a certification, stating that the product is fit

for human consumption, and it has been produced in compliance with the U.S. health standards for food manufacturing.

Non-Food Animal and Plant Products

The Agricultural Quarantine Directorate of the Ministry of Agricultural Development is the agency in charge of this category. They have a list of requirements for specific products, which may change at any moment due to phytosanitary concerns that may arise. Applicants must fill out a form requesting a Phytosanitary License. Procedures must be done in person and in the Spanish language. Information may be accessed at: www.mida.gob.pa go to: Cuarentena Agrop, then go to: Solicitud de Importacion. Or contact the Executive Director of Agricultural Quarantine (contact data below on Appendix I of this report).

Appendix I. Government Regulatory Agency Contacts:

Panamanian Food Safety Authority (AUPSA) National Directorate of Food Imports Regulations

Ricardo J. Alfaro Avenue, Sun Towers Mall, 2nd Floor. Office No. 70

Panama City, Republic of Panama.

Telephones: (507) 522-0000; or 522-0042

Fax: (507) 522-0014

Website: www.aupsa.gob.pa

Ministry of Agricultural Development (MIDA)

Executive Directorate of Agricultural Quarantine

Curundo Heights, Manuel E. Melo Street, Building 577, ground floor

Panama City, Republic of Panama.

Telephone: (507) 232-5340

Fax: (507) 507-0877

Website: www.mida.gob.pa

Ministry of Health (MINSA) Food Protection Department

⁽²⁾ AUPSA issued the Import Requirement Resolution number AUPSA-DINAN-077-2009 establishing that when the Certificate of Free Sale is presented during product registration, it does not need to be presented with each shipment.

Any certificate issued by a U.S. federal, state or local competent authority, including the Certificate of Free Sale, generally indicates that the product is manufactured in the United States, or is originated in the United States; other attest, i.e.: "Country of Origin: United States". When the certificate does not indicates any origin of the product, then AUPSA's inspector at the Port of Entry, may or may not request for a Certificate of Origin, to ensure that the product is from the United States. Also, a Certificate of Origin is necessary when importing under a tariff-rate quota or under a Tariff preferential treatment of the U.S. – Panama Trade Promotion Agreement, which is enforced since October 31, 2012.

Ancon, Culebra Street, Building 253, ground floor.

Panama City, Republic of Panama.

Telephone: (507) 512-9180 Fax: (507) 512-9114

Website: www.minsa.gob.pa

National Authority of Customs (ANA)

Curundu, Dulcidio Gonzalez Avenue, building 1009

Panama City, Republic of Panama.

Telephone: (507) 506-7484

Fax: (507) 506-6240 Website: www.ana.gob.pa

Ministry of Commerce and Industry (MICI)

General Directorate for Industrial Property Registration

Ricardo J. Alfaro Avenue, Plaza Edison, 2nd floor.

Panama City, Republic of Panama.

Telephones: (507) 560-0705 or 560-0700 extension 2105

Website: www.digerpi.gob.pa

Ministry of Commerce and Industry (MICI)

Technical Regulations Department and Codex Alimentarius Focal Point

Ricardo J. Alfaro Avenue, Plaza Edison, 3rd floor.

Panama City, Republic of Panama.

Telephones: (507) 560-0600 extension 2389, or 560-0716

Website: www.mici.gob.pa

Appendix II. Other Import Specialist Contacts:

Association of Traders and Distributors of Food and similar of Panama (ACOVIPA)

Ricardo J. Alfaro Avenue, Century Tower Plaza

Panama City, Republic of Panama

Telephone: (507) 236-2459 Website: http://acoviparetail.org/

Industrial Union of Panama (Sindicato de Industriales de Panama) Ricardo J. Alfaro Avenue, Building "Ricardo Galindo Quelquejeu"

Panama City, Republic of Panama

Telephone: (507) 230-0169 Website: www.industriales.org