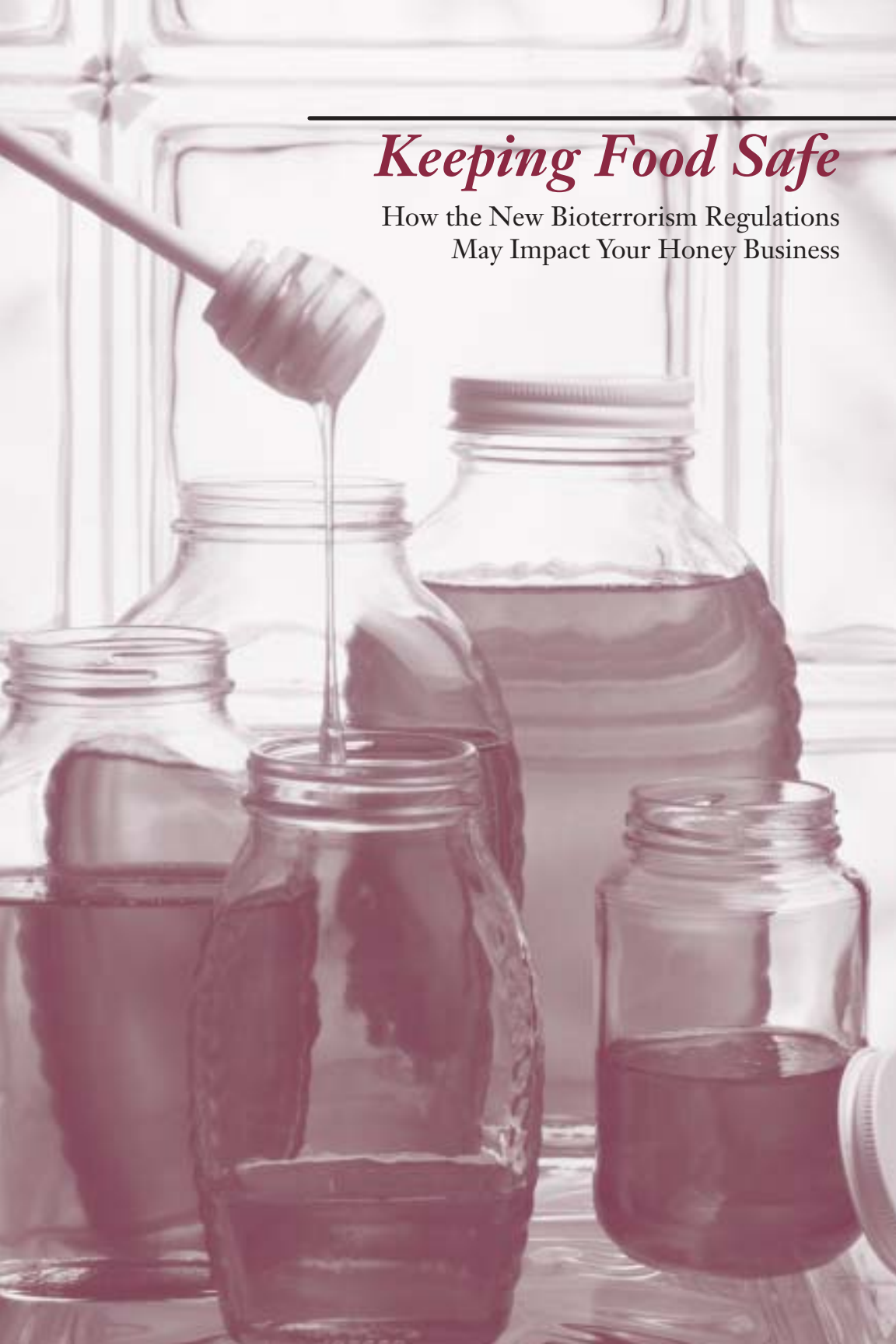

Keeping Food Safe

How the New Bioterrorism Regulations
May Impact Your Honey Business



The Public Health, Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) was enacted to protect the public from threatened or actual terrorist attack on the U.S. food supply. During 2003 the FDA has published the regulations to implement these food safety measures.

These new regulations apply to all facilities that manufacture/process, pack or hold food for consumption in the United States.

The Bioterrorism Act will require many honey operations to:

- Register their facility with the FDA
- Establish and maintain records on honey, additives, flavorings
- Make records available to the FDA on short notice
- Understand detention rules
- Give prior notice of imported shipments

There are four provisions of the Bioterrorism Act that will impact many honey operations:

Registration of Food Facilities

Reason for the Requirement

In the event of a potential or actual Bioterrorism incident or outbreak of food-borne illness, facility registration information will help the FDA to determine the location and source of the event and permit the FDA to notify facilities that may be affected.

Registration Procedure

All domestic or foreign facilities that manufacture, process, pack, distribute, receive or hold food for consumption by humans or animals must register their facility with the FDA by Dec. 12, 2003. Each facility location must be registered. Registration is free.

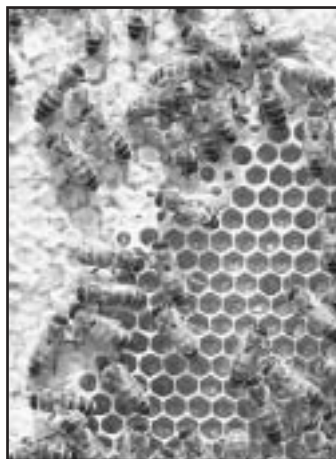
Facilities are encouraged to register via the Internet at www.cfsan.fda.gov/~furls/ovffreg.html.

A paper copy of the registration form may be obtained from the FDA by calling (800) 216-7331 or (301) 575-0156 or by mailing a request to:

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

Or simply visit www.nhb.org/leg/index.html#federal to download a copy of the registration instructions and form. You may also call the National Honey Board office to request these materials.

Company information, all trade names, emergency contact information, category of food and type of activity conducted, type of storage and dates of operation (if seasonal) are required registration components.



Registration information changes or cancellations must be submitted within 30 days of the change.

For more information, visit www.cfsan.fda.gov/~dms/fsbtac12.html.

Establishment and Maintenance of Records

Reason for the Requirement

The regulations will require that food facilities establish and maintain records. These records will allow the FDA to conduct a tracing investigation of a food or animal product if it becomes necessary. Food facilities will be required to identify the immediate previous source as well as the immediate subsequent recipient of all food.

Record Availability

Food facilities will be required to maintain records, for not longer than two years, and to make records available to the FDA when the agency has reasonable belief that food is adulterated and presents a threat of adverse health consequences or death to humans or animals.

Timeline for Compliance

All businesses must comply with the record keeping and access requirements within the time specified after the final regulation is published (Dec. 12, 2003):

10 or fewer full-time employees	18 months
11 to 499 full-time employees	12 months
500 or more full-time employees	6 months

For more information, visit www.fda.gov/oc/bioterrorism/records_fs.html.

Administrative Detention

Reason for the Requirement

The Bioterrorism Act authorizes the FDA to detain an article of food for which there is credible evidence or information indicating a threat of serious adverse health consequences to humans or animals and to expedite court actions on perishable foods. All food would be subject to this regulation whether or not it enters interstate commerce.

Detention Notification Procedures

The regulation provides for the detention of food for up to 30 days and would allow the FDA to order the food be moved to a secure facility. It is important to note that this section really describes the obligations and procedures that the FDA must follow. The burdens to the industry are not significantly different than those that currently exist. States can already exercise authority to detain food and the FDA and U.S. Customs work together to detain adulterated or misbranded imported product.

For more information, visit www.fda.gov/oc/bioterrorism/detention_fs.html.

Prior Notice of Imported Food Shipments

Reason for the Requirement

The prior notice provision of the Bioterrorism Act requires that importers give prior notice of food imported or offered for import into the United States beginning Dec. 12, 2003. This will allow the FDA time to review, evaluate and assess information before a food product arrives and shift resources to target inspections, to intercept contaminated products and to help ensure movement of safe food to market. While most of the information required is common invoice data usually provided by importers or brokers to U.S. Customs when goods arrive in the United States, the Bioterrorism Act requires that the FDA now receive advance information on import shipments.

Prior Notice Procedures

Under the proposed rule, notice must be made by noon the calendar day before the day that the imported food arrives at the border crossing at the port of entry. The proposed rule provides that prior notice may not be submitted more than 5 days before arrival at a U.S. port.

For more information, visit www.cfsan.fda.gov/~dms/fsbtac13.html.

Exemptions

Exempt from registration regulations are:

- Farms
- Retail food operations
- Restaurants
- Nonprofit operations that prepare food for or serve food directly to consumers
- Fishing vessels not engaged in processing
- Facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture

Exempt from records maintenance are:

- Farms
- Restaurants
- Nonprofit operations that prepare food for or serve food directly to consumers
- Fishing vessels not engaged in processing
- Persons regulated exclusively by the U.S. Department of Agriculture under various statutes

Definitions

Farms are defined as facilities in one general physical location devoted to growing and harvesting crops, the raising of animals, or both. The term “farm” also includes facilities that pack or hold food provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.

Restaurants are defined as facilities that prepare and sell food directly to consumers for immediate consumption. Facilities that prepare food for 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 these regulations.

Retail food establishments, such as groceries, delis and roadside stands that sell food directly to consumers as their primary function, are exempt. An establishment that manufactures/processes, packs or holds food and whose primary function is to sell food directly to consumers, including food that the establishment manufactures/processes from that establishment is a retail food establishment and is not required to register or maintain records as required by these regulations.

Retail food establishments also are exempt from maintaining records on immediate subsequent recipients when foods are sold directly to consumers. However, retail facilities, with fewer than 10 employees that are located in the same general location as a farm and sell unprocessed food grown on the farm or on another farm located in the same general physical location, are excluded from the requirement to establish and maintain records on both immediate previous sources and immediate subsequent recipients. This exemption also applies to processed foods such as baked goods, jams, jellies and maple syrup as long as all the ingredients were grown or raised on that farm.

A **foreign facility** is excluded if food from it undergoes further manufacturing/processing (including packaging) by another facility outside the United States. The facility is not exempted from record keeping if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package or other minimal activity. The facility that conducts this activity also must establish and maintain records.



A final note on exemptions — a facility is only exempt if all of its activities are covered by an exemption. Any non-exempt use requires the facility to be registered.

IMPORTANT

There are many provisions of these regulations — only summarized above. Contact the FDA with questions regarding requirements as they pertain to your specific situation.

Frequently Asked Questions about the Bioterrorism Act

What facilities must comply with these Bioterrorism regulations?

Owners, operators or agents in charge of domestic or foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States. A facility is not the same as a company. Each establishment or structure must be registered.

I'm a honey producer. Do I need to register and maintain records?

If you sell to a packer or sell honey to another outlet, you would need to register. If you produce honey and consume it all at your location or sell food directly to consumers (roadside stand), you would be exempt from registration and record keeping. Please check with the FDA to confirm the requirements for your situation.

What facilities are exempt?

Farms, retail food establishments, restaurants, nonprofit establishments that prepare food for or serve food directly to consumers and fishing vessels not engaged in processing are exempt. (See definitions of farms, retail food establishments and restaurants.)

Why are honey producers not exempt as farmers?

Honey producers would likely meet the farm exemption if it were not for the activity of extracting honey. We believe honey extraction will be considered "processing." Thus, beekeepers who extract must register and comply with these regulations.

How often must I register?

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

Is there a fee for registration?

There is no fee for registration or for updates of any registration.

How do I register?

The easiest way to register is via the Internet at www.cfsan.fda.gov/~furlk/ovffreg.html.

What information is required?

Information includes: name, address, phone number of facility, all trade names used by the facility, food product categories, emergency contact information, a statement certifying that the information submitted is true.

The registration form asks that I check the appropriate product category. Should I mark "food sweeteners?"

Honey is not referenced as a food sweetener in the applicable statute so the FDA helpline recommends that you check box 37 "None of the Above Mandatory Categories."

How long will it take to register?

The FDA estimates that it will take one or two hours to read the regulations. Filling out the registration form will take less than one hour.

Is registration information available to the public?

No information submitted under this regulation will be made available to the public.

How long do I need to maintain required records?

The proposed rule would require records to be created when food is received, released or transported, with the records to be retained for two years from that date.

What records must I maintain for FDA review?

The records would have to:

- 1. Identify the immediate (non-transporter) previous sources, whether foreign or domestic, of all foods received, including the name of the firm and the responsible individual; address; telephone number; fax number and e-mail address; type of food, including brand name and specific variety; date received; lot number or other identifier if available; quantity and type of packaging (e.g., 12 oz. bottles); the name, address, telephone number — and, if available, fax number and e-mail address — of the transporter who brought it.*
- 2. Identify the immediate (non-transporter) subsequent recipients of all foods released, including the name of the firm and the responsible individual; address; telephone number; fax number and e-mail address; type of food, including brand name and specific variety; date released; lot number or other identifier if available; quantity and type of packaging; the name, address, telephone number — and, if available, fax number and e-mail address — of the transporter who transported the food from you.*

What format must records be in?

There is no particular record format specified as long as the required information is present. Existing records, such as invoices, purchase orders and bills of lading, may be sufficient. The records must be created at the time the covered activities take place and must be maintained at the establishment.

This is a summary of the Bioterrorism Act and its regulations. For more information, please contact the FDA or visit www.cfsan.fda.gov.

Watch for further information from the National Honey Board as the regulations are finalized. Notices will be posted on Bee-Mail, the Nucleus, www.nhb.org and in further publications. Or call us for additional information.



National Honey Board
390 Lashley Street
Longmont, CO 80501-6045
www.nhb.org

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