

MARKET ACCESS ADVICE

Reference Number: MAA 2014-19
Date of Issue: 03 November 2014

Date of Effect: Immediate

United States - Registration updates for establishments exporting food and beverage products

Attention	Industries	All food commodity groups
	Department	Central and Regional offices
	of	ATMs and FOMs
	Agriculture	OPVs and Meat inspection staff
Affected Markets		United States
Further Information		Please contact exports@agriculture.gov.au if you have any queries.

The following information in relation to the United States (US) Food and Drug Administration (FDA) establishment registration requirements is in addition to advice provided in fish Market Access Advice MAA 2014-15.

The FDA has provided the following information for clarification purposes: :

Registration fees and charges: There is no fee required to register a food facility.

<u>Using a third-party or "registrar"</u>: Food facility registrants are not required to use a third-party business or "registrar" to register their facilities with the FDA. The FDA is aware that private businesses are offering services (such as US agent listing and registration renewal services) to food facilities. The FDA would like to remind registrants that the FDA is not affiliated with these private businesses, nor do they act on the FDA's behalf.

Registration process: Food facilities that are required to register with the FDA must register directly with the FDA electronically, by mail or fax, or by CD-ROM for multiple submissions.

A food facility may register, update, or cancel its registration itself (or authorise another person to do so on its behalf) at http://www.access.fda.gov. Alternatively, a food facility may register, update, or cancel a registration by mail by requesting the appropriate form from the FDA at 1-800-216-7331 or 301-575-0156 outside the US, or by e-mail at furls@fda.gov.

US agents may charge a fee for their services, which is solely an issue to be decided between the food facility and the person who agrees to serve as the food facility's US agent.

<u>Certificate of registration</u>: Food facilities do not need a certificate of registration. The FDA does not issue a certificate of registration, nor does the FDA recognise a certificate of registration issued by a private business. The FDA issues a registration number to registered food facilities. Any registered food facility may obtain its registration number by contacting the FDA.

<u>Listing information</u>: Food facilities that have registered and do not have their listing information or PIN should not re-register. Instead, a food facility can contact the FDA for help at 1-800-216-7331 or 301-575-0156, or by e-mail at furls@fda.gov.

A food facility will be asked to provide information on its company's letterhead signed by the owner, operator, or agent-in-charge of the facility to verify the information. Once the FDA verifies the identity of the food facility, FDA will provide the facility access to its account.

The information provided above is current at the time of writing and is intended for use as guidance only and should not be taken as definitive or exhaustive. The Commonwealth endeavours to keep information current and accurate, however, it may be subject to change without notice. Exporters are encouraged to verify these details with their importers prior to undertaking production/exports. The Commonwealth will not accept liability for any loss resulting from reliance on information contained in this notice.