

US Food & Drug Administration

Bioterrorism Act of 2002

Overview

Counter-terrorism is changing the way Australia is doing business with the US. In response to the Bioterrorism Act, the FDA has issued proposed rules on the registration of food facilities, prior notice of imported foods and record keeping.

1. Registration of facilities

Any site that manufactures, processes, packs or holds food, which will be imported into the US for human or animal consumption must first be registered with the US FDA. Existing exporters must be registered by 12 December 2003. A facility is exempted from registration if food or wine from that facility undergoes further processing or packaging outside the United States. A facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package.

Any food or wine arriving for import to the US that is not from a registered site will be held at the port of entry.

Samples for trade shows will also have to be registered and comply with the prior notice requirement.

2. Prior Notice of Imported Food

FDA must be notified by the US importer, purchaser, consignee or agent of the details of any food entering the United States by noon the calendar day prior to its arrival at the port of entry. The information required concerns the product identity, manufacturer, growers, importers, country of origin, transportation and arrival information, among others. Australian exporters may need to have this information available to their US consignees for the Prior Notice submission.

Prior notice applies to each separate article in a container (eg, if there are different products—for example, Chardonnay and Shiraz—in one container, a separate notification form must be submitted for each).

Notice must be received no more than five days before arrival and no less than noon the day prior to arrival. If notice is not filed, FDA will not allow shipment to unload.

There is no indication that the FDA will allow any forms from other agencies (Customs, AQIS, etc) to be substituted from their prior notice forms.

3. Recordkeeping

All facilities which are required to register must also maintain complete records. There is no specific form for the record keeping, so existing forms needed for other purposes (taxes, customs, AQIS, etc.) can be used as long as all needed information is included.

Information needed is still being finalised, but will include:

1. Source of product.
2. Method of transport between source and facility.
3. Method of transport out of facility.
4. Next destination of product after leaving facility.
5. There must be a source list for each ingredient used in processing the product that comes in to the manufacturing plant (list of ingredients is needed, quantities used are not).

Records must be available for inspection for two years and must be available for inspection within four hours if requested during regular business days or eight hours if it is not during business hours.

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Compliance deadlines, dated from December 2003, for record keeping requirements are:

- Six months for companies with over 500 employees
- 1 year for companies with 10 to 500 employees
- 18 months for companies with fewer than 10 employees

In summary, the 3 key requirements are:

REQUIREMENT	RESPONSIBILITY	ACTION REQUIRED
Registration of facility	Producer	Subscribe to FDA's Bioterrorism Act E-Mail List http://www.fda.gov/oc/bioterrorism/bioact.html to receive updates and notification of when the registration format is in place
Prior notification of shipment	US importer or broker	Discuss with your US representative and clearly allocate responsibility
Recordkeeping	Producer	Ensure your internal systems will provide the required information

Austrade advice

As registration is free and should be possible on-line, the registration process itself should not prove too onerous for exporters.

However, it is critical that exporters fulfil the requirements before the deadline, as non-compliance could mean shipments are held at Customs and possibly destroyed. As exact registration procedures will not be finalised until 12 October 2003, exporters should in the interim focus on ensuring that their arrangements for Prior Notification and Recordkeeping are in place.

Once the Registration Process deadline is reached, exporters will need to allow additional shipping time to ensure their delivery deadlines are met – there are already additional delays and costs (eg x-raying of containers on arrival in US ports) which will probably be exacerbated by these new procedures. This should be considered for first shipments as well as factored into shipments to replenish stocks or satisfy re-orders. There is also likely to be less flexibility to make last-minute changes to shipments.

Further information

FDA website

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

AWBC website

www.awbc.com.au

Austrade contacts

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