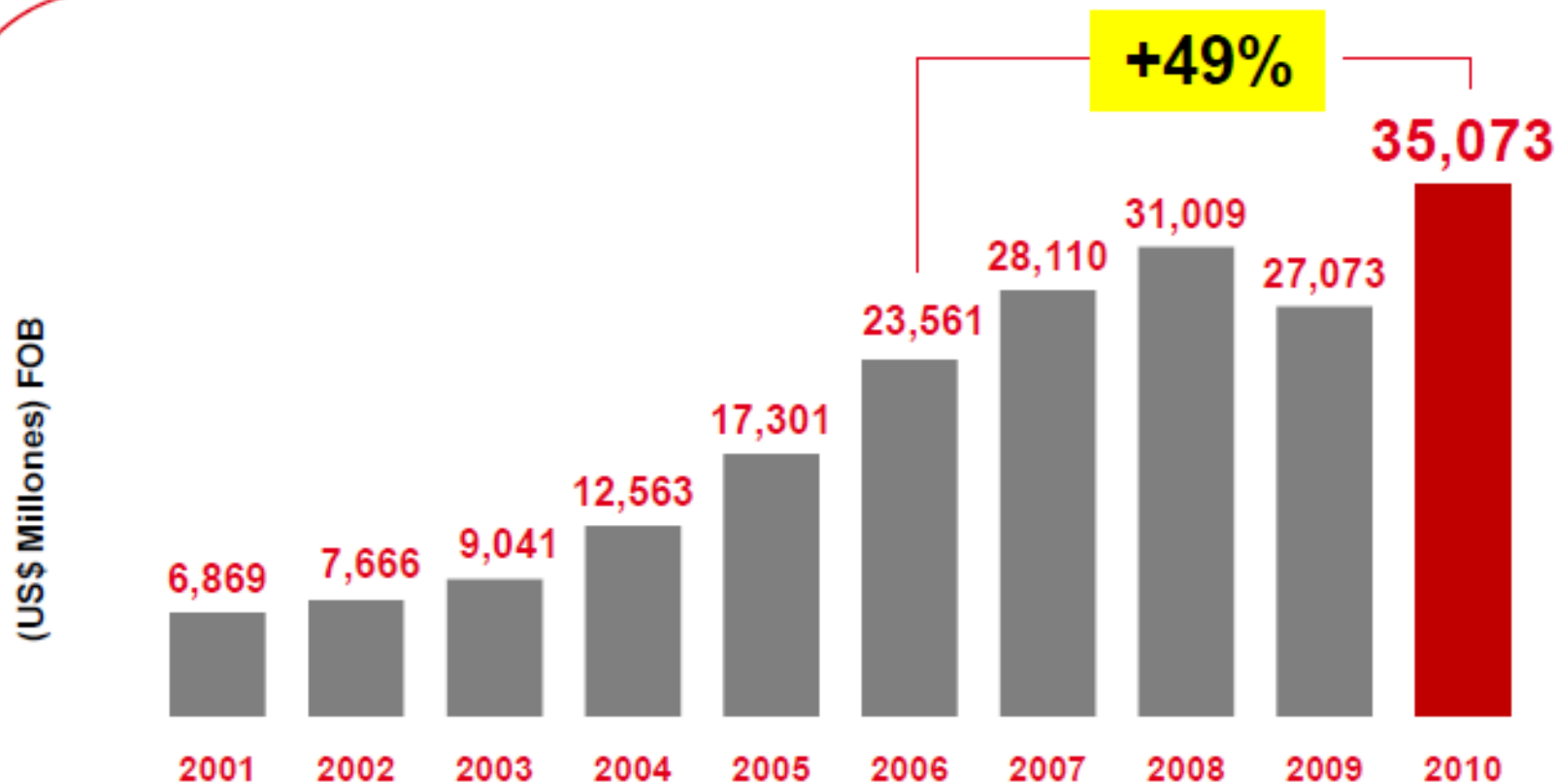


LEY DE BIOTERRORISMO

***Requisitos para la Exportación
de Alimentos a los EEUU***



Las exportaciones peruanas

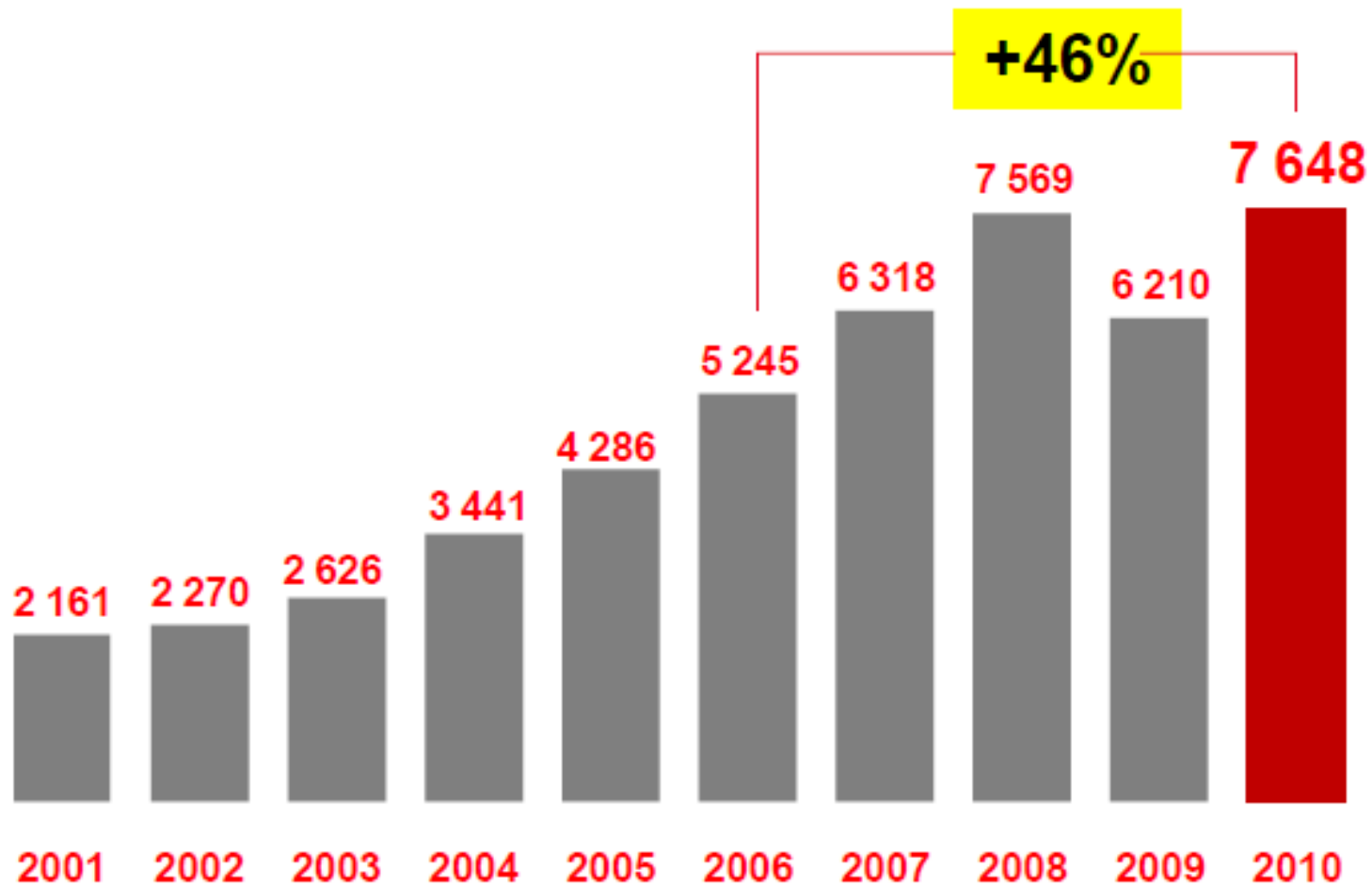


Fuente: SUNAT, INEI. Elaboración: PROMPERÚ.



Las exportaciones no tradicionales

(US\$ Millones FOB)

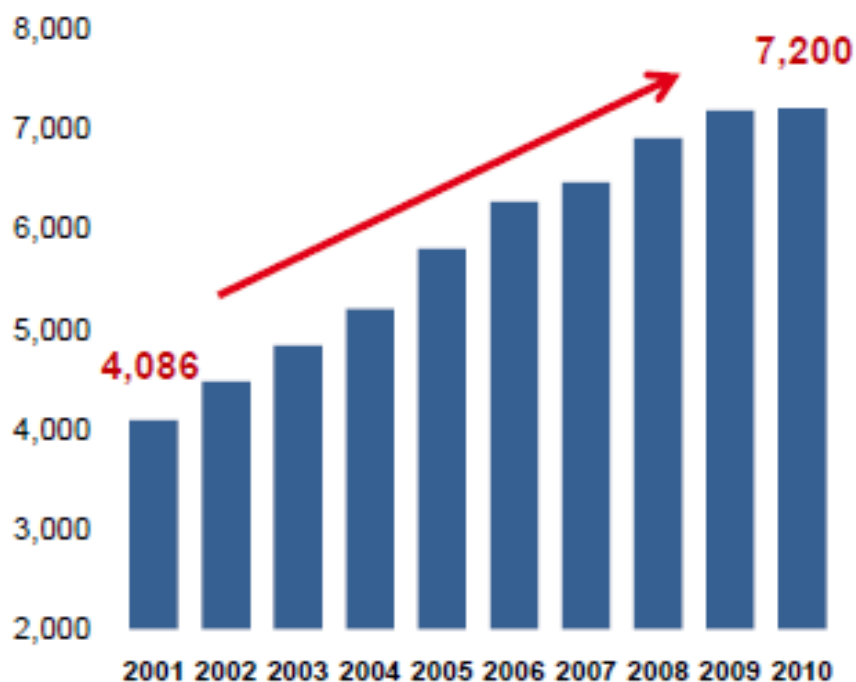


Fuente: SUNAT. Elaboración: PROMPERÚ

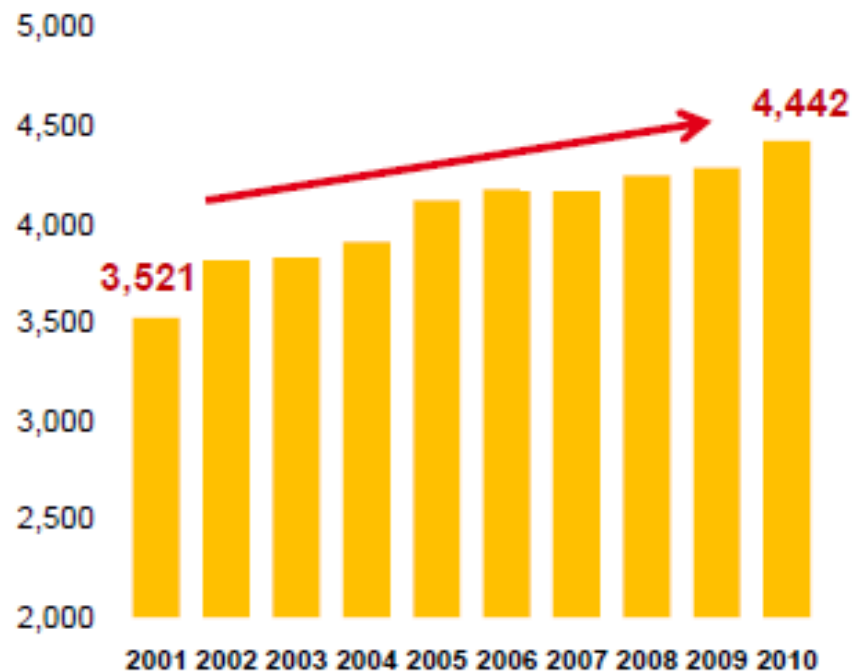


Las exportaciones no tradicionales

Número de Empresas Exportadoras



Nº de Partidas Arancelarias Exportadas (productos)



Agro y agroindustrias:
1480 empresas / 147 países
513 partidas arancelarias



Exportaciones agro y agroindustria

Valor Exportado 2010: **US\$ 2,190 MM**
Crecimiento 2009 – 2010 **20%**
Crecimiento 2006 – 2010 **81%**

PRODUCTOS

Alto crecimiento (2006 – 2010)

Uvas frescas	255%
Paltas	118%
Aceitunas conserva	209%
Mangos	55%

Producto Emblemático

Espárragos (3 presentaciones)	34%
----------------------------------	-----

Los nuevos:

Camote procesado
Aceite de sacha inchi

MERCADOS

Importante crecimiento

Estados Unidos	62%
Brasil	216%

170% crecen envíos al bloque
asiático - **China** **612%**

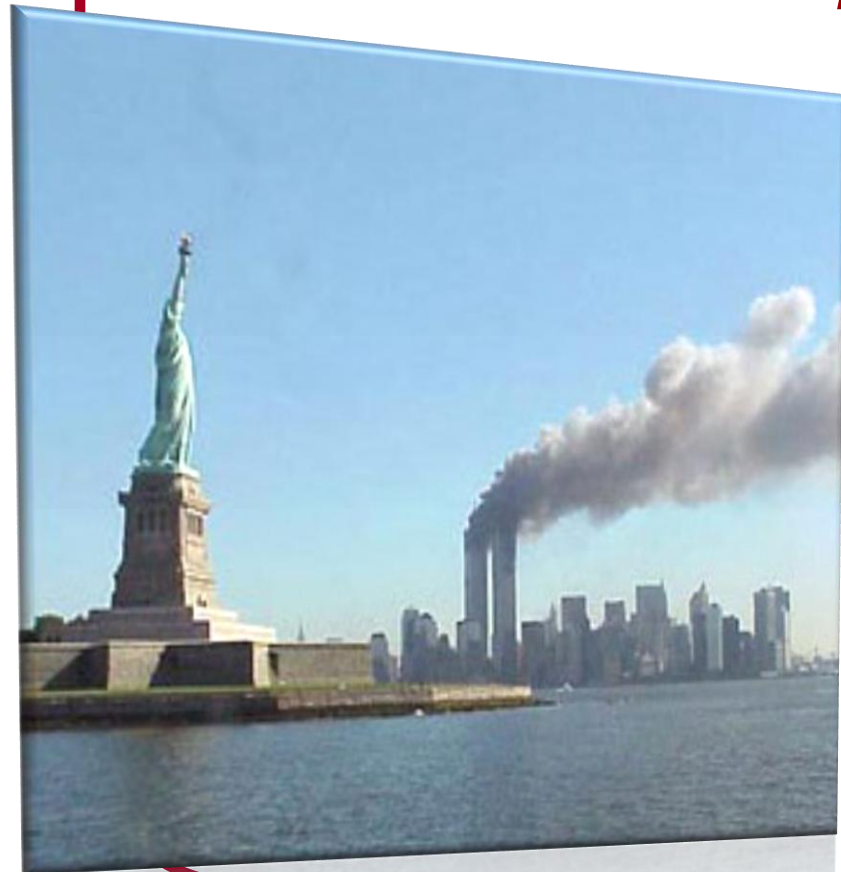
EMPRESAS

Grandes exportadoras: **41**

Mypes exportadoras: **1,154**

Gran temor en la población de los EEUU

11 de Septiembre 2001





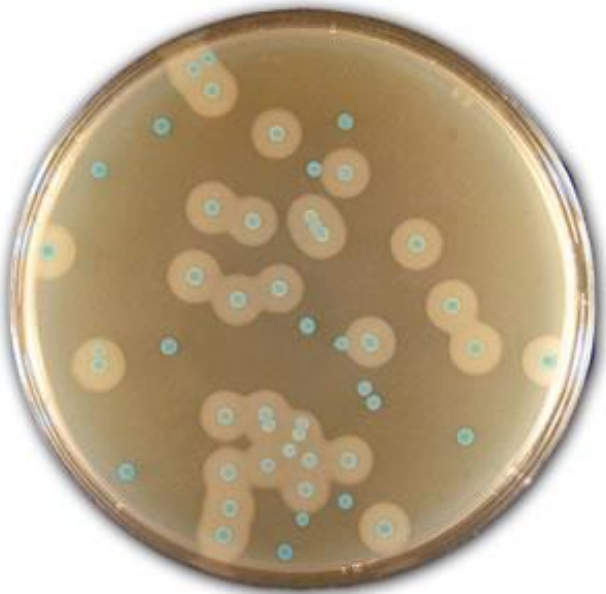
¿Qué es *Bioterrorismo*?

- 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.

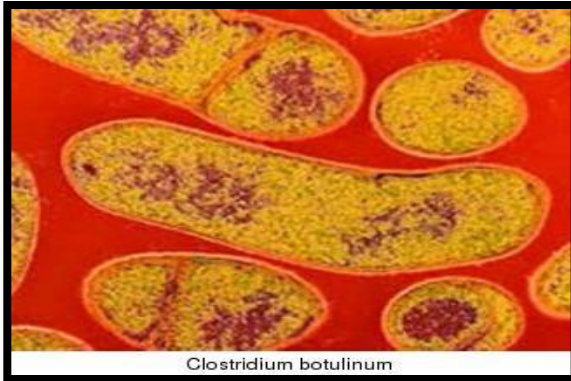




• Los alimentos podrían utilizarse como vehículo para perpetrar ataques terroristas



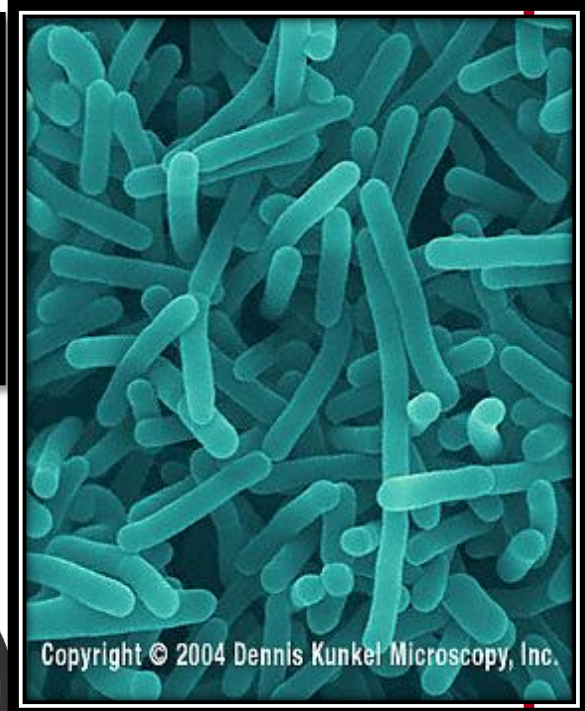
Agentes utilizados para perpetrar ataques de bioterrorismo



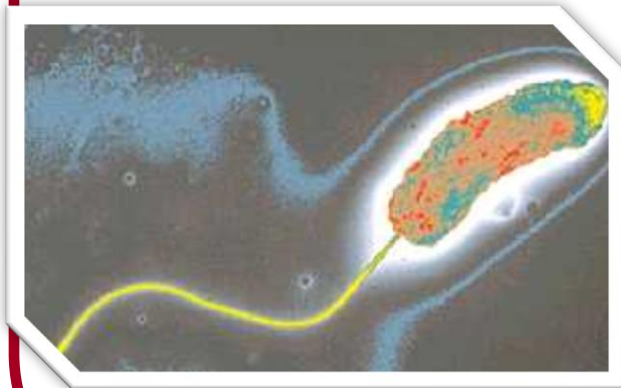
Clostridium botulinum



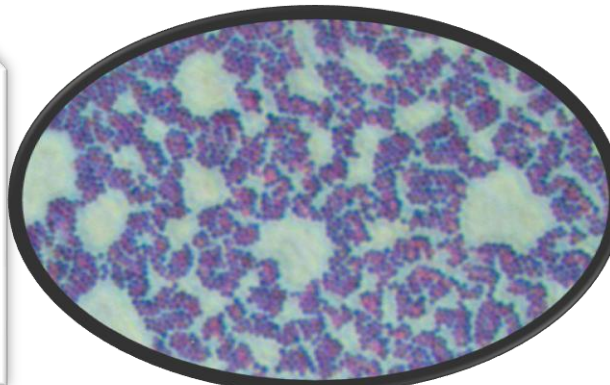
Salmonella



Listeria



Vibrio cholerae – Cólera



Staphylococcus

¿Cómo afecta el Bioterrorismo?

- Mayores controles en las importaciones de productos y puntos de desembarque de pasajeros y mercancías.
- Nuevas leyes y regulaciones:
Normativa EEUU contra el bioterrorismo
– *The Bioterrorism Act of 2002*



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

(Ley de Bioterrorismo - 2002)



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

Regulatory Information

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Legislation

[Other Laws Affecting FDA](#)[Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#)

Bioterrorism Act of 2002

[✉ Sign up for Bioterrorism Act email updates.](#)

The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002.

The Bioterrorism Act is divided into five titles

- [Title I -- National Preparedness for Bioterrorism and Other Public Health Emergencies](#)
- [Title II -- Enhancing Controls on Dangerous Biological Agents and Toxins](#)
- [Title III -- Protecting Safety and Security of Food and Drug Supply](#)
- [Title IV -- Drinking Water Security and Safety](#)
- [Title V -- Additional Provisions](#)

Page Last Updated: 02/19/2010

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players.](#)

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)***

¿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**

¿Quién debe registrar la instalación?

- **Todo propietario o persona a cargo de una instalación debe registrarla ante la FDA y Obtener su Número de Registro**
- **Puede autorizar a un tercero (importador, transportista, representante, exportador familiar, etc.) a realizar el registro en representación de la instalación.**

¿CÓMO SE REGISTRA UNA INSTALACIÓN?

- **Llenando un formulario electrónico proporcionado por la FDA a través de su página WEB:**
www.fda.gov
- **Enviando el formulario escrito por FAX o correo postal a la FDA** (en desuso por las ventajas que ofrece la vía electrónica)

U.S. Food and Drug Administration (HFS-681)
5600 Fishers Lane
Rockville, MD, USA 20857
877 332-3882

¿Cómo se llena el Formulario electrónico para Registrar una Instalación?

1) Creando una “**CUENTA FDA**” en la sección *Food Industry* de la Página Web de la FDA

LOGIN

Existing account holders, enter your account ID and password.

Account ID:

Password:

[Forgot your password?](#)

Food

Drugs ▶

Medical Devices ▶

Vaccines, Blood & Biologics ▶

Animal & Veterinary ▶

Cosmetics ▶

Radiation-Emitting Products ▶

Tobacco Products ▶

Key Topics

- Dietary Supplements
- Food Defense
- Food Ingredients & Packaging
- Food Safety
- International Activities
- Labeling & Nutrition
- News & Events

Consumer Resources

- Consumers
- Health Care Professionals
- Health Educators
- Students & Teachers

Industry Resources

- Color Additives
- Facility Registration
- Guidance Documents
- Prior Notice of Imports
- Reportable Food Registry

More Information on Food ▶

Science & Research

- Combination Products
- Critical Path Initiative
- Clinical Trials
- Pediatrics
- Rare Diseases

Public Health Focus

- Stolen Albuterol Solution
- New Center for Tobacco Products
- FDA Transparency Task Force -- Participate in Blog
- Commissioner's Speech on Enforcement -- Watch Video
- Expanded Access to Investigational Drugs



Food

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[Home](#) > [Food](#) > [Guidance, Compliance & Regulatory Information](#) > [Registration of Food Facilities](#)

Guidance, Compliance & Regulatory Information

▶ Registration of Food Facilities

Registration/Cancellation by Paper (Mail or FAX) or CD-ROM

[Online Registration](#)

Resources for You

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

Registration of Food Facilities

[Login / Create Account](#)

OMB Approval Number: **0910-0502**

OMB Expiration Date: **05/31/2010**

[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

Spotlight

- [Notice To Remind Informants of Food Facility Databases](#)
- [Important Regarding Registration](#)
- [Register Online Q](#)
- [New Feature Facility \(FFRM\)](#)

Compliance

- [Summary](#)

July 7, 2009 See [Egg Safety Final Rule](#)

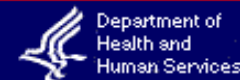
August 27, 2009 See [Reminder to Update Your Information in Food Facility Registration](#)

NEW USERS	LOGIN
Create New Account See Instructions See Tutorials Help Desk	<p>Existing account holders, enter your account ID and password.</p> <p><input type="text"/></p> <p>Password: <input type="password"/> Forgot your password?</p> <p><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><input type="radio"/> I understand</p> <p><input type="button" value="Login"/></p>

Llenar los Datos de la Cuenta FDA: Nombre, dirección, teléfono, password, etc.)



U.S. Food and Drug Administration



[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](#) 

*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.

La FDA le proporcionará el Nombre de Usuario (Account ID)

CREATE AN ACCOUNT

» Get Help 

You have successfully created an Account. Your account ID is **uni87258**

YOU WILL NEED TO REMEMBER YOUR ACCOUNT ID AND PASSWORD
TO LOGIN TO THE SYSTEM IN THE FUTURE.

[Click here to login](#)

**Imprima esta página y escriba en ella el password que eligió,
respetando mayúsculas, minúsculas, números y caracteres**

¡YA ESTAMOS LISTOS PARA REGISTRAR UNA INSTALACIÓN!

FDA Industry Systems - Accounts Management - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.access.fda.gov/oa/>

FDA U.S. Food and Drug Administration Department of Health and Human Services

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

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

FDA Industry Systems

[Food Facility Registration](#) | [Prior Notice](#) | [Acidified and Low-Acid Canned Food](#)

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" below.

If you already have an account, enter your account ID and password.

NEW USERS	LOGIN
Create New Account	Existing account holders, enter your account ID and password.
See Instructions	Account ID: <input type="text"/>
See Tutorial	Password: <input type="password"/> Forgot your password?
Help Desk	<p>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.</p> <p><input type="checkbox"/> I understand</p>

Coloque su
Account ID

Coloque su
Password

Click en
"Login"

INGRESE AL FORMULARIO ELECTRÓNICO DE REGISTRO DE INSTALACIONES

Account Management

- » Edit Account Profile
- » Change My Password
- » Update System Access
- » Create a Subaccount
- » Deactivate a Subaccount
- » Reactivate a Subaccount

Welcome

You are logged in as **fda22292**

Welcome to the FDA Industry Systems.

You are logged in to your account for company **FDA**

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.

FDA Unified Registration Listing Systems

Food Facility Registration



Low Acid Canned Food

Other FDA Systems

Prior Notice

PÁGINA DE INICIO DEL FORMULARIO DE REGISTRO DE INSTALACIONES

FFRM MAIN MENU

Register a Food Facility

Update Facility Registration

Cancel/Change 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: 10/31/2006

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.

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](#)

¿QUÉ INFORMACIÓN SE COLOCA EN EL FORMULARIO?

- Nombre, razón social, dirección y teléfono de la instalación
- Nombre, dirección, teléfono y correo electrónico del propietario o persona a cargo de la instalación
- Nombre, dirección, teléfono y correo electrónico del **agente en EE.UU**

- Tipo de alimento procesado en la instalación (frutas, conservas, especias, etc.)
- Nombre, dirección teléfono y correo electrónico de la persona que llenó el formulario, en caso que el propietario lo haya designado
- Declaración de autenticidad y exactitud de la información brindada.

¿Quién es el Agente en los Estados Unidos?

- Persona de contacto requerida por la FDA en EE.UU
- Deberá residir en EE.UU
- Es un vínculo directo entre la FDA y la instalación, para cualquier comunicación rutinaria o de emergencia.
- No necesariamente tiene que estar vinculado a las actividades productivas o comerciales de la instalación

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.

ENVIOS EXENTOS DE NOTIFICACIÓN PREVIA

- Muestras de alimentos para análisis fisicoquímicos destructivos o que los imposibilita para un posterior consumo
- Alimentos para consumo personal de los viajeros.
- Alimentos preparados en casa de un viajero o familiares y transportados en el equipaje para obsequiar en EE.UU

- Alimentos que se encuentren en tránsito en EE.UU, pero que no son sacados de los terminales aéreos o marítimos.
Ejemplo: vuelos haciendo escala en EE.UU

¿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.

¿CÓMO SE EMITE LA NOTIFICACIÓN PREVIA?

1) Ingresando a la **Cuenta FDA:**

LOGIN
Existing account holders, enter your account ID and password.

Account ID:

Password: [Forgot your password?](#)

- Account Management**
- >> Edit Account Profile
 - >> Change My Password
 - >> Update System Access
 - >> Create a Subaccount
 - >> Deactivate a Subaccount
 - >> Reactivate a Subaccount

Welcome You are logged in as **fda22292**

Welcome to the FDA Industry Systems.
You are logged in to your account for company **FDA**

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FDA Unified Registration Listing Systems

Food Facility Registration

Low Acid Canned Food

Other FDA Systems

Prior Notice



Welcome to the Prior Notice System Interface

The Prior Notice System Interface enables you to submit Prior Notices for Imported Food Articles to the Food and Drug Administration (FDA).

Get Started

- ▶ Overview of how to submit a Prior Notice for Food Importation.

Learn New Features

- ▶ Overview of New Features available in this version of the Prior Notice System Interface.

Create New Web Entry

Creating a Web Entry is the first step in creating Prior Notices. A Web Entry contains information that one or more food articles you intend to import share (e.g., arrival information). After Creating a Web Entry, create, review, and submit Prior Notices. Prior Notices include information about the Product, its Quantity and Packaging, and other related information, such as the Manufacturer or Grower/Consolidator and the Shipper.

You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. The system automatically "Completes" Web Entries with submitted Prior Notices when the Prior Notice submission timeframe elapses (see the "Complete Web Entry" Help topic).

Find Existing Web Entry

- ▶ Use this feature to find Web Entries that you have already created.

Find Existing Prior Notice

- ▶ Use this feature to find Prior Notices that you have already created. To submit Holding Facility information for a Prior Notice submitted via PNSI by this account or another account within the same company, search for the Prior Notice and click the Submit Holding Facility button.

View/Submit Holding Facility

- ▶ To submit Holding Facility information for a Prior Notice that has been submitted via the U.S. Customs' and Border Protection (CBP) Automated Commercial System (ACS) or by another PNSI user of a different company click on the View/Submit Holding Facility button.

WEB ENTRY: Tipo de envío, lugar de arribo, fecha y hora de arribo, datos del importador, datos del transportista, datos de la persona o empresa que emite la Notificación Previa.

1 Web Entry (Create)

Select the Entry Type for the Web Entry and click on the Next button. Refer to the Help for the descriptions of the entry types.

*Entry Type:

- Baggage
- Consumption
- Consumption, Express Courier
- Foreign Trade Zone (FTZ)
- Immediate Transportation (IT)
- Informal
- Mail (Commercial)
- Mail (Non-Commercial Sender)
- Temporary Importation under Bond (TIB)
- Transportation and Exportation
- Transportation and Exportation, Express Courier

Copyright ©

Port of Arrival

Enter the Port Code for the Port of Arrival and the Anticipated Arrival Date and Time. The time should be in the time zone of the Port of Arrival. If you do not know the Port Code, select the state and click on the Find Port Code button. Indicate the Anticipated Border Crossing, if available.

Port: Alameda, CA (2813)

State:

OR *Port Code:

Anticipated Border Crossing:

*Anticipated Arrival Date: (MM/DD/YYYY)

*Anticipated Arrival Time: (24-hour clock HH:MM)

INGRESE LOS DATOS DEL IMPORTADOR

1 Web Entry: Importer (Enter)

If the Importer is the same facility as the Submitter, enable the checkbox below and then click on the Save button. Note: If you enable this checkbox, the system will not save any other data you enter for the Importer.

Importer same Facility as Submitter

If the Importer is NOT the same Facility as the Submitter, do one of the following:

- >> If you have the Importer's Food Facility Registration Number, enter it along with the Facility Name and the City.
- >> If you do not have the Importer's Food Facility Registration Number, enter at least all required address items denoted by an asterisk (*).

Food Facility Registration Number:

*Name: Black's Importing, Inc

*Street Address: 123 Main Street

*City: Los Angeles

* Country Subdivision: California (state, province, etc.)

*Country: United States

[Change Country](#)

* ZIP/Mail Code:

[Save](#)

[Cancel](#)

INGRESE LOS DATOS DEL TRANSPORTISTA

Carrier

The Carrier is the transporter of the food from the "Country from which the article is shipped" into the United States. Select the applicable Mode of Transportation and then click on the Enter Carrier button to provide information about the Carrier.

*Mode of Transportation:

- Air
- Air Container
- Land, Automobile
- Land, Other
- Land, Pedestrian
- Land, Truck

Enter Carrier

Please refrain from using your browser's BACK button. Using your browser's BACK button may result in your having to re-enter the information.

Please refrain from using your browser's BACK button. Using your browser's BACK button may result in your having to re-enter the information.

1 Web Entry: Carrier (Enter)

Mode of Transportation: Air **Change Mode**

Enter the International Air Transport Association (IATA) Two-Character Code. If you do not know the IATA Code, click on the Find Code button to search for the code by Carrier Name. If the carrier does not have an IATA Code, the Carrier Name and the Country of the Carrier are required (marked with two asterisks **).

* IATA Code: **Find Code**

** Carrier Name:

** Country of the Carrier:

Enter the following information about the shipment (required items marked with an asterisk):

Airway Bill Master is an 11-digit numeric code that is comprised of 2 parts: the 3-digit Airline Prefix code issued by IATA plus the 8-digit Airway Bill number issued by the carrier. IATA issues the Airline Prefix code to air carriers of freight cargo. This code is a standard element of Airway Bills. The Two-Character IATA Code values returned by the "Find Code" function above for the Carrier Code are not acceptable for use in the Airway Bill Master field.

Flight Number:

* Airway Bill - Master:

Airway Bill - House:

Save

Cancel

INGRESE LOS DATOS DEL EMISOR DE LA NOTIFICACIÓN PREVIA

1 Web Entry: Submitter (Enter)

If you, the Transmitter, are also the Submitter, enable the checkbox below and then click on the Save button. Note: If you enable this checkbox, the system will not save any other data you enter for the Submitter.

Submitter same Individual as Transmitter

If you are NOT the Submitter, do one of the following:

>> If you have the Submitter's Food Facility Registration Number, enter it along with the Facility Name and the City.

>> If you do not have the Submitter's Food Facility Registration Number, enter at least all required items denoted by an asterisk (*).

Food Facility Registration Number:

*Business Name:

*Street Address:

*City:

* Country Subdivision: (state, province, etc.)

*Country: United States [Change Country](#)

* ZIP/Mail Code:

Enter the Submitter's Name and provide the phone, fax, and e-mail, if they exist.

*First Name:

*Last Name:

Phone:

Fax:

e-mail:

[Save](#)

[Cancel](#)

EMISIÓN DE LA NOTIFICACIÓN PREVIA PROPIAMENTE DICHA

[1 Create Web Entry](#) [2 Create Prior Notice](#)

1 Web Entry (View)

[Copy](#) [Cancel](#)

This page displays all known information about the Web Entry. You may edit information in the Web Entry or its related facilities by clicking on the appropriate Edit button, if there are no submitted Prior Notices associated with it. To create a new Prior Notice, click on the Create Prior Notice option above.

Web Entry

[Edit](#)

Entry Identifier: ###-0026206-7

Status: Open

Port of Arrival: Alameda, CA (2813)

Entry Type: Consumption

Anticipated Arrival Date and Time: 11/15/2004 09:30

Anticipated Border Crossing:

Number of Intended Prior Notices: 4

Submitter

[Edit](#)

Byron Import Company
11 21st Street
Los Angeles, California 90001
UNITED STATES

Registration Number: 16606225908
Name: John Byran
Phone:
Fax:
e-mail:

Importer

[Edit](#)

Black's Importing, Inc.
123 Main Street
Los Angeles, California 90001
UNITED STATES

Registration Number:

Carrier

[Edit](#)

Mode of Transportation: Air
Carrier Name: AMERICAN AIRLINES
Carrier Country:
Carrier Code (IATA): AA

Airway Bill - Master: ABC12345678

Prior Notices

None available.

[1 Create Web Entry](#)

[2 Create Prior Notice](#)



2 Prior Notice: Article (Create)

To create a Prior Notice, enter the Article information. You must enter or select a value for each item marked with an asterisk, "*".

Entry Identifier: +++4183744-0

*Country from which the Article is Shipped:

Product Information

Enter the exact seven-character Product Code. Use the Search button to find the Product Code. Use "99", meaning "Not Elsewhere Classified", as the last two characters of the Product Code ONLY if a specific code for food does not exist.

*FDA Product Code:

*Common or Usual Name/Market Name:

Production Identifiers

Production Identifiers are the Lot Codes, Production Codes, or other identifiers associated with products. The production identifiers are mandatory if the product is required to bear such numbers by the FD&C Act or by FDA regulations. Use the Add and Delete buttons to add or remove Production Identifiers.

Quantity and Packaging

You may invoke the wizard to build the Quantity and Packaging for this Article by clicking on this button.

For packaged food, enter the weight or volume of the smallest (Base) unit. For, example, 16 "ounces, weight (avdp)", if the smallest unit is a 16 oz can. If the product has no packaging, enter the net weight or volume as the Base Unit and check the Bulk-shipment checkbox. The system will ignore all Packaging information if the Bulk-shipment checkbox is checked.

You must create a separate Prior Notice for each article of food with a different base unit.

*Base Unit (Number and Measure): Bulk-shipment (no packages)

For packaged food, provide the estimated quantity of food that will be shipped, described from the largest container to smallest package size (up to five packaging levels may be provided). For example, 500 Cases, with 40 Cans per Case (The weight of the individual can is the base unit).

INGRESE LA CANTIDAD, PESO Y TIPO DE ENVASE Y EMBALAJE DEL ALIMENTO

Quantity and Packaging

You may invoke the wizard to build the Quantity and Packaging for this Article by clicking on this button. **Wizard**

For packaged food, enter the weight or volume of the smallest (Base) unit. For, example, 16 "ounces, weight (avdp)", if the smallest unit is a 16 oz can. If the product has no packaging, enter the net weight or volume as the Base Unit and check the Bulk-shipment checkbox. The system will ignore all Packaging information if the Bulk-shipment checkbox is checked.

You must create a separate Prior Notice for each article of food with a different base unit.

*Base Unit (Number and Measure): Bulk-shipment (no packages)

For packaged food, provide the estimated quantity of food that will be shipped, described from the largest container to smallest package size (up to five packaging levels may be provided). For example, 500 Cases, with 40 Cans per Case (The weight of the individual can is the base unit).

	Number	Package Type	
Largest Package to Smallest Package	<input type="text"/>	<input type="text"/>	Total Quantity:
	<input type="text"/>	<input type="text"/>	Calculate
	<input type="text"/>	<input type="text"/>	
	<input type="text"/>	<input type="text"/>	
	<input type="text"/>	<input type="text"/>	

Save **Cancel**

Please refrain from using your browser's BACK button while in the application process. Using your browser's BACK button may result in your having to re-enter the information.

INGRESE LOS DATOS DE LA ÚLTIMA INSTALACIÓN QUE PROCESÓ EL ALIMENTO (Manufacturer)



**PRIOR NOTICE
SYSTEM INTERFACE**
UNITED STATES FOOD AND DRUG ADMINISTRATION



FDA

[Home](#) | [Contact Us](#) | [Help](#) | [» Logoff](#)

Juan Mathews, PROMPEX

3 Submit Prior Notice

[Web Entry](#) [Article](#) [Related Facilities](#)

2 Prior Notice: Related Facilities (View)

[Copy](#) [Cancel PN](#)

Entry Identifier: +++-4183744-0

Article Number: 0001

Manufacturer

If the food is no longer in natural state, the Country of Production is generally the country where the food was made. Select the FDA Country of Production from the drop-down list. Then, click on the Enter Manufacturer button.

*FDA Country of Production: 

Enter Manufacturer

Shipper

Select the Country where the Shipper's business is located. Then, click on the Enter Shipper button.

*Country: 

Enter Shipper

3 Submit Prior Notice

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Prior Notice v2.0.01 - May 15, 2009

3, 1, Thu Sep 10 15:21:48 EDT 2009

**COLOQUE AQUÍ EL NÚMERO DE
REGISTRO FDA DE LA INSTALACIÓN**

INGRESE LOS DATOS DE LA PERSONA O EMPRESA QUE DESPACHA EL PRODUCTO (Shipper)

2 Prior Notice: Shipper (Enter)

If the Shipper is the same Facility as another that you have already entered for this Prior Notice, select the Facility and click on the Save button. Note: If you do this, the system will ignore any other data you enter for the Shipper.

Shipper same Facility as:

Otherwise, do one of the following:

- >> If you have the Shipper's Food Facility Registration Number, enter it along with the Facility Name and the City.
- >> If you do not have the Shipper's Food Facility Registration Number, enter at least all required address items denoted by an asterisk (*).

Food Facility Registration Number:

*Name:

*Street Address:

*City:

Country Subdivision: (state, province, etc.)

*Country: Canada [Change Country](#)

ZIP/Mail Code:

Should this Facility be the default Shipper for new Prior Notices for this Web Entry?

Save

Cancel



Submit Prior Notice

[Web Entry](#)

[Article](#)

[Related Facilities](#)

2 Prior Notice: Related Facilities (View)

[Copy](#)

[Cancel PN](#)

Entry Identifier: ###-0026206-7

Article Number: 0001

Manufacturer

[Edit](#)

Montreal Soup
123 Main Street
Montreal, Quebec
CANADA

Registration Number:
12345678900

Shipper

[Edit](#)

Shipper is same as the Manufacturer or Grower/Consolidator

Owner

[Edit](#)

Byron Grocery Supply
123 Hill Lane
Los Angeles, California 90001
UNITED STATES

Ultimate Consignee

[Edit](#)

Ultimate Consignee is same as the Owner

Holding Facility (Required if this Prior Notice is Submitted Post Refusal)

If U.S. Customs and Border Protection (CBP) has directed this article to a Holding Facility, click on the Enter Holding Facility button to provide specific information about the Holding Facility.

[Enter Holding Facility](#)

You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection (CBP) to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. Completing the Web Entry indicates that you do not need to submit further Prior Notices for this Web Entry.

The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.200(f)). After you submit all Prior Notices and Complete the Web Entry, it is recommended that you provide a copy of the Web Entry Submission Confirmation to the Carrier for presentation to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) at the Port of Arrival.

Prior Notice: Submitted

[View Web Entry](#)[Copy](#)[Cancel PN](#)[Print/Save](#)

Transmitter: CFSAN Tester

Submitted: 11/01/2004 17:35:39

Confirmation Number: 040004979825

Web Entry

Entry Identifier: ###-0026210-1

Status: Open

Port of Arrival: Alameda, CA (2813)

Anticipated Border Crossing:

Anticipated Arrival Date and Time: 11/05/2004 09:30

Entry Type: Consumption

Submitter

Byron Import Company
11 21st Street
Los Angeles, California 90001
UNITED STATESRegistration Number: 16606225908
Name: John Byran
Phone:
Fax:
e-mail:

Importer



Prior Notice Confirmation: Submitted

For your records only.

Transmitter: [REDACTED]
Confirmation Number: 070062432064

Submitted: 05/15/2007 17:16:56

WEB ENTRY

Entry Identifier: ###-2519383-4
Port of Arrival: FedEx - Memphis, Memphis, TN (2095)
Anticipated Arrival: 05/17/2007 06:00
Status: Completed
Entry Type: Consumption, Express Courier

Submitter

[REDACTED] Name: [REDACTED]
Lima - 18, Lima L-18 Phone: [REDACTED]
PERU Fax: [REDACTED]
e-mail: f. [REDACTED]

Importer

New port Beach, California 92660
UNITED STATES

Carrier

FEDERAL EXPRESS Mode of Transportation: Express Courier - Air
UNITED STATES Airway Bill or Tracking Number: 862280024700
Carrier Code (IATA): FX

ARTICLE

Article Number: 0006
FDA Country of Production: Peru (PE)
Country from which the Article is Shipped: Peru (PE)

Product Information

FDA Product Code: 03FDT99
FDA Product Description: CRACKERS (NON FILLED) N.E.C., LAMINATED, PACKAGED FOOD (NOT COMMERCIALY STERILE)
Common or Usual Name/Market Name: [REDACTED]

Production Identifiers

None

Quantity and Packaging

Total Quantity: 260 Grams
Base Unit: 65 Grams
Packaging from largest to smallest package: 1 Box
2 Tube
2 Package

Related Facilities

Manufacturer

[REDACTED] Registration Number: [REDACTED]
Angamos Oeste
Miraflores, Lima L-18 PERU

Shipper

Shipper is same as the Manufacturer or Grower/Consolidator

Owner

Owner is same as the Manufacturer or Grower/Consolidator

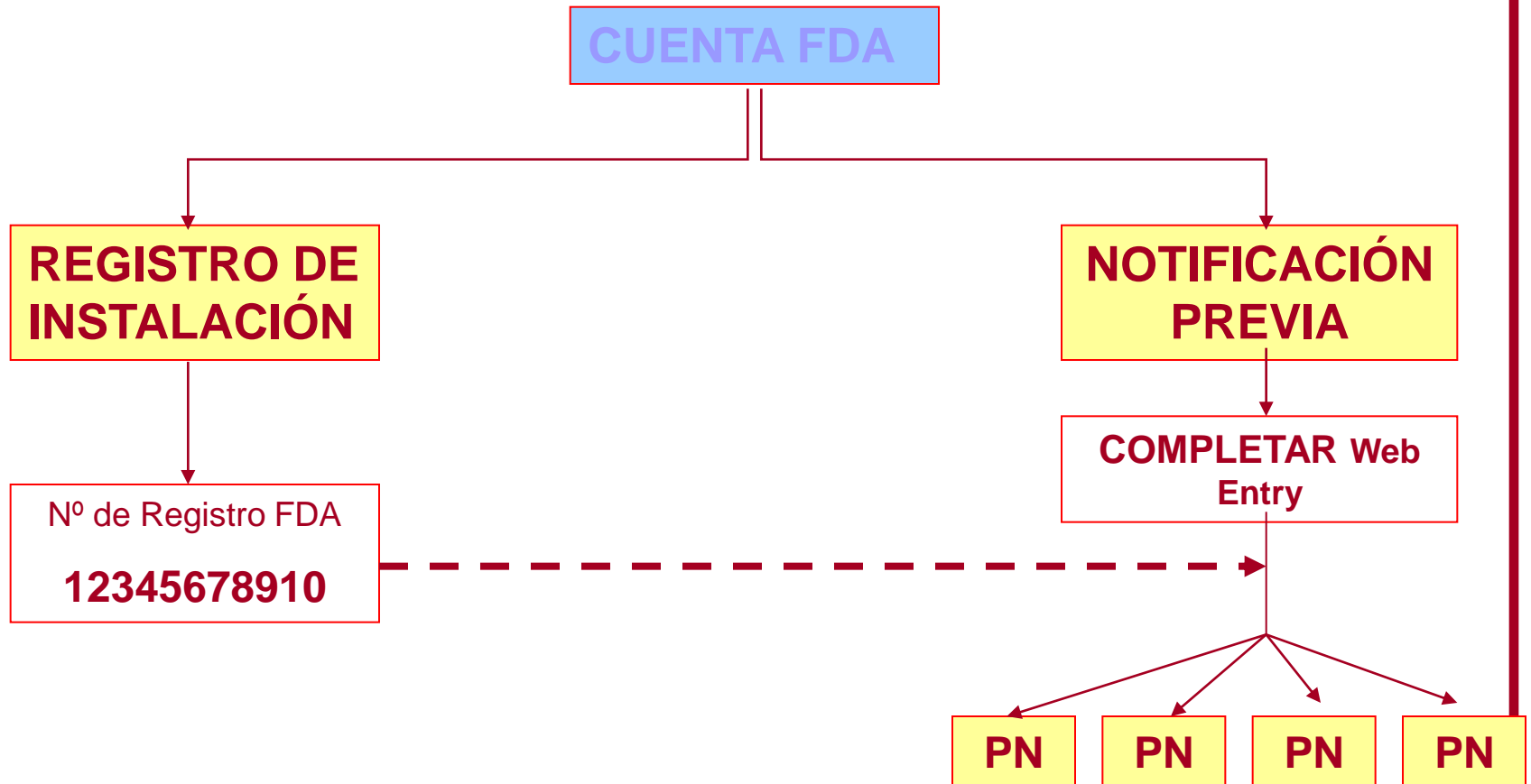
Ultimate Consignee

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

DEPARTAMENTO DE GESTION DE LA CALIDAD

TEL: 6167400 Anexo 2501

Iván Serpa Cárdenas iserpa@promperu.gob.pe

Gracias por su Atención

Iván Serpa Cárdenas

Telf: (511) 6167400 Anexo 2501

E-mail: iserpa@promperu.gob.pe

