

LEY DE BIOTERRORISMO

Requisitos para la Exportación de Alimentos a los EEUU



COMISIÓN DE PROMOCIÓN DEL PERÚ PARA LA EXPORTACIÓN Y EL TURISMO

Ing. Iván Serpa

Mayo 2012

PROGRAMACIÓN DE LAS JORNADAS DE LA CALIDAD

FECHA	TEMA
20 de junio	Requisitos fitosanitarios para la agroexportación - SENASA
27 de junio	Requisitos Sanitarios para la Exportación de Alimentos - DIGESA
04 de julio	Requisitos sanitarios para la exportación de productos hidrobiológicos - SANIPES
11 de julio	Requisitos para exportar alimentos a EEUU - Parte I - PROMPERU
18 de julio	Requisitos para exportar alimentos a EEUU - Parte II - PROMPERU
01 de agosto	Requisitos para exportar alimentos al mercado asiático - TRADE TRAINING
08 de agosto	Requisitos para exportar alimentos a la Unión Europea – EQ SOLUTIONS
15 de agosto	Requisitos para exportar alimentos a Brasil - TRADE TRAINING
22 de agosto	Buenas Prácticas Agrícolas – Globalgap – GRUPO PERUGAP
29 de agosto	Las Buenas Prácticas De Manufactura en la industria de alimentos – KMR

FECHA	TEMA
12 de setiembre	Las Buenas Prácticas en el sector manufacturero -PROMPERU
26 de setiembre	Sistemas Integrados de Gestión e indicadores de gestión - SGS
03 de octubre	Certificación Orgánica: NOP/USDA Organic Agricultura Ecológica/UE. – CONTROL UNION
10 de octubre	La certificación Fair Trade (Comercio Justo) - Coordinadora Nacional de Pequeños Productores de Comercio Justo del Peru
17 de octubre	Certificación Kosher: Certificaciones culturales y religiosas para exportación – CERTIFICACIONES RELIGIOSAS
24 de octubre	Certificación Halal: Requisitos del Mercado Musulmán - ASOCIACION ISLAMICA DEL PERU
31 de octubre	Buenas Prácticas Ambientales: huella de carbono, huella de agua – NSF
07 de noviembre	Importancia de las Normas Técnicas Peruanas –PROMPERU
14 de noviembre	Rastreabilidad de Alimento – GS1
21 de noviembre	La seguridad en la cadena logística de las exportaciones – Sistema de gestión en control y seguridad BASC



Evitemos detenciones o rechazos

Sistema de alertas sanitarias





Reporte de rechazos - IRR

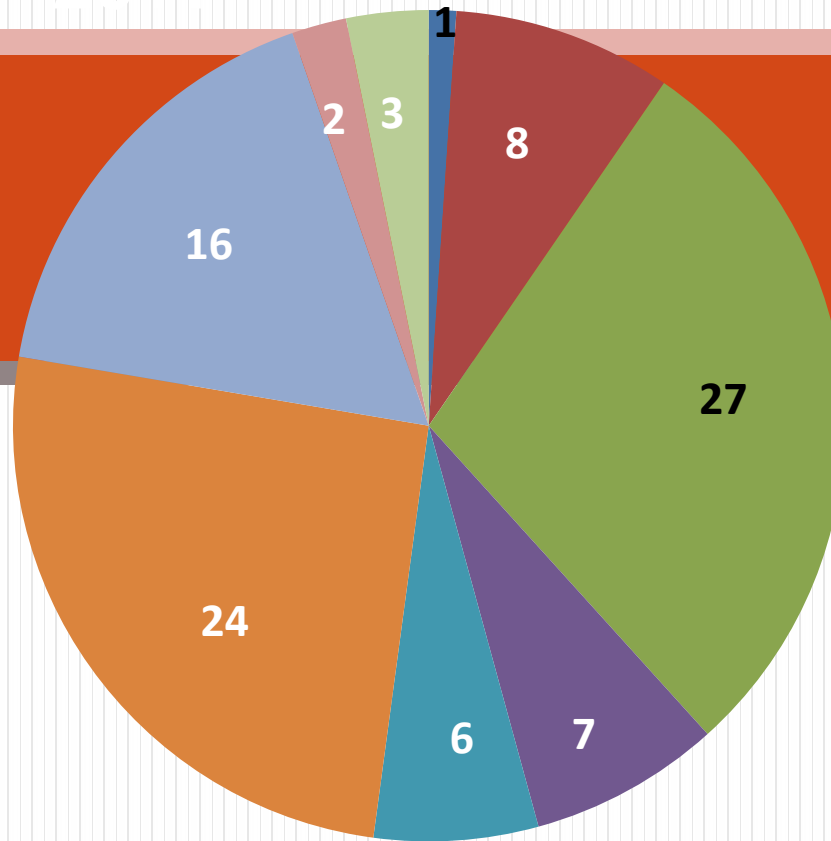
- Actualizado mensualmente

- Acceso público:

http://www.accessdata.fda.gov/scripts/ImportRefusals/ir_index.cfm

DETENCIONES Y RECHAZOS DE ALIMENTOS A ESTADOS UNIDOS

AFLATOXINAS	1
ETIQUETADO	8
SUCIEDAD	27
LACF	7
NO ENGLISH	6
INGREDIENTE INAPROBADO	24
PESTICIDAS	16
INGREDIETE VENENOSO	2
SALMONELLA	3
TOTAL	94



■ AFLATOXINAS

■ ETIQUETADO

■ SUCIEDAD

■ LACF

■ NO ENGLISH

■ INGREDIENTE INAPROBADO

■ PESTICIDAS

■ INGREDIETE VENENOSO

■ SALMONELLA



Ley contra el bioterrorismo



Bioterrorismo: empleo criminal de sustancias dañinas contra una población con el propósito de generar enfermedad, muerte, pánico y terror.

11 de setiembre de 2001

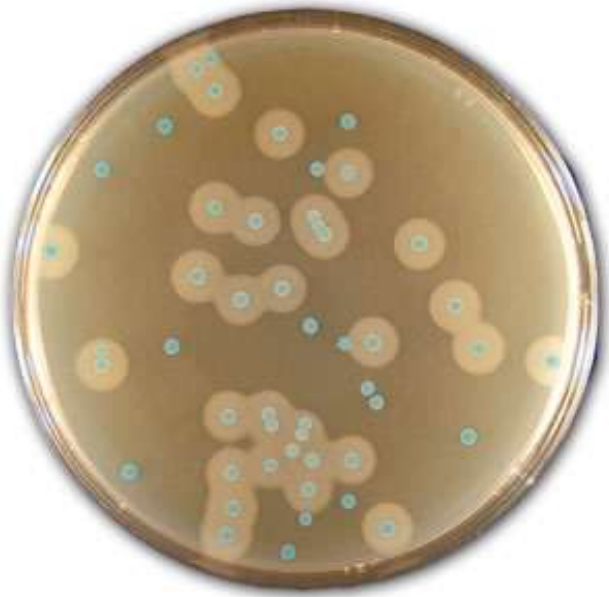
¿Qué es Bioterrorismo?

- Es el término utilizado para definir el empleo criminal de sustancias dañinas contra una población con el propósito de generar enfermedad, muerte, pánico y terror.



¿Qué es *Bioterrorismo*?

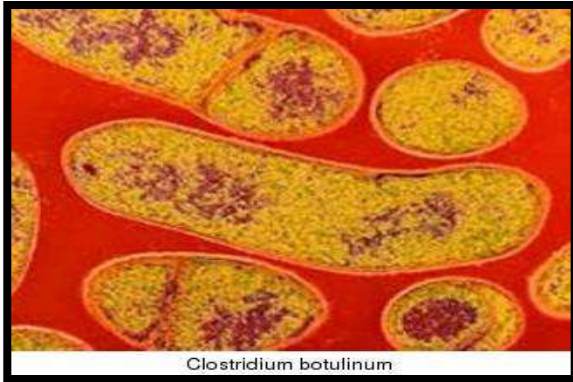
- ***Los alimentos podrían utilizarse como vehículo para perpetrar ataques terroristas***



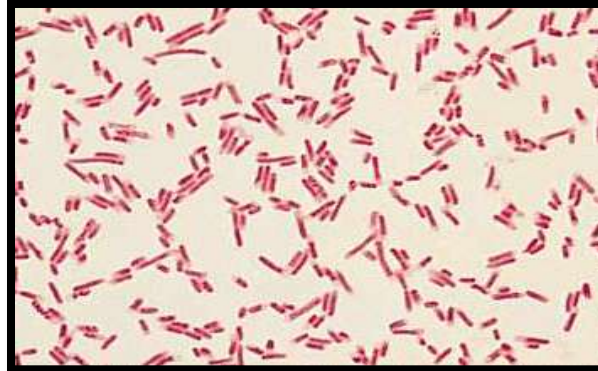
¿Casos de Bioterrorismo?

- 300 AC. En la literatura griega, romana y persa se habla del uso de cadáveres animales para contaminar el agua del enemigo.
- 1346 sitio de Kaffa. Se catapultó cadáveres con peste bubónica sobre la ciudad.
- Primera Guerra Mundial. Se acusó a los alemanes de desarrollar anthrax, cólera y peste.
- Segunda Guerra Mundial. Programa de armas biológicas desarrollado por Japón en Manchuria. El programa abarcó varios años murieron más de 10,000 personas.
- URSS. Se sospecha que usaron micotoxinas en las guerras de Laos, Camboya y Afganistan
- 1984 EEUU. Seguidores del grupo Rajneeshe contaminaron un supermercado y varios restaurantes con Salmonella en el estado de Oregon. 750 personas afectadas

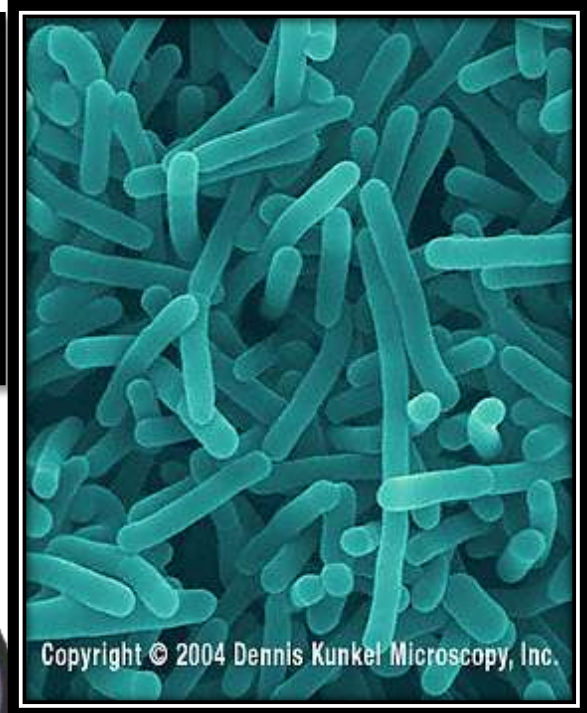
Agentes utilizados para perpetrar ataques de bioterrorismo



Clostridium botulinum

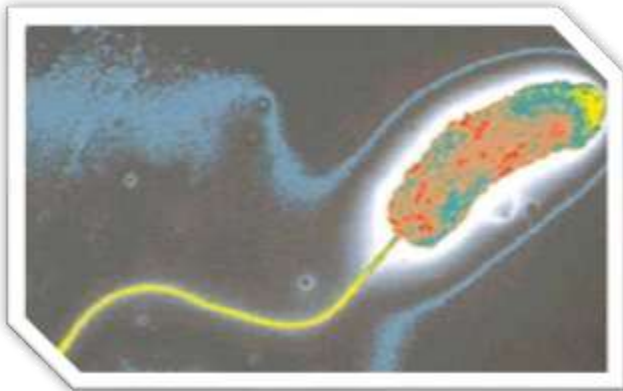


Salmonella

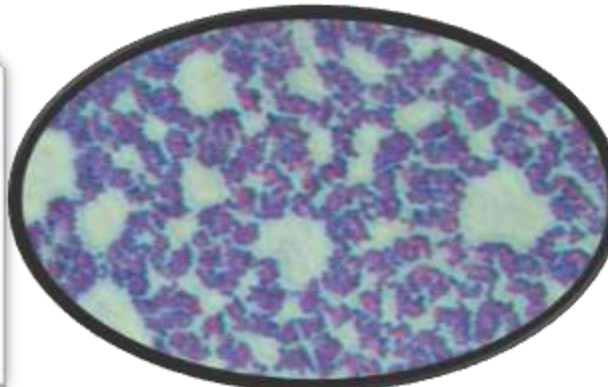


Copyright © 2004 Dennis Kunkel Microscopy, Inc.

Listeria



Vibrio cholerae – Cólera



Staphylococcus

Ley de Seguridad de la Salud Pública y Preparación y Respuesta ante el Bioterrorismo

(Ley de Bioterrorismo - 2002)

Alcance

Alcance:

- *Todos los alimentos domésticos e importados que se comercializan en el comercio interestatal.*
- *Agua embotellada*
- *Bebidas con menos de 7% de porcentaje de alcohol*
- *Huevos*



Rol y Responsabilidades

- * Inspecciones de establecimientos de alimentos (producción y almacenamiento).
- * Realiza investigaciones en seguridad del alimento.
- * Vigilancia de los alimentos para consumo animal
Autoriza la comercialización de colorantes y otros aditivos alimentarios
- * Autoriza el uso de medicamentos alimentarios
- * Desarrollo de guías, códigos, interpretaciones y su coordinación con los estados
- * Establece las Buenas Prácticas de Manufactura, Programas HACCP y otros estándares relacionados.
- * Emprende acciones de control y penalización
- * Promueve educación al sector productor y consumidor.

Ley de Bioterrorismo

- Título I: Preparación nacional contra el bioterrorismo y otras emergencias en salud pública
- Título II: Incremento a los controles sobre agentes biológicos peligrosos y toxinas
- *Título III: Protección de la inocuidad y seguridad del suministro de alimentos y medicamentos*
- Título IV: Seguridad y garantía del agua potable
- Título V: Disposiciones adicionales

Título III: Protección de la inocuidad y seguridad del suministro de alimentos y medicamentos

- Detención Administrativa (Sec. 303)
- *Registro de Instalaciones Alimenticias (Sec. 305)*
- Establecimiento y Mantenimiento de Registros (Sec. 306)
- *Notificación Previa de Alimentos Importados (Sec. 307)*

¿Qué exige la Food and Drug Administration (FDA) en el marco de la Ley de Bioterrorismo?

- Que las instalaciones que manufacturen, procesen o envasen alimentos que vayan a ser exportados a EEUU estén *registradas ante la FDA* (Registration of Food Facilities)
- Que todo *embarque* de alimentos sea *previamente notificado a la FDA antes de ingresar a EEUU* (Prior Notice)

Registro de Instalación

- ¿Quién tiene que registrarse?
 - Fabricantes o procesadores
 - Empacadores
 - Operaciones de almacenamiento
- ¿Cómo me registro?
 - Página Web
 - <http://www.access.fda.gov>
 - Por Correo
 - CD

The image shows a screenshot of the FFRM (Food Facility Registration Module) web form. The form is titled "FFRM Food Facility Registration Module" and includes the FDA logo. It is divided into two main sections:

SECTION 1 - FACILITY NAME/ADDRESS INFORMATION

This section contains the following fields:

- Facility Name (Text input)
- Facility Street Address, Line 1 (Text input)
- Facility Street Address, Line 2 (Text input)
- City (Text input)
- Country (Text input)
- State/Province/Territory (Dropdown menu)
- ZIP Code (Postal Code) (Text input)

Below these fields are two tables for phone numbers:

Country Code	Area Code	Phone Number	Extension
***PHONE NUMBER	(0-9999)	(0-9999)	(0-99999999)

Country Code	Area Code	Phone Number
FAX NUMBER	(0-9999)	(0-9999) (0-99999999)

S-MAIL ADDRESS (Text input)

SECTION 2 - OPTIONAL FACILITY/ADDRESS INFORMATION

This section contains the following fields:

- Facility Name (Text input)
- Address, Line 1 (Text input)
- Address, Line 2 (Text input)
- City (Text input)
- Country (Text input)
- State/Province/Territory (Dropdown menu)
- ZIP Code (Postal Code) (Text input)

Below these fields are two tables for phone numbers:

Country Code	Area Code	Phone Number	Extension
***PHONE NUMBER	(0-9999)	(0-9999)	(0-99999999)

Country Code	Area Code	Phone Number
FAX NUMBER	(0-9999)	(0-9999) (0-99999999)

S-MAIL ADDRESS (Text input)

¿Qué alimentos están sujetos a la jurisdicción de FDA?

- Pescados y mariscos
- Carnes, embutidos
- Leche y derivados
- Huevos
- Frutas y vegetales frescos o secos
- Cereales, granos y menestras
- Productos de panadería
- Golosinas y confitería
- Alimentos en conserva
- Bebidas alcohólicas
- Refrescos
- Aditivos alimentarios
- Alimento para animales domésticos (inclusive mascotas)
- Café, té, infusiones
- Suplementos nutricionales



Registro de Instalaciones *(food facility registration)*



¿Qué es una Instalación Alimenticia?

Instalación – es una estructura o estructuras en la cual se fabrica/procesa, envasa o almacena alimentos para consumo humano o animal en EE.UU.

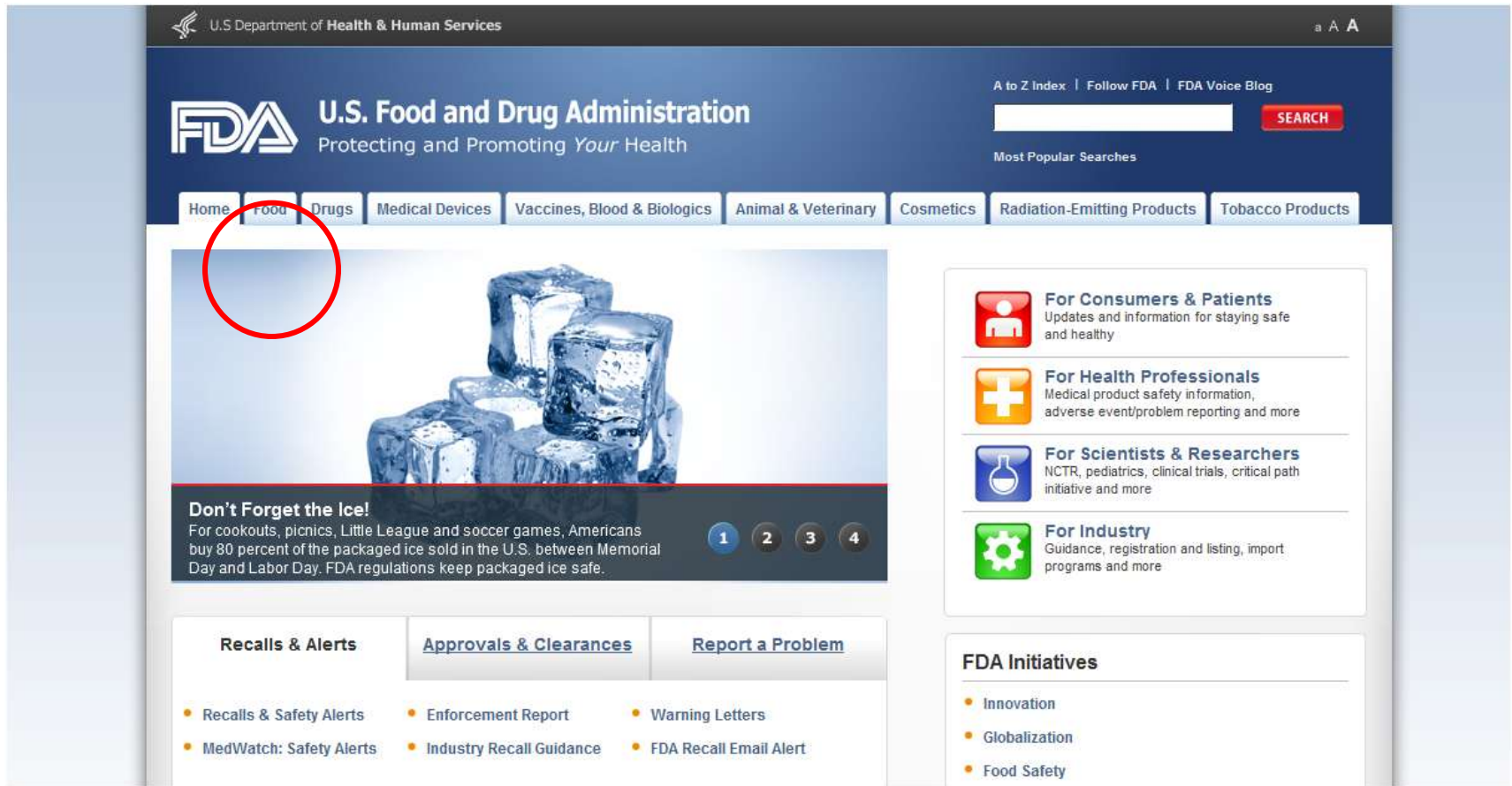


No es una instalación:

- Vehículos de transporte si sólo mantienen alimentos en el desarrollo de su negocio como transportadores.
- La residencia privada de una persona
- Un campo de cultivo (parcela, chacra)
- Establecimientos para la distribución y recolección de agua potable no embotellada

Pasos para el registro de una instalación

1° Ingresar a www.fda.gov Hacer click en el ícono “Food”



The screenshot shows the homepage of the U.S. Food and Drug Administration (FDA). At the top, the U.S. Department of Health & Human Services logo is on the left, and accessibility icons (a, A, A) are on the right. The main header features the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". To the right of the header is a search bar with a "SEARCH" button and a "Most Popular Searches" section. Below the header is a navigation menu with tabs for "Home", "Food", "Drugs", "Medical Devices", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", "Radiation-Emitting Products", and "Tobacco Products". The "Food" tab is circled in red. Below the navigation menu is a large banner image of ice cubes with the text "Don't Forget the Ice!" and a sub-headline: "For cookouts, picnics, Little League and soccer games, Americans buy 80 percent of the packaged ice sold in the U.S. between Memorial Day and Labor Day. FDA regulations keep packaged ice safe." To the right of the banner is a sidebar with four sections: "For Consumers & Patients" (Updates and information for staying safe and healthy), "For Health Professionals" (Medical product safety information, adverse event/problem reporting and more), "For Scientists & Researchers" (NCTR, pediatrics, clinical trials, critical path initiative and more), and "For Industry" (Guidance, registration and listing, import programs and more). Below the banner and sidebar are three main content areas: "Recalls & Alerts" (with sub-items: Recalls & Safety Alerts, MedWatch: Safety Alerts, Enforcement Report, Industry Recall Guidance, Warning Letters, FDA Recall Email Alert), "Approvals & Clearances", and "Report a Problem". At the bottom right is a section for "FDA Initiatives" (with sub-items: Innovation, Globalization, Food Safety).

2º Hacer click en el ícono “Registration of Food Facilities”

The image is a screenshot of the FDA website's main navigation area. It features several sections: 'Resources for You' with links for various audiences; a 'Search Food' box; 'News and Events' with recent headlines; 'Information for Industry' where the 'Registration of Food Facilities' link is circled in red; 'Tools and Resources' with links to FDA basics and forms; and 'Contact FDA' with phone numbers and email addresses.

Resources for You

- What's New in Food
- Consumers
- Health Educators
- Health Care Professionals
- Industry
- Students & Teachers
- En Español

Search Food

SEARCH

News and Events

- Investigation of Multistate Outbreak of Salmonella Bareilly and Salmonella Nchanga Infections Associated with Nakaochi Scrape AA or AAA Frozen Raw Tuna from India
- Investigation of Multistate Outbreak of Human Salmonella Infantis Infections Linked to Dry Dog Food
- Foods and Veterinary Medicine Strategic Plan 2012 - 2016
- 05/17/2012 Important Information for Food Distributors, Retailers, and Food Service Operators Regarding the Sourcing of Molluscan Shellfish from Korea
- 04/27/2012 FDA challenges marketing of DMAA products for lack of safety evidence

More News and Events

Information for Industry

- **Registration of Food Facilities**
- Reportable Food Registry for Industry
- Retail Food Protection
- Current Good Manufacturing Practices (CGMPs)
- Prior Notice of Imported Foods
- Acidified and Low-Acid Canned Foods

Tools and Resources

- FDA Basics
- FDA Basics for Industry
- About the Center for Food Safety and Applied Nutrition
- CFSAN Publication Order Form (PDF - 545KB)
- International Outreach & Technical Assistance
- CFSAN FOIA Electronic Reading Room

Contact FDA

1-888-SAFEFOOD
1-888-723-3366

Outreach and Information Center (HFS-009)
Consumers:
consumer@fda.gov
Industry:
industry@fda.gov
Center for Food Safety and Applied Nutrition
Food and Drug Administration

• Sign Up for Recall Email Updates

3° Hacer click en el ícono “Login/Create Account”

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | FDA Voice Blog

SEARCH

Most Popular Searches

Home Food Drugs Medical Devices Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Radiation-Emitting Products Tobacco Products

Food

Home Food Guidance, Compliance & Regulatory Information Registration of Food Facilities

Registration of Food Facilities

[Login / Create Account](#)
OMB Approval Number: **0910-0502**
OMB Expiration Date: **08/31/2013**
[See OMB Burden Statement.](#)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA has established new regulations requiring that

- Food facilities are registered with FDA, and
- FDA be given advance notice on shipments of imported food.

The Bioterrorism Act requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA by December 12, 2003.

Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S. are required to register the facility with the FDA.

Domestic facilities are required to register whether or not food from the facility

Spotlight

- [Notice To Industry: Reminder to Update Your Information in the FDA Food Facility Registration Database](#)
- [Important FDA Notice Regarding Firms Offering Registration Services](#)
- [Register a Food Facility Online Quick Start Guide](#)
- [New Features in the Food Facility Registration Module \(FFRM\)](#)

Resources for You

- [Compliance Policy Guide - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#)
- [Questions and Answers Regarding Registration of Food Facilities](#)

Compliance Info.

4° Ingresar para crear una cuenta de usuario

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact FDA FURLS Helpdesk at 1-800-216-7331 to confirm that the caller is acting on behalf of FDA.


NEW USERS	LOGIN
<p data-bbox="330 948 852 991">Create New Account</p> <p data-bbox="330 1029 852 1072">See Instructions</p> <p data-bbox="330 1110 852 1153">See Tutorials</p> <p data-bbox="330 1192 852 1235">Help Desk</p>	<p data-bbox="962 939 1493 961">Existing account holders, enter your account ID and password.</p> <p data-bbox="981 975 1248 1003">Account ID: <input type="text"/></p> <p data-bbox="981 1032 1460 1061">Password: <input type="password"/> Forgot your password?</p> <p data-bbox="962 1096 1541 1132"><small>Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.</small></p> <p data-bbox="1180 1143 1315 1165"><input type="radio"/> I understand</p> <p data-bbox="1213 1193 1290 1222"><input type="button" value="Login"/></p>

5° Seleccionar los sistemas que se necesitarán

[Skip Navigation](#) | [FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

[FDA Industry Systems Home](#) | [Browser Requirements](#) | [FAQ](#) | [Help Desk](#)

CREATE AN ACCOUNT

[» Get Help](#) 

Note: You cannot use your Food Facility account to register a medical device establishment. You must create a separate account to register your medical device establishment and vice versa.

Select the systems you will need to access:

~~FDA Unified Registration Listing Systems~~

Food And Drug Facility Registration Device Registration And Listing

Please select registration system

Food Facility Registration

Low Acid Canned Food

Drug Facility Registration

Shell Egg Producer Registration


~~Other FDA Systems~~

Prior Notice

[FDA Industry Systems Home](#) | [Browser Requirements](#) | [FAQ](#) | [Help Desk](#)

[Skip Navigation](#) | [FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

6° Llenar toda la información que se requiera , nombre, cargo, teléfonos, correos electrónicos, password, etc.

CREATE AN ACCOUNT » Get Help 

*Enter your account information. Fields marked with an * are required.*

* First Name:

Middle Initial:

* Last Name / Surname:

(Please enter 'NONE' if Job Title is not applicable)

* Job Title:

* Company / Last Name (Surname):

Passwords must be at least 8 characters but no more than 32, contain uppercase and lowercase letters, numbers and special characters (e.g %, \$). YOU WILL NEED TO REMEMBER YOUR PASSWORD TO LOGIN IN THE FUTURE.

* Password :

* Confirm Password :

Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country Code is not required for US phone numbers.

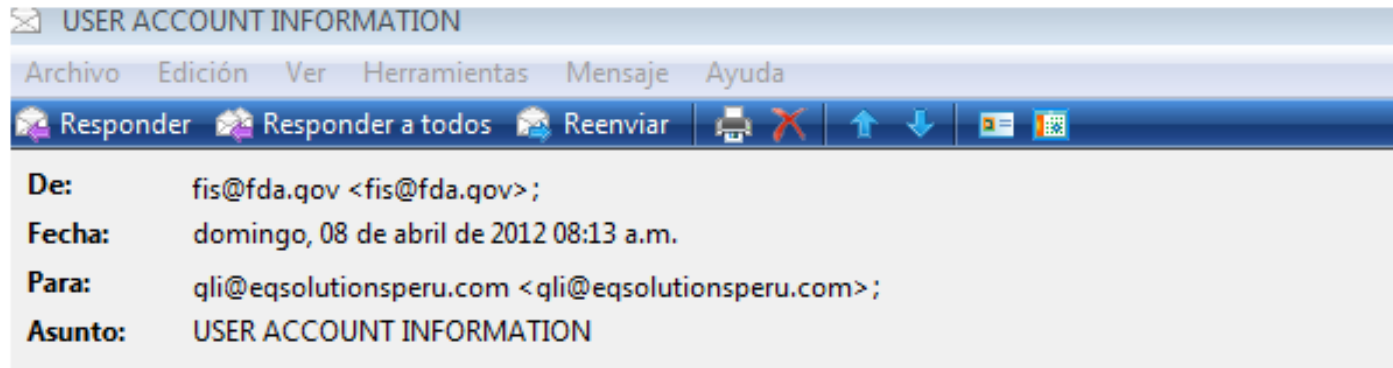
	Country Code (e.g. 033)	Area/City Code (e.g. 101)	Phone Number (e.g. 5551111)	Extension (e.g. 1111)
* Phone Number:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code (e.g. 033)	Area/City Code (e.g. 101)	Fax Number (e.g. 5551111)
FAX Number:	<input type="text"/>	<input type="text"/>	<input type="text"/>

Enter your e-mail address. If you do not enter an e-mail address, requests or changes to your password will be sent via postal mail.

**(Note: E-mail is mandatory for Device Registration & Listings and Prior*

Si toda la información se ha llenado de manera correcta, usted recibirá un correo de la FDA confirmando su registro y proporcionándole su Account ID.



Dear FDA Industry Systems Account User,

Please do not reply to this notification/e-mail.

You have created a new account. The Account ID is eoq66423.
Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to <https://www.access.fda.gov/#top>

8° Ingrese a “Food Facility Registration”

The screenshot displays the FDA Industry Systems user interface. At the top, a blue header bar contains the text "U.S. Food and Drug Administration". Below this, a navigation bar includes links for "Skip Navigation", "FDA Home Page", "Search FDA Site", "FDA A-Z Index", and "Contact FDA". A secondary navigation bar contains links for "FDA Industry Systems Home", "Browser Requirements", "FAQ", "Help Desk", and "logout".

The main content area is divided into two sections. On the left is an "Account Management" sidebar with a dark blue header and a light blue background, containing links: "» Edit Account Profile", "» Change My Password", "» Update System Access", "» Create a Subaccount", "» Deactivate a Subaccount", and "» Reactivate a Subaccount". The main section has a dark blue header with "Welcome" and "You are logged in as eoq66423". Below the header, the text reads: "Welcome to the FDA Industry Systems. You are logged in to your account for company E&Q Solutions SAC". A red warning message follows: "You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account."

The "FDA Unified Registration Listing Systems" section features five buttons: "Food Facility Registration" (circled in red), "Device Registration & Listing", "Shell Egg Registration", "Drug Facility Registration", and "Low Acid Canned Food". Below this is the "Other FDA Systems" section with a "Prior Notice" button.

At the bottom, a navigation bar contains links for "FDA Industry Systems Home", "Browser Requirements", "FAQ", "Help Desk", and "logout".

9° Ingrese a “Register a Food Facility”

FFRM Food Facility Registration Module |  >> FURLS Home

FFRM MAIN MENU

- Register a Food Facility**
- Update Facility Registration
- Cancel Registration Status
- Link Registration to your Account
- Search Facility Registrations
- Manage Registrations Among Accounts
- Confirm Notification Receipt

Form Approval: OMB No.0910-0502
Expiration date: 08/31/2013
See OMB Statement at end of form

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please Note:
The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

✖ Left_bottom_image

10° A continuación deberá llenar con información 08 hojas electrónicas

Ingresar que en nuestro caso se trata de un “foreign registration”; si por primera vez va a registrar su instalación colocar un “no”

FFRM Food Facility Registration Module | [» FURLS Home](#)
[» FFRM Home](#)

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08

Get Help ?

SECTION 1 TYPE OF REGISTRATION

* - These fields are required

*FACILITY LOCATION
FOREIGN REGISTRATION ▾

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?
*Yes No

If "yes", provide the following information, if known

Previous owner's name

Previous owner's registration number

>> Continue

Ingresar el nombre y datos de contacto de su agente en EEUU

FFRM Food Facility Registration Module | [» FURLS Home](#)
[» FFRM Home](#)

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08

Get Help

[« Back to Step 03](#) [» Continue](#)
[« Cancel & Start Again From Section 1](#)

SECTION 7 UNITED STATES AGENT

**** - These fields are required only if the section applies**

[» AutoFill Address](#) [» Clear](#)

Autofill Address will fill the address fields automatically using data in Section 7 from the last registration entered.

****NAME OF U.S. AGENT**

TITLE


****COUNTRY/AREA**

****ADDRESS, Line 1**

ADDRESS, Line2

Please enter 'NONE' in zip code field if zip codes are not used in selected Country/Area
****ZIP CODE**



Get Help 

[« Back to Step 04](#)

[» Continue](#)

[« Cancel & Start Again From Section 1](#)

SECTION 8 SEASONAL FACILITY DATES OF OPERATION (Optional)

(GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS)

DATES OF OPERATION


SECTION 9 TYPE OF ACTIVITY CONDUCTED AT FACILITY (Optional)

(CHECK **ALL** TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING, PROCESSING, PACKING OR HOLDING OF FOOD)

- Warehouse/Holding Facility (e.g. storage facilities, including storage tanks, grain elevators)
- Acidified/Low Acid Food Processor
- Interstate Conveyance Caterer/Catering Point
- Molluscan Shellfish Establishment
- Commissary
- Contract Sterilizer
- Labeler/Relabeler
- Manufacturer/Processor
- Resealer/Repacker

En caso que corresponda se ingresa datos de: Frecuencia de operaciones; tipos de actividades que desarrolla la instalación (fábrica, almacén, etc)



Get Help 

[« Back to Step 05](#) [» Continue](#)

[« Cancel & Start Again From Section 1](#)

SECTION 10 TYPE OF STORAGE (FOR FACILITIES THAT ARE PRIMARILY HOLDERS) (Optional)

- Ambient (neither frozen nor refrigerated) Storage
- Refrigerated Storage
- Frozen Storage

SECTION 11a GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.

At least one category must be selected.

- 1. Alcoholic Beverages

[21 CFR 170.3 (n) (2)]

- 2. Baby (Infant and Junior) Food Products including Infant Formula

En caso que corresponda se ingresa datos de: tipo de almacenamiento del producto; categorías de productos que maneja la instalación ya sea para consumos animal o humano.

COMPLETE EL FORMULARIO Y LA INSTALACIÓN QUEDARÁ REGISTRADA

SECTION 1 TYPE OF REGISTRATION

* - These fields are required

*FACILITY LOCATION
[Please Select] ▾

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?
 *Yes No
 If "yes", provide the following information, if known
 Previous owner's name

 Previous owner's registration number

SECTION 2 FACILITY NAME / ADDRESS INFORMATION

* - These fields are required

>> AutoFill Address >> Clear

*FACILITY NAME

*FACILITY STREET ADDRESS, Line1

FACILITY STREET ADDRESS, Line2

*CITY

*COUNTRY
United States ▾

*STATE/PROVINCE/TERRITORY
[Please Select] ▾

*ZIP CODE (POSTAL CODE)

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
*PHONE NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>

E-MAIL ADDRESS

SECTION 3 OPTIONAL: PREFERRED MAILING ADDRESS INFORMATION

(complete this section only if different from Section 2, Facility Name/Address Information)

*** - This section is optional. If you intend to complete this section, the fields marked with *** are necessary for the system to process a complete response

>> AutoFill Address >> Clear

Autofill Address will fill the address fields automatically using data in Section 3 from the last registration entered

***NAME

***ADDRESS, Line1

ADDRESS, Line2

***CITY

***COUNTRY
[Please Select] ▾

***STATE/PROVINCE/TERRITORY
[Please Select a Province] ▾

***ZIP CODE (POSTAL CODE)

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
***PHONE NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>

E-MAIL ADDRESS

<< Back to Step 01 >> Continue
 << Cancel & Start Again From Section 1

SECTION 4 PARENT COMPANY NAME/ADDRESS INFORMATION

(IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 and 3). IF INFORMATION IS THE SAME AS ANOTHER SECTION, CHECK WHICH SECTION:
 Section 2 - Facility Address Information or
 Section 3 - Preferred Mailing Address Information

** - These fields are required only if the section applies

>> AutoFill Address >> Clear

Autofill Address will fill the address fields automatically using data in Section 4 from the last registration entered

**NAME OF PARENT COMPANY

**STREET ADDRESS OF PARENT COMPANY, Line 1

STREET ADDRESS OF PARENT COMPANY, Line2

**CITY

**COUNTRY
[Please Select] ▾

**STATE/PROVINCE/TERRITORY
[Please Select a Province] ▾

**ZIP CODE (POSTAL CODE)

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
**PHONE NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>

E-MAIL ADDRESS

..... hasta la sección
13 (considerar que hay
secciones obligatorias
sólo cuando
corresponda)

..... Registration Successful !

Your Registration Number is 11234567890

Your PIN is [C@658bcd

Please keep the registration number and PIN for your records.

The registration number is required for all communications with FDA regarding this registration.

The PIN will allow you to access a registration online, if the registration was initially submitted as a paper form.

Please refer to the help section for more details.

[<< Back to Main](#)

[>> View Complete Registration](#)

NOTIFICACIÓN PREVIA (Prior Notice)



Notificación Previa (Prior Notice)

- La Notificación previa es un aviso electrónico enviado a la FDA sobre los productos alimenticios que se exportan a EE.UU antes que éstos ingresen a territorio estadounidense

ENVIOS QUE REQUIEREN NOTIFICACIÓN PREVIA (Además de las exportaciones)

- Muestras comerciales y regalos
- Alimentos que transitan a través de EE.UU hacia otro país
- Alimentos enviados por correo o servicio de Courier
- Alimentos enviados para análisis de calidad.
- Alimentos que serán consumidos en las ferias

¿QUIÉN ENVÍA LA NOTIFICACIÓN PREVIA?

- Cualquiera de las partes que tenga conocimiento de la información requerida por la FDA (Puede ser el exportador, el importador, el transportista, el agente o inclusive un tercero designado por las partes)
- Es responsabilidad del exportador asegurarse que este trámite se realice.

¿CUANDO SE ENVÍA LA NOTIFICACIÓN PREVIA?

La Notificación Previa deberá enviarse entre **15 días** y:

- **Ocho Horas Antes** si arribará a EE.UU por vía marítima.
- **Cuatro Horas Antes**, si arribará por vía aérea o férrea.
- **Dos horas antes** si ingresará por vía terrestre.



Prior Notice Confirmation: Submitted

For your records only.

Transmitter: [REDACTED]
 Confirmation Number: 120144631736

Submitted: 05/22/2012 19:12:01

WEB ENTRY

Entry Identifier: ###-6030314-2
 Port of Arrival: Miami Int'L Airport, FL (5206)
 Anticipated Arrival: 05/23/2012 07:00

Status: Completed
 Entry Type: Consumption

Submitter

[REDACTED]
 Jr. Camilo Carrillo 139 - Jesus Maria
 Lima, Lima Lima 11
 PERU

Name: Denis Falcon
 Phone: 051-1-4250854
 e-mail: d.falcon@cossiperu.com

Importer

[REDACTED]
 2871 MIDDLETON CR. KISSIMME
 MIAMI, Florida 34743
 UNITED STATES

Carrier

LAN PERU S.A.
 Carrier Code (IATA): LP

Mode of Transportation: Air
 Airway Bill - Master: 14541816950

ARTICLE

Article Number: 0001
 FDA Country of Production: Peru (PE)
 Country from which the Article is Shipped: Peru (PE)

Product Information

FDA Product Code: 20DGD99
 FDA Product Description: BERRY JUICE, N.E.C. BERRY JUICE OR CONCENTRATES, Plastic, Synth, RAW - FRESH, FROZEN, NATURAL STATE
 Common or Usual Name/Market Name: PULPA CONGELADA DE AGUAYMANTO

Production Identifiers

None

Quantity and Packaging

Total Quantity: 50 Kilograms
 Base Unit: 5 Kilograms
 Packaging from largest to smallest package: 2 Box
 5 Bag

Refusal Information

Related Facilities

Manufacturer

[REDACTED]
 Pasco PERU

Registration Number: 16054102222

Shipper

Shipper is same as the Submitter

Owner

Owner is same as the Importer

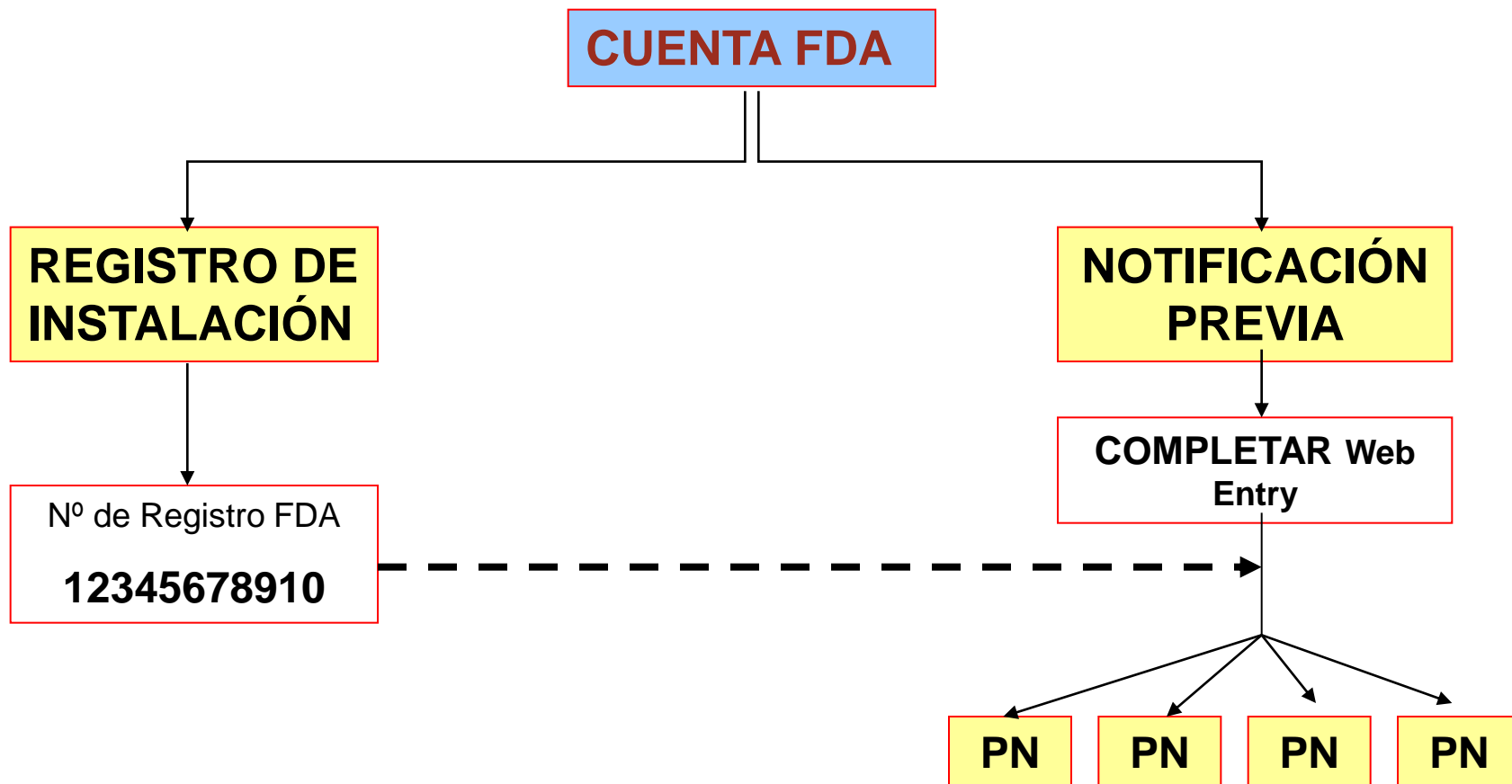
Ultimate Consignee

Ultimate Consignee is same as the Importer

Holding Location

Article Not Held

RESUMEN



FRECUENCIA DE LOS TRÁMITES Y COSTO

TRÁMITE	FRECUENCIA	COSTO
REGISTRO DE INSTALACIONES	POR ÚNICA VEZ PARA CADA LOCAL	SIN COSTO
NOTIFICACIÓN PREVIA	PARA CADA EMBARQUE Y TIPO DE PRODUCTO	

CONSULTAS DIVERSAS

¿SE PUEDE MODIFICAR EL REGISTRO DE INSTALACIÓN?

- Si. Todos los datos que se consignaron para registrar una instalación son modificables (Nombre dirección, teléfono, agente, etc.), no obstante, el número de registro seguirá siendo el mismo

¿SE PUEDE MODIFICAR UNA NOTIFICACIÓN PREVIA ENVIADA?

- NO. En caso no se tenga seguridad de la información notificada, la notificación deberá cancelarse y enviarse una nueva.

¿DONDE PUEDO OBTENER MAS INFORMACIÓN SOBRE LA LEY CONTRA EL BIOTERRORISMO?

- Directamente de la página Web de la FDA:

<http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>

- Página Web de PROMPERÚ, sección “Departamento de Gestión de la Calidad” www.promperu.gob.pe

Gracias por su Atención

Ing. Iván Serpa

Telf: (511) 616-7400 anexo 2501

E-mail: iserpa@promperu.gob.pe

