



# Australian Food Exports to the USA

## USA to Require Registration of Foreign Food Facilities

### Registration

#### Summary

After President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), Food and Drug Administration (FDA) proposed a regulation that would require domestic and foreign facilities that manufacture, process, pack, or hold food (human or animal) for consumption in the United States have to register with FDA by December 12, 2003.

Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about all facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event.

Failure to register is considered a prohibited act and can result in civil action, criminal action and even debarment of any person who has been convicted of a felony. Foreign facilities that fail to register and attempt to import food into the United States, the food will be held at the port of entry unless FDA directs its removal to a secure facility.

#### The Types of Food Included

The following types of food are included in the regulation:

1. Articles used for food or drink for man or other animals,
2. Chewing gum, and
3. Articles used for components of any such article.

This may include: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods.

#### Affected Facilities

The Bioterrorism Act defines foreign facilities as any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.

For example:

- A foreign facility that prepares a finished food and places it into packages suitable for sale and distribution in the United States.
- If the further manufacturing/processing is of a de minimis nature (like only adding labels), both the facility conducting the de minimis activity and the facility immediately prior are required to register.
- The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States.
- Facilities located outside the United States that take possession, custody or control of finished foods for holding, packing, and/or storage prior to export to the United States, are required to register.
- Also foreign facilities that pack and/or hold food subsequent to the processing and packaging process to register with FDA.

FDA estimates the number of foreign manufacturers that would be affected by the regulation to be 125,450, foreign holder to be 77,427 and facilities that do de minimis processing or packaging 34,437.

#### Designated U.S. Agent

A foreign facility may designate a U.S. agent as its agent in charge for purposes of registering the foreign facility.

The U.S. agent needs to be:

1. A person residing or maintaining a place of business in the United States.
2. Available to assist FDA in contacting foreign facilities.
3. Act as a communications link between FDA and the facility, such that FDA will treat representations provided by the U.S. agent to FDA as those of the foreign facility, and will consider information FDA provides to the U.S. agent as the equivalent of providing the same information or documents directly to the foreign food facility.



4. Able to register on behalf of the foreign facility.

Only one U.S. agent per foreign facility is permitted.

*What information is needed?*

*Initial Registration*

Information required includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories; and a certification statement that includes the name, title/position, and phone number (e-mail address and fax number if available) of the registrant.

Also the name, address, phone number, fax number, and e-mail address of the U.S. agent for foreign facilities need to be submitted.

*Future Updates*

Under the proposed rule, facilities would also be required to submit updates within 30 days when any information on their registration form changes, including cancellation of the registration on a separate form. All information submitted is not subject to disclosure and will not be publicly available.

*Registration Number*

The foreign facility's U.S. Agent can do the registration electronically and FDA will notify the registrant that it has received the facility's registration and assign the facility a unique registration number. All registration information must be submitted in English.

*Non-Compliance*

Failure of a foreign facility to register is considered a prohibited act. The United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act and, can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

The article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the facility is registered and the article of food no longer is subject to a hold. While any article of food is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

**For more information, contact:**

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