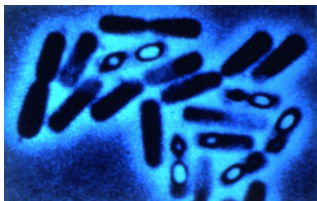


LEY CONTRA EL BIOTERRORISMO

REQUISITO INDISPENSABLE PARA LA EXPORTACIÓN DE ALIMENTOS A LOS ESTADOS UNIDOS

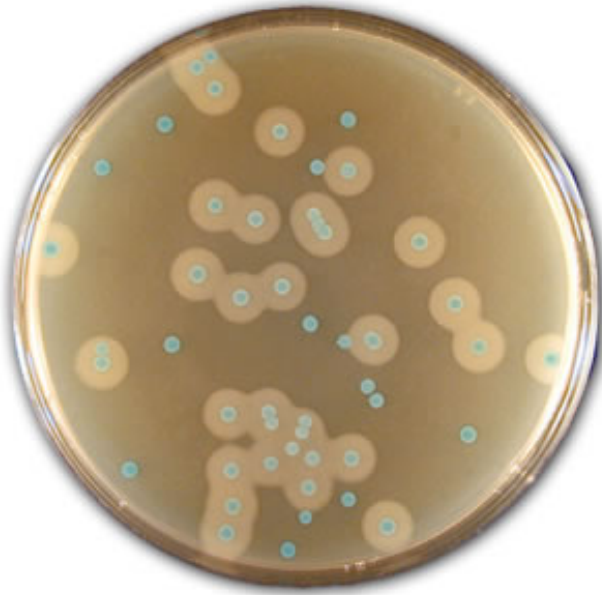
Miguel A. Watts González
PROMPERÚ



PÁNICO EN LA POBLACIÓN DE EE.UU



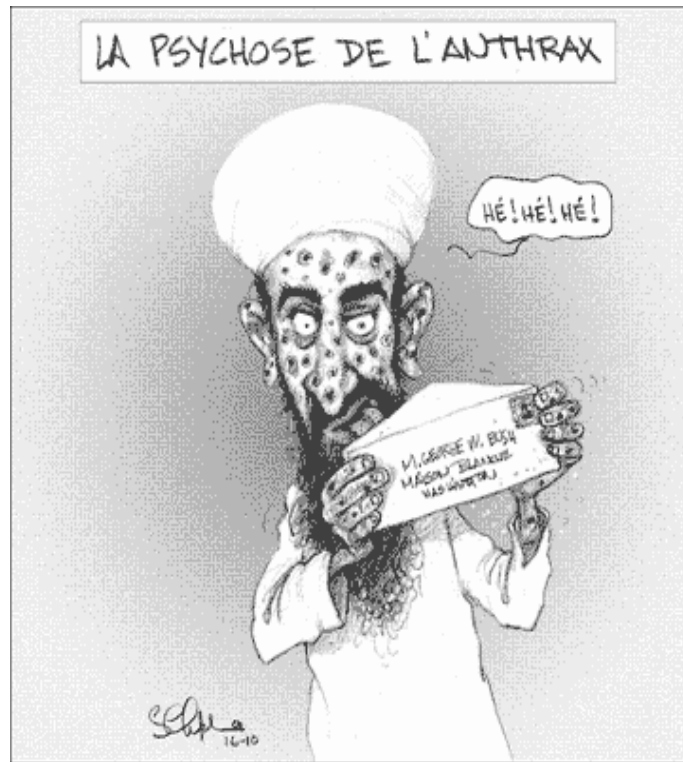
LOS ALIMENTOS PODRÍAN UTILIZARSE COMO VEHÍCULO PARA PERPETRAR ATAQUES TERRORISTAS



- *Clostridium botulinum* – Botulismo
- *Vibrio cholerae* – Cólera
- *Salmonella spp*, *Escherichia coli*,
- Entre otros



BIOTERRORISMO



Empleo criminal de agentes patógenos contra una población con el propósito de generar enfermedad, muerte, pánico y terror.

INICIATIVAS DE DEFENSA EN LOS PAÍSES AMENAZADOS

Mayores controles de las importaciones de alimentos y puntos de desembarque de pasajeros y mercancías

Nuevas leyes y regulaciones:

USA Food And Drug Administration (FDA)

“The Bioterrorism Act of 2002”

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

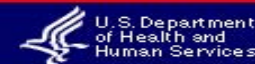
Título III: Protección de la inocuidad y seguridad del suministro de alimentos y medicamentos

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

<http://www.fda.gov/oc/bioterrorism/bioact.html>



U.S. Food and Drug Administration



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The Bioterrorism Act of 2002

The Act

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.

Complete Text: [HTML](#); [PDF](#)

The Bioterrorism Act is divided into five titles:

- [Introduction](#)
- [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

Plans for Implementing the Act

Title I (National Preparedness)

[Section 123](#) (Animal Trials):
[Federal Register Notice](#)
[View Comments](#)

Title III (Safety of Food and Drug Supply):

[Subtitle A](#) (Food Supply Protection)

[Section 301](#) (Security Strategy)
[Section 302](#) (Food Adulteration)

[Report to Congress: Testing for Food Adulteration](#) (February 2005)

[Section 303](#) (Detention)
[Final Rule](#) (June 4, 2004)
[Press Release](#) (May 27, 2004)
[Fact Sheet](#)
[More Information](#)

[Section 305](#) (Registration)
[Final Rule](#) (PDF)
[Press Release](#) (Sept. 28, 2005)
[Interim Final Rule](#) (PDF)
[Press Release](#) (Oct 16, 2003)
[Fact Sheet](#) (Spanish version)
[Questions and Answers](#)

Register Your Food Facility

- [Register Online](#)
- [Register via Mail/Fax](#)
- [Registration Help Desk](#)
- [Verification of Registration](#)

Prior Notice-Food Imports

- [Information/Login](#)
- [Plan for Uniform System and Coordinated Timeframes](#)
- [Compliance Summary Information](#)

[Updates on Requirements](#)

[Help Desk](#)

Recent Activities

¿QUE EXIGE LA *Food And Drug Administration* (FDA) EN EL MARCO DE LA LEY CONTRA EL BIOTERRORISMO?

- Que las instalaciones que manufacturen, procesen o envasen alimentos que vayan a ser exportados a EE.UU estén registradas ante la FDA (***Food Facility Registration***)
- Que todo embarque de alimentos sea previamente notificado a la FDA antes de ingresar a territorio estadounidense (***Prior Notice***)

¿QUÉ ALIMENTOS ESTÁN SUJETOS AL CUMPLIMIENTO DE LA LEY CONTRA EL BIOTERRORISMO?

TODOS AQUELLOS QUE FINALMENTE VAYAN A SER CONSUMIDOS EN EE.UU

- 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)



INSTALACIÓN *(Facility)*

Establecimiento o estructura (fábrica, planta, packing, factoría, almacén, etc.) donde se fabrican, manufacturan, procesan, envasan, acondicionan o almacenan alimentos que vayan a ser exportados a EE.UU.

INSTALACIÓN *(Facility)*

No es una instalación:

- Residencias particulares (garajes, patios, azoteas)
- Campos de cultivo o granjas de cría
- Vehículos de transporte (excepto los barcos-factoría de productos pesqueros)

LA LEY EXIGE QUE LAS INSTALACIONES SE REGISTREN ANTE LA FDA

- 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 ACCEDE Y 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?](#)



U.S. Food and Drug Administration



U.S. Department of Health and Human Services

Search

GO

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[A-Z Index](#)
[Site Map](#)

Products FDA Regulates

Food

Foodborne Illness, Nutrition, Dietary Supplements...

Drugs

Prescription, Over-the-Counter, Generic...

Medical Devices

Pacemakers, Contact Lenses, Hearing Aids...

Biologics

Vaccines, Blood Products...

Animal Feed and Drugs

Livestock, Pets...

Cosmetics

Safety, Labeling...

Radiation-Emitting Products



Consumer Health Information

- [Coping with Memory Loss](#)
- [All Consumer Health](#) > >

FDA NEWS

- [USDA Clears Swine for Processing](#)
- [FDA Approves Expanded Use for Surgical Sealant](#)
- [FDA Issues Health Risk Alert for 'True Man' and 'Energy Max' Products](#)
- [FDA Announces Results of Investigation Into Illegal Promotion of OxyContin by The Purdue Frederick Company, Inc.](#)
- [FDA Approves Neupro Patch for Treatment of Early Parkinson's Disease](#)

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[Reference Room](#)

Food Industry

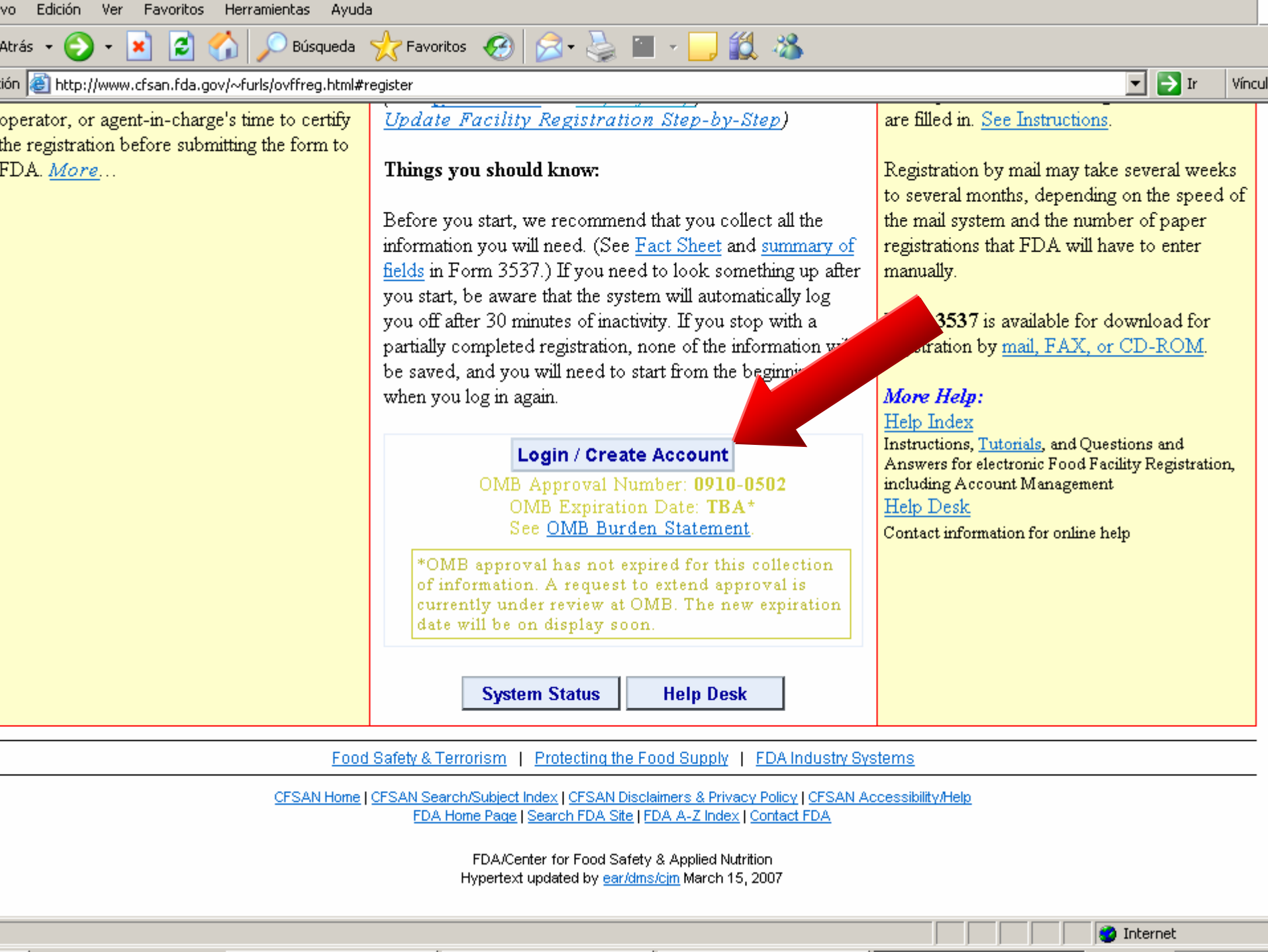
- [Register a Facility](#)
- [Prior Notice of Imports](#)

Hot Topics

- [Pet Food Recall](#)
- [Losing Weight](#)
- [Buying Medicines Online](#)
- [Counterfeit Drugs](#)
- [Imported Drugs](#)
- [Counterterrorism](#)
- [Bioterrorism Act](#)
- [More Hot Topics...](#)

FDA Activities

- [About FDA](#)
- [FDA FY 2008 Budget](#)
- [Advisory Committees](#)
- [Clinical Trials](#)
- [Consumers](#)
- [Professionals](#)
- [Facts@FDA](#)
- [Field Operations](#)
- [Freedom of Information](#)
- [Imports](#)
- [International](#)
- [MedWatch](#)
- [Pediatrics](#)
- [Science](#)
- [Toxicological Research](#)
- [User Fees](#)



operator, or agent-in-charge's time to certify the registration before submitting the form to FDA. [More...](#)

[Update Facility Registration Step-by-Step](#)

Things you should know:

Before you start, we recommend that you collect all the information you will need. (See [Fact Sheet](#) and [summary of fields](#) in Form 3537.) If you need to look something up after you start, be aware that the system will automatically log you off after 30 minutes of inactivity. If you stop with a partially completed registration, none of the information will be saved, and you will need to start from the beginning when you log in again.

are filled in. [See Instructions.](#)

Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

3537 is available for download for registration by [mail](#), [FAX](#), or [CD-ROM](#).

Login / Create Account

OMB Approval Number: **0910-0502**
OMB Expiration Date: **TBA***
See [OMB Burden Statement](#).

*OMB approval has not expired for this collection of information. A request to extend approval is currently under review at OMB. The new expiration date will be on display soon.

More Help:

[Help Index](#)
Instructions, [Tutorials](#), and Questions and Answers for electronic Food Facility Registration, including Account Management
[Help Desk](#)
Contact information for online help

[System Status](#) [Help Desk](#)



U.S. Food and Drug Administration



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[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

[Create New Account](#)

[See Instructions](#)

[See Tutorial](#)

[Help Desk](#)

Existing account holders, enter your account ID and password.

Account ID:

Password: [Forgot your password?](#)

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.

I understand



LLENAR LOS DATOS DE LA CUENTA FDA: Nombre, dirección, teléfono, password, etc.)

CREATE AN ACCOUNT [» Get Help ?](#)

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

* First Name:

Middle Initial:

* Last Name / Surname:

* Job Title:

* Company Name:

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"/> |
| 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.

E-Mail Address:

Confirm E-Mail:

Select and answer a secret question. If you forget your password, you will need to provide this information.

* Secret Question:

* Secret Answer:

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.

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

[Click here to login](#)

¡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/oaaf/>

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](#)

[See Instructions](#)

[See Tutorial](#)

[Help Desk](#)

Existing account holders, enter your account ID and password.

Account ID:

Password: [Forgot your password?](#)

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.

I understand

Microsoft Office, Microsoft Word, Microsoft PowerPoint, Microsoft Outlook, 8:44 PM

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

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

*STATE/PROVINCE/TERRITORY

*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 | <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

***STATE/PROVINCE/TERRITORY

***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

**STATE/PROVINCE/TERRITORY

**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**

¿QUÉ INFORMACIÓN SE COLOCA EN EL FORMULARIO?

- 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.

EL AGENTE EN 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

ENVIOS EXENTOS DE NOTIFICACIÓN PREVIA

- 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 **5 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.
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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



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:

Find Port Code

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: ###-1046362-4

*Country from which the Article is Shipped:

Please enter the Harmonized Tariff Schedule (HTS) Code as a six or eight or ten digit number. For more information on HTS codes click here: [HTS Codes](#)

*Harmonized Tariff Schedule (HTS) Code:

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:

Search >>

*Common or Usual Name/Market Name:

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" value="100"/> | <input type="text" value="Case"/> | Total Quantity: 64,000 Ounces, weight (avdp) |
| | <input type="text" value="40"/> | <input type="text" value="Can, Cylindrical"/> | Calculate |
| | <input type="text"/> | <input type="text"/> | |
| | <input type="text"/> | <input type="text"/> | |
| | <input type="text"/> | <input type="text"/> | |

Save

Cancel

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

2 Prior Notice: Manufacturer (Enter)

The Product Code you entered indicates that the product is no longer in its natural state, meaning the article of food has been made from one or more ingredients or has been synthesized, prepared, treated, modified, or manipulated.

- >> If the Manufacturer is required to register, enter the Manufacturer's Food Facility Registration Number along with the Facility Name and the City to identify the Facility. The Registration Number is issued to the Manufacturer when the facility is registered with the Food and Drug Administration via the Food Facility Registration Module (FFRM). You should contact the Manufacturer to get the appropriate Registration Number.
- >> If the Manufacturer is not required to register, enable the checkbox below, select a reason for the Manufacturer Registration Number Exemption or Identity of the Manufacturer Not Provided and provide the remainder of the facility address (Street Address; Country Subdivision, if applicable; and ZIP/Mail Code, if applicable).

Manufacturer is not required to register or Manufacturer Identity not known

Reasons for
Registration Number
Exemption
or Identity of
Manufacturer Not
Provided:

* Food Facility
Registration Number

COLOQUE AQUÍ EL NÚMERO DE REGISTRO FDA DE LA INSTALACIÓN

* Name:

Street Address:

* City:

Country Subdivision:

 (state, province, etc.)

Country:

Canada (CA) [Change Country](#)

ZIP/Mail Code:

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

 No

Save

Cancel

INGRESE LOS DATOS DEL PROPIETARIO DE LA MERCADERÍA (*Owner*)

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

Owner same Facility as:

Otherwise, do one of the following:

- >> If you have the Owner's Food Facility Registration Number, enter it along with the Facility Name and the City.
- >> If you do not have the Owner'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: United States (US) [Change Country](#)

* ZIP/Mail Code:

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

[Save](#)

[Cancel](#)

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

ZIP/Mail Code:

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



3 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 (1.2.2(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 STATES

Registration 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]
Lima - 18, Lima L-18
PERU

Name: [REDACTED]
Phone: [REDACTED]
Fax: [REDACTED]
e-mail: [REDACTED]

Importer

[REDACTED]
New port Beach, California 92660
UNITED STATES

Carrier

FEDERAL EXPRESS
UNITED STATES
Carrier Code (IATA): FX

Mode of Transportation: Express Courier - Air
Airway Bill or Tracking Number: 862280024700

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]
Angamos Oeste
Miraflores, Lima L-18 PERU

Registration Number: [REDACTED]

Shipper

Shipper is same as the Manufacturer or Grower/Consolidator

Owner

Owner is same as the Manufacturer or Grower/Consolidator

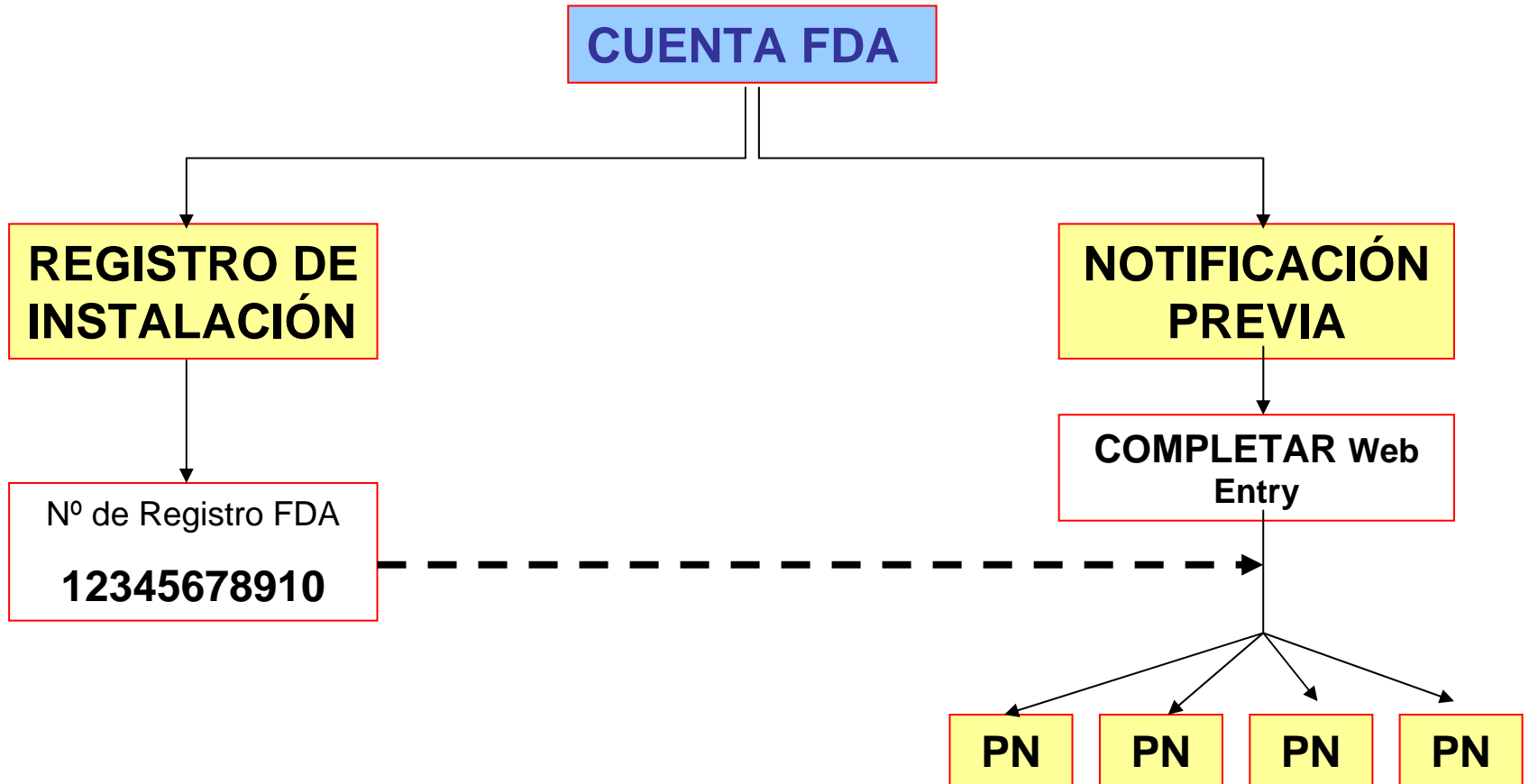
Ultimate Consignee

Ultimate Consignee is same as the Importer

Holding Location

Article Not Held

RESUMEN

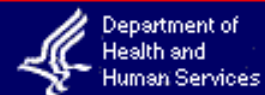


FRECUENCIA DE LOS TRÁMITES Y COSTO

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



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

[FDA Home Page](#) | [CFSAN Home](#) | [Search](#) | [Q & A](#) | [Help](#)

June 30, 2003

Protecting the Food Supply

FDA Notice Regarding Firms Offering Registration Services

FDA is aware that various firms may be offering their services to assist domestic and/or foreign facilities to register with FDA. Please note that these firms are not affiliated with FDA, nor has the agency contracted with any firms to register facilities. Facilities must be registered with FDA by December 12, 2003. You can register electronically at www.fda.gov/FURLS beginning on October 16, 2003 at 6:00 P.M. EDT. There is no registration fee.

October 16, 2003 - Registration of Food Facilities: [Electronic Registration via the Internet](#) (Overview and Background)



CONSULTAS DIVERSAS

Si exporto productos a Japón haciendo tránsito en EEUU, debo registrar mi instalación?

- No. Siempre y cuando los productos no salgan de los terminales correspondientes (aereo, marítimo)

¿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
- Las modificaciones se hacen ingresando el código “PIN” suministrado conjuntamente con el Número de Registro

¿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/oc/bioterrorism/bioact.html>
- Página Web de PROMPERÚ, sección “Calidad y Normatividad” www.prompex.gob.pe

CALL CENTER - BIOTERRORISMO

**Calidad y Normatividad
Gerencia de Agro y Agroindustrias
TEL: 222-1222 Anexo 301**

**Comisión de Promoción del Perú
para la Exportación y el Turismo**

PROMPERÚ

(EX - PROMPEX y PromPerú)

Claudia Solano Oré : csolano@prompex.gob.pe

Miguel Watts González : mwatts@prompex.gob.pe

GRACIAS POR SU ATENCIÓN

Miguel A. Watts González

Tel: 222-1222 Anexo 301

mwatts@prompex.gob.pe

**Comisión de Promoción del Perú
para la Exportación y el Turismo**

PROMPERÚ

(EX - PROMPEX y PromPerú)

www.fda.gov



REQUISITOS PARA LA EXPORTACIÓN DE ALIMENTOS A ESTADOS UNIDOS

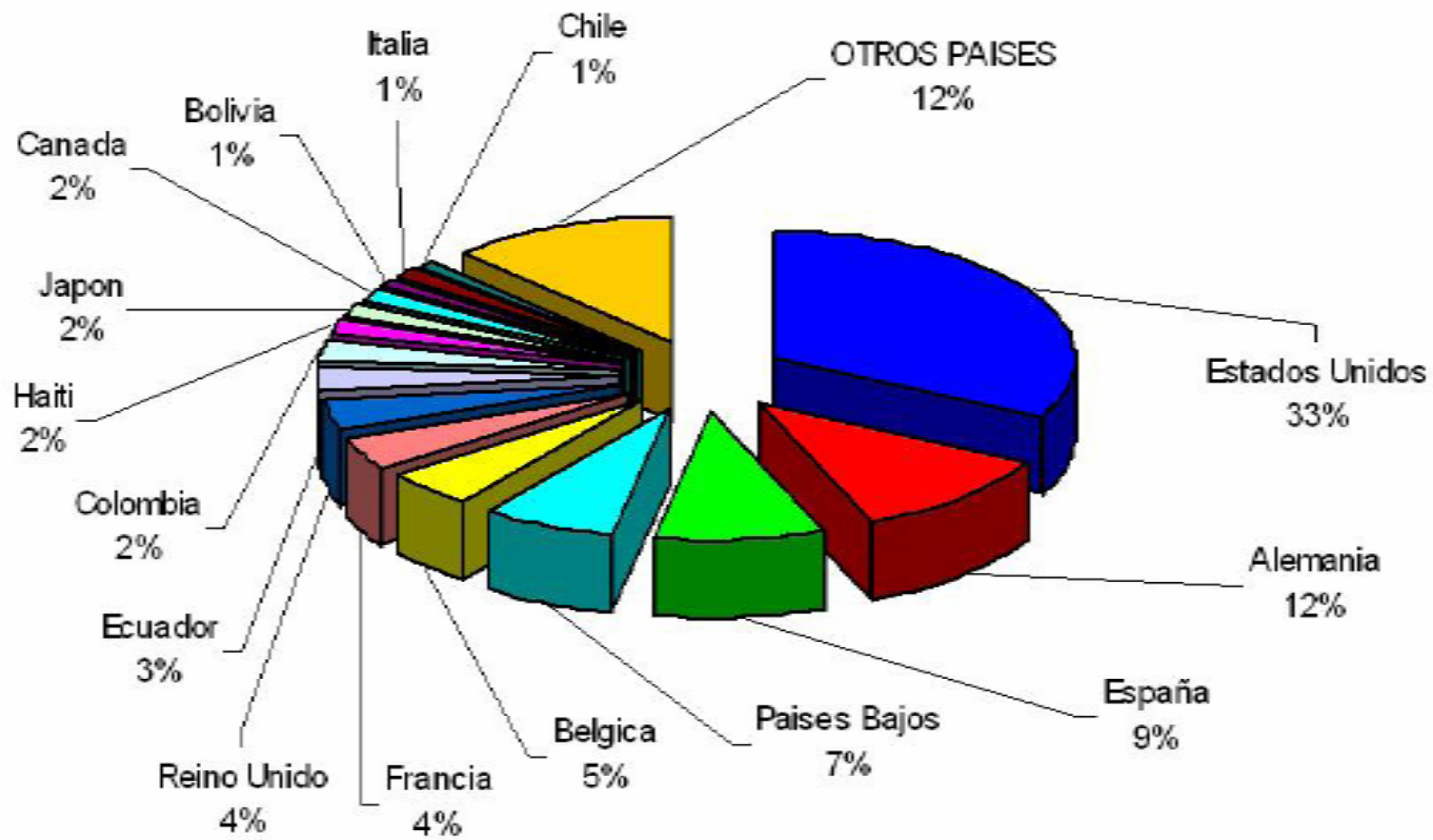
LEY FDA CONTRA EL BIOTERRORISMO



COMISIÓN DE PROMOCIÓN DEL PERÚ PARA LA EXPORTACIÓN Y EL TURISMO

Miguel A Watts González

PROMPERÚ





El comercio de alimentos con Estados Unidos

- Principal mercado externo de alimentos del Perú (frescos y Procesados)
- Principales productos:
 - Espárragos frescos y en conserva
 - Alcachofas en conserva
 - Mangos frescos
 - Uvas frescas



Autoridades Competentes

- **Food and Drug Administration (FDA):** alimentos de consumo humano y animal, excepto bebidas con alcohol, productos con más de 2% de carne y agua embotellada. También incluye productos hidrobiológicos
- **Food Safety Inspection Center (FSIS)** del USDA: productos cárnicos
- ***Alcohol and Tobacco Trade and Tax Bureau (TTB)*** del Departamento del Tesoro: bebidas alcohólicas



Autoridades competentes

- Por otra parte, el ***Animal and Plant Health Inspection Service (APHIS)***, dependiente del USDA, se encarga de velar por la sanidad vegetal y animal de los productos alimentarios importados a los EEUU.



Requisitos FDA

- Demostrar la inocuidad del producto a través de:
 - Cumplir con las BPM: 21 CFR Parte III.
<http://www.cfsan.fda.gov/%7EIRD/scfr110.html>
 - LMR establecidos por la *Environmental Protection Agency* (EPA)
 - Aditivos y colorantes permitidos.
<http://vm.cfsan.fda.gov/%7Edms/eafus.html>

Requisitos FDA

Etiquetado de los alimentos

Helvética Regular de cuerpo 8 y un punto de espacio

Barra de tres puntos

Helvética Black de cuerpo 8 a 4 puntos de espacio

Barra centrada de separación de nutrientes de 1/4 punto (2 puntos de espacio por encima y 2 por debajo)

Helvética Regular de cuerpo 8, 4 puntos de espacio

Helvética Regular cuerpo 8, 4 puntos de espacio y boliches de cuerpo 10

| Nutrition Facts | |
|--|---------------------------|
| Serving Size 1 cup (228g) | |
| Servings Per Container 2 | |
| Amount Per Serving | |
| Calories 260 | Calories from Fat 120 |
| % Daily Value* | |
| Total Fat 13g | 20% |
| Saturated Fat 5g | 25% |
| Cholesterol 30mg | 10% |
| Sodium 660mg | 28% |
| Total Carbohydrate 31mg | 10% |
| Dietary Fiber 0g | 0% |
| Sugars 5g | |
| Protein 5g | |
| Vitamin A 4% | Vitamin C 2% |
| Calcium 15% | Iron 4% |
| *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: | |
| Calories: | 2,000 2,500 |
| Total Fat | Less than 65g 80g |
| Sat Fat | Less than 20g 25g |
| Cholesterol | Less than 300mg 300mg |
| Sodium | Less than 2,400mg 2,400mg |
| Total Carbohydrate | 300g 375g |
| Dietary Fiber | 25g 30g |
| Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4 | |

Franklin Gothic Heavy o Helvética Black alineada a izquierda y derecha, no inferior a cuerpo 13

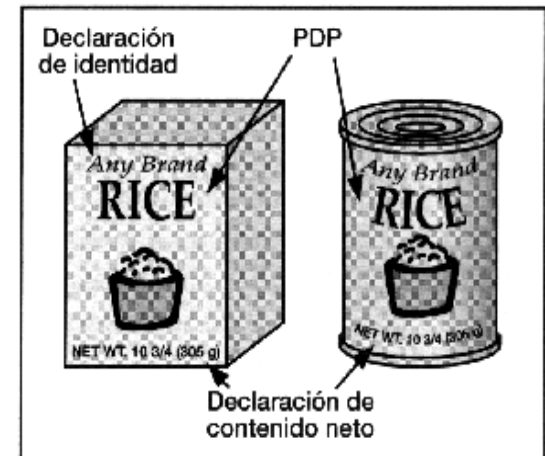
Barra de 7 puntos

Helvética Black de cuerpo 8

Toda la información está introducida en una caja de barra de 1/2 punto y a tres puntos del texto

Barra de 1/4 de punto

Todo lo que aparece por debajo de las vitaminas y minerales (notas a pie de página) es de cuerpo 6 y un punto de espacio



Requisitos fitosanitarios



- Sólo es posible exportar aquellos productos frescos que tengan permitido el ingreso por parte del Organismo de Protección Fitosanitaria de EE.UU (APHIS):
- <https://manuals.cphst.org/q56/Q56Main.cfm>

Requisitos fitosanitarios



- **No todas las frutas frescas se pueden exportar a todos los países del mundo, previamente es necesario que se aperture el mercado por el tema fitosanitario, mediante la negociación entre autoridades para demostrar que bajo las condiciones de cultivo y transporte no existe riesgo de introducción de plagas cuarentenarias en el país importador**



Ley Contra el Bioterrorismo

www.fda.gov

