



U.S. Food and Drug
Administration

Protecting the U.S. Food Supply



U.S. Department of Health
and Human Services

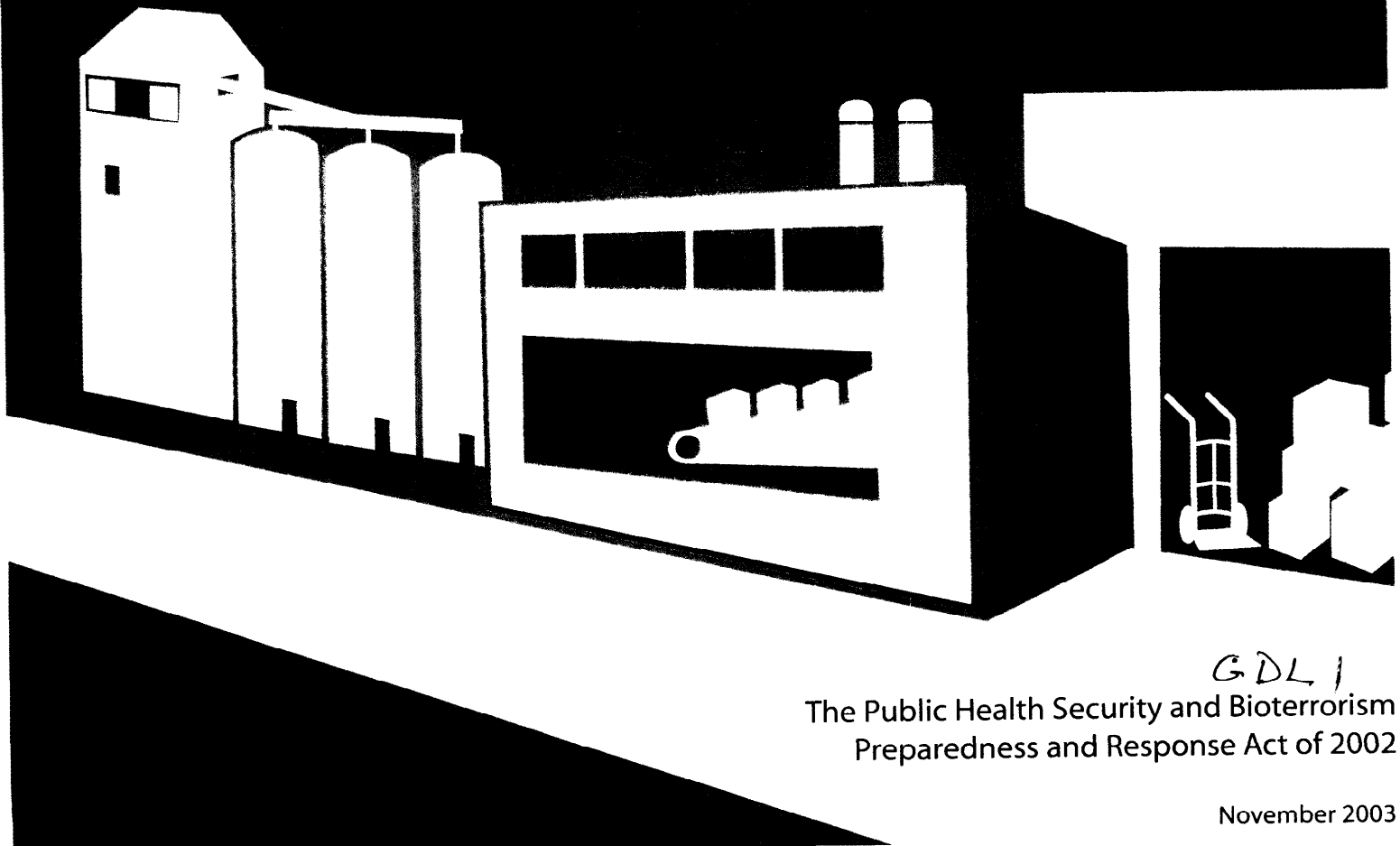
What You Need to Know About **REGISTRATION OF**

FDA Food Security Information for Domestic and Foreign:

Manufacturers or Processors

Packers

Holding Facilities



GDL 1

The Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

November 2003



U.S. Food and Drug
Administration



U.S. Department of Health
and Human Services

This guidance document is a restatement of the Food and Drug Administration's (FDA's) current requirements for registration of food facilities presented in simplified format and language. As guidance, it is not binding on either FDA or the public. FDA notes, however, that the regulation that is the basis for this pamphlet establishes requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulation at 21 CFR Part 1, Subpart H, in addition to reading this pamphlet.

The Food and Drug Administration has prepared this guidance to restate the legal requirements set forth in 21 CFR 1.225 through 1.243 concerning registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guide is intended to help any entity, regardless of size, to comply with the regulations that require domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA. This document also serves as FDA's Small Entity Compliance Guide (SECG), in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

INTRODUCTION

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.

These regulations go into effect on December 12, 2003.

Purpose of this Booklet

This booklet was created to inform domestic and foreign food facilities about the new food facility registration law and regulations. It contains important information that may affect your firm.

The information in this booklet also appears online at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

ABOUT REGISTRATION

Food Facility Registration Requirement

Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in the regulation, for human or animal consumption in the U.S. must register with FDA by December 12, 2003.

Why Registration Is Required

Food facility registration will help FDA to:

- Determine the location and source of a potential bioterrorism incident or an outbreak of food-borne illness; and
- Quickly notify facilities that may be affected.

What It Costs

There is no fee for registration or updates to a registration.

HOW REGISTRATION AFFECTS YOU

Which Facilities Must Register

If your facility is in one of following food industry sectors, you must register your facility with FDA by December 12, 2003.

Food Industry Sectors Affected

- Domestic and foreign manufacturers or processors*
- Domestic and foreign packers*
- Domestic and foreign storage operations *

Foods Handled by More Than One Foreign Facility

If...	Then...
A foreign facility that manufactures, processes, packs, or holds food sends it to another foreign facility for further manufacturing/processing or packaging before the food is exported to the U.S.	Only the second foreign facility is required to register.
The second foreign facility performs only a minimal activity, such as putting on a label	Both facilities must register.
Any foreign facility packs or holds food after the last foreign manufacturer/processor of the food	The foreign packer or holder must register.

* Domestic facilities must register whether or not food from the facility enters interstate commerce.

Food Included in the Regulation

Registration pertains only to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption by humans or animals in the U.S.

The following chart gives examples of the types of food that are included in or excluded from the “food” definition in the facility registration regulation. If your facility handles ANY of the included foods, it must be registered.

INCLUDED Food	EXCLUDED Food
<ul style="list-style-type: none">• Dietary supplements and dietary ingredients• Infant formula• Beverages (including alcoholic beverages and bottled water)• Fruits and vegetables• Fish and seafood• Dairy products and shell eggs• Raw agricultural commodities for use as food or components of food• Canned and frozen foods• Bakery goods, snack food, and candy (including chewing gum)• Live food animals• Animal feeds and pet food	<ul style="list-style-type: none">• Food contact substances• Pesticides

Note: A facility that manufactures/processes, packs, or holds a food contact substance or pesticide is NOT required to register with FDA.

Facilities That Do Not Have to Register

If your facility is involved in one of the following activities, it does NOT have to register with FDA.

These Facilities DON'T Have to Register

- **Private residences of individuals**, even though food may be manufactured/processed, packed, or held in them.
- **Non-bottled water drinking water collection and distribution establishments and structures**, such as municipal water systems.
- **Transport vehicles that hold food only in the usual course of their business as carriers.**
- **Farms** — i.e., facilities in one general location devoted to growing and harvesting crops (washing, trimming outer leaves, and cooling produce are part of harvesting) and/or raising animals (including seafood). The term “farm” also includes facilities that manufacture/process, pack, or hold food, provided that all food used in those activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- **Restaurants** — i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers, are not restaurants for purposes of the rule.
- **Retail food establishments**, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual food sales directly to consumers are of greater dollar value than annual sales to other buyers.
- **Nonprofit food facilities**, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. This includes central food banks, soup kitchens, and nonprofit food delivery services.
- **Fishing vessels that harvest and transport fish.** Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- **Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture**, that is, facilities handling only meat, poultry, or egg products.

When Your Facility Must Register

The deadline to register your facility with FDA is December 12, 2003.

Facilities that go into business after December 12, 2003, must register before they begin manufacturing/processing, packing, or holding operations.

How Often Your Facility Must Register

Registration is required only once for each food facility. However, if required registration information about your facility changes, you must update the registration.

Who May Register

The owner, operator, or agent in charge of a facility, or an individual authorized by one of them, may register that facility.

Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the U.S. and is physically present in the U.S., for purposes of registration. The U.S. agent may be authorized to register the facility.

What If Your Facility Fails to Register

Failure to register your facility, update required elements, or cancel registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action against persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act, or both.

If a foreign facility is required to register but fails to do so, food from that facility that is offered for import into the U.S. is subject to refusal. The food may be held within the port of entry, unless directed elsewhere by FDA or the Customs and Border Protection Service (CBP).

FDA plans to issue enforcement guidance on the agency's policies regarding refusals of imported food or holds of imported food. This guidance document will be available to the public, and FDA will publish a notice of its availability in the Federal Register.

REGISTERING YOUR FACILITY

How to Register Your Facility

Registrants must use Form 3537 to register or update a registration. This form is available online and in paper form. A business with multiple facilities may also register on CD-ROM. FDA will process paper and CD-ROM submissions in the order received.

Note: FDA does not allow registration in person.



Online Registration

You can save time by registering online at <http://www.access.fda.gov/>. This web site offers online help and operates 24 hours a day, seven days a week. You can access the site wherever the Internet is available — including libraries, copy centers, schools, and Internet cafes.

An Online Registration Help Desk is available on business days, from 7:00 AM until 11:00 PM U.S. Eastern Standard Time to help you.

To Contact the Online Registration Help Desk:

By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-210-0247
By email	Go to http://www.cfsan.fda.gov/~furls/helpf2.html and complete the form



Paper Registration

If your facility does not have reasonable access to the Internet, you can request a copy of **Form 3537** from FDA by mail or phone. The form can be mailed or faxed to you.

To Request the Form:

By mail	Write to: U.S. Food and Drug Administration HFS-681 5600 Fishers Lane Rockville, MD 20857 USA
By phone	Call 1-800-216-7331 or 301-575-0156 (7:00 a.m. to 11:00 p.m. U.S. Eastern Standard Time)

Fill out the form completely and legibly and mail it to the above address, or fax it to **301-210-0247**.

Note: Paper registration is less efficient than online registration. It takes longer to receive confirmation for paper registration. And, if your form contains omissions or errors, FDA will return it for corrections without registering your facility — resulting in further delay.



CD-ROM Registration

If your business has a large number of food facilities, you may wish to submit multiple registrations on a CD-ROM by mail. You can do so, provided that each registration uses the same preferred mailing address. The CD-ROM you use must have ISO 9660 (CD-R or CD-RW) data format.

To Register by CD-ROM:

1. Go to <http://www.cfsan.fda.gov/~furls/papercd.html> and download the Portable Document Format (PDF) version of **Form 3537**.
2. Fill in a separate copy of the form electronically for each facility.
3. Use the same preferred mailing address for each facility.
4. Save the form for each facility under a different file name:
 - a. The file name can be up to 32 characters long.
 - b. Use the first part of the file name to identify the parent company.
5. Copy the files to a CD-ROM with ISO 9660 (CD-R or CD-RW) data format.
6. Enclose one signed copy of the certification statement that appears on the registration form (Box 13).
7. Mail the CD-ROM to:

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville, MD 20857

Note: If you send a CD-ROM that does not comply with the above specifications, FDA will return it without processing, which will delay registration.

Information Required for Registration

FDA requires you to provide the following information for facility registration.

Required Information

- Facility name, address, phone number, and emergency contact phone number
- Parent company name, address, and phone number (if applicable)
- Name, address, and phone number of the owner, operator, or agent in charge
- All trade names the facility uses
- Applicable food product categories, as listed on the registration form
- Name, address, and phone number of a foreign facility's U.S. agent, and phone number of the facility's emergency contact if it is someone other than the U.S. agent
- Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so

Optional Registration Information

FDA also requests optional registration information. Although you are not required by law to comply with this request, FDA encourages you to do so — particularly if your facility handles products such as infant formula, certain dietary supplements, and animal feed — as those products may be the target of a food-related emergency.

Optional Information Requested

- Facility fax number and email address
- Preferred mailing address, if different from that of the facility
- Fax number and email address of the owner, operator, or agent in charge of the facility
- Fax number and email address of the parent company (if applicable)
- For a foreign facility: the fax number and email address of its U.S. agent
- Type of activity conducted at the facility (i.e., processing, packing, etc.)
- Food categories not included in the required information; these are listed in section 11a of Form 3537 (where they are marked optional), or in section 11b (where all food categories listed are optional)
- Type of storage (if it's a holding facility)
- Whether the facility manufactures/processes, packs, or holds most or all of the product categories identified in 21 CFR 170.3
- Approximate dates of operation (if the facility's business is seasonal)

Facility Registration Screen

Here is a sample screen from the FDA registration web site (<http://www.access.fda.gov/>).

FFRM

Food Facility
Registration Module

1 2 3 4 5 6 7 8 9 10

SEARCH

SEARCH BY FACILITY ID: OR COMPANY:

OR SEARCH BY STATE AND ZIP CODE:

1. THESE FIELDS ARE REQUIRED

SEARCH BY FACILITY ID: OR COMPANY:

OR SEARCH BY STATE AND ZIP CODE:

FACILITY STREET ADDRESS, LINE1

FACILITY STREET ADDRESS, LINE2

CITY

STATE

FACILITY PHONE NUMBER PREFIX
[Please Select]

FACILITY PHONE NUMBER SUFFIX
[Please Select]

NUMBERS ARE: NO. APPLICANT, DISTRICT OR JURISDICTION, COUNTY, COUNTRY (Country Code not required for US phone numbers)

Company Code	Region Code	Phone Number	Country
01-0001	01-0001	01-00011111	01-0001

ZIP CODE

FILE NUMBER

0-FILE, ANSWER

2. THESE FIELDS ARE OPTIONAL

NUMBERS ARE: NO. APPLICANT, DISTRICT OR JURISDICTION, COUNTY, COUNTRY (Country Code not required for US phone numbers)

Company Code	Region Code	Phone Number	Country
01-0001	01-0001	01-00011111	01-0001

ZIP CODE

FILE NUMBER

0-FILE, ANSWER

How Registration Is Confirmed

After you register your facility, FDA will confirm the registration and assign a registration number.

If You Register...	You Will Receive Confirmation
Online	Immediately — electronically
By fax	By fax
By surface mail or CD-ROM	By surface mail

Note: Assignment of a registration number means only that the facility is registered. It does NOT convey FDA approval or endorsement of the facility or its products.

Confidentiality of Registration Information

The list of registered facilities and submitted registration documents are not subject to disclosure under the Freedom of Information Act. This confidentiality does not apply to information obtained by other means or that has previously been disclosed to the public.

How to Update Registration Information

If any of the required information on your registration form changes — for example, if there is a new operator, agent in charge, or U.S. agent — the owner, operator, or agent in charge, or an individual authorized by one of them, must notify FDA within 60 days.

You can submit information changes online (regardless of how you originally registered), by paper, or on CD-ROM.

To Update Your Registration:	
Online	Go to http://www.access.fda.gov/ *
By paper	Use the paper registration process described on page 8
By CD-ROM	Enter the changes on CD-ROM (see page 8)

In the case of new ownership, the former owner must cancel the facility's registration within 60 days and the new owner must register the facility before beginning operations.

How to Cancel Registration

If your facility goes out of business or comes under new ownership, you must cancel its registration within 60 days using Form 3537a. You can do this electronically at <http://www.access.fda.gov/>, or you can request the form from FDA and use the paper registration process described on page 8.

* Use the password that was issued with your facility's registration number. If you originally registered by paper or CD-ROM, you will need to follow the online instructions to set up an account.

How to Comment on the Regulation

The registration regulation is currently an interim final rule. This means the regulation has the full force of law, but FDA is providing a 75-day comment period (ending December 24, 2003) on specific issues related to it. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days, beginning in March, 2004.

How to Get More Information

Additional information is available at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

For more details and information on the specific requirements of the facility registration regulation, please refer to the **Fact Sheet on FDA's New Food Bioterrorism Regulation: Interim Final Rule — Registration of Food Facilities**. This fact sheet is available online at <http://www.cfsan.fda.gov/~dms/fsbtac12.html>.

FDA's FOOD FACILITY REGISTRATION REGULATION AT-A-GLANCE

WHAT It Is: Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in the regulation, for human or animal consumption in the U.S. must register with FDA by December 12, 2003.

WHY It's Required: To help FDA to determine the location and source of a potential or actual bioterrorism incident or an outbreak of food-borne illness, and permit the agency to notify quickly facilities that may be affected.

WHICH Facilities Must Register: Domestic and foreign manufacturers/processors, packers, and storage operations that handle foods included in the regulation.

Examples of WHICH Foods Require Facility Registration:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

WHEN Facilities Must Register: By December 12, 2003.

WHO May Register: The owner, operator, or agent in charge of a facility, or an individual authorized by one of them, may register that facility.

Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the U.S. and is physically present in the U.S., for purposes of registration. The U.S. agent may be authorized to register the facility.

HOW to Register:

Online	Go to http://www.access.fda.gov/ (24 hours a day, 7 days a week).
By Mail or Fax	<ol style="list-style-type: none"> 1. Request Form 3537 from FDA (1-800-216-7331 or 301-575-0156). 2. Mail or fax the completed form to: U.S. Food and Drug Administration HFS-681 Fishers Lane Rockville, MD 20857 U.S.A. Fax: 301-210-0247
On CD-ROM <small>(For multiple facilities using the same mailing address)</small>	<ol style="list-style-type: none"> 1. Download Form 3537 at http://www.cfsan.fda.gov/~furls/papercd.html. 2. Create separate electronic files for each facility. 3. Submit files on CD-ROM (ISO 9660 CD-R or CD-RW format). 4. Include a signed certification statement. 5. Send to the above address.

Get HELP: (business days, 7:00 AM to 11:00 PM U.S. EST)

By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-210-0247
By email	Go to http://www.cfsan.fda.gov/~furls/helpf2.html and complete the form

WHAT Information is Required:

- Facility name, address, phone number, and emergency contact phone number
- Parent company name, address, and phone number (if applicable)
- Name, address, and phone number of the owner, operator or agent in charge
- All trade names the facility uses
- Applicable food product categories, as specified in FDA regulation 21 CFR 170.3
- Name, address, phone number, and emergency contact phone number of a foreign facility's U.S. agent
- Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so

HOW Registration Is Confirmed: FDA confirms the registration either electronically (online registration) or by mail (paper or CD-ROM registration), and assigns a registration number.

What If ...

IF...	Then...
Required registration info changes	You must notify FDA within 60 days (online or by mail or fax).
There's a change in ownership	The former owner must cancel registration within 60 days and the new owner must re-register.
Your facility goes out of business	You must cancel registration.
A domestic facility fails to register	The Federal government can bring a civil or criminal action against the owner, operator, or agent in charge. However, FDA will use discretion in enforcing the regulation during the comment period (see below).
A foreign facility fails to register and then tries to import food into the U.S.	The food will be held at the port of entry, unless otherwise directed by FDA or CBP.

Comments and Compliance

FDA will provide a 75-day comment period (ending December 24, 2003) on issues related to this regulation. For the 4 months following December 12, 2003, FDA plans to focus on education and training to assist facilities required to register to comply with the rule. FDA will use discretion in enforcing the regulation, while at the same time ensuring public health protection.

Get More Info: For more information, go to <http://www.fda.gov/oc/bioterrorism/bioact.html>.



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



For more information, go to
<http://www.fda.gov/oc/bioterrorism/bioact.html>



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