



**Australian Government**

**Department of Agriculture, Fisheries and Forestry**

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**Registration for establishments exporting food and beverage products – update**

This advice updates information provided in the previous market access advice on registration updates for establishments exporting food and beverage products to the United States (US).

The Department of Agriculture, Fisheries and Forestry (DAFF) has received further advice about the re-registration of establishments that export or supply food or beverage products to the US under the jurisdiction of the US Food and Drug Administration (FDA).

Exporters are advised that the FDA deadline for the re-registration of establishments has now been extended until 31 January 2013. There is also additional information available on the FDA website that was added in December 2012 on amendments that have been made to Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act):

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm331959.htm>

The following information from this website may be of interest to establishments that need to update their registration:

- **What types of establishments need to update their registration?**

The same type of food facilities that were required to register with FDA under section 415 of the FD&C Act are required to register with FDA and renew such registrations every other year. Those facilities are domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States (21 CFR 1.225). For purposes of section 415, the term “facility” in relevant part does not include farms, restaurants, and retail food establishments (section 415(c)(1) of the FD&C Act; 21 CFR 1.226).

- **How can registration be submitted?**

The owner, operator, or agent in charge of the facility, or a person authorized by one of them, can submit a facility's registration electronically at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm2>. You may also use the electronic system to update your registration information or submit a cancellation (e.g., due to change in ownership or going out of business). Alternatively, you may use paper Form FDA 3537 to register your facility, renew, and to update your registration information by fax or mail. For updates, you also may send the information by fax or mail on your company's letterhead. You should include your registration number in the update communication. Form FDA 3537 is available for download at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm#3>. You can request the paper forms and submit completed forms by fax to 301-436-2804 or by mail to: U.S. Food and Drug Administration, Food Facility Registration (HFS-681), 5100 Paint Branch Pkwy, College Park, MD 20740. You also may request the paper forms by phone at 1-800-216-7331 or 301-575-0156. FDA currently also provides for submission of registration information on CD-ROM. Additional information relating to CD-ROM submissions is available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm073728.htm#cd4>.

- **Does FDA require registration to be submitted in an electronic format?**  
Registrations can continue to be submitted using the paper process, until the effective date of an electronic format requirement. FDA encourages use of the electronic format now because it is more efficient, provides for immediate submission of the registration information, and provides for immediate issuance of the registration number. It will be compulsory to use the electronic format for registration from January 4, 2016.
- **When does a facility that is required to register with FDA need to submit a registration renewal to FDA?**  
Section 415(a)(3) of the FD&C Act requires facilities that are required to register with FDA to renew their registrations every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. Because there was a delay in FDA's implementation of biennial registration renewal for the 2012 cycle, and registration renewal did not become available until October 22, 2012, FDA intends to exercise enforcement discretion with respect to registration renewals submitted to FDA after December 31, 2012 for a period of 31 days, until January 31, 2013.

There is information about the establishments that may be exempt from registration in the Code of Federal Regulations, Title 21. Food and Drugs, Chapter 1, Subchapter A, Part 1, Subpart H. This is available online at: <http://cfr.vlex.com/vid/1-226-who-does-not-have-under-this-19703877>

## **Registration of Food Facilities, General Provisions**

### ***1.226 - Who does not have to register under this subpart***

- (a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labelling or any similar activity of a de minimis nature;
- (b) Farms;
- (c) Retail food establishments;
- (d) Restaurants;
- (e) Non-profit food establishments in which food is prepared for, or served directly to, the consumer;
- (f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, processing means handling, storing, preparing, shucking, changing into

different market forms, manufacturing, preserving, packing, labelling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;

- (g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

As provided in the previous market access advice, information on registration is available online at: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm> , and step-by-step instructions on how to complete the registration form is available online at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/ucm073706.htm>

Exporters requiring further clarification are encouraged to contact their importer or visit the FDA website.

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