

## **UNDERSTANDING FDA’S FOOD FACILITY REGISTRATION REQUIREMENTS**

*By John Allan, International Dairy Foods Association, and Rich Draper, The Ice Cream Club, Inc.*

### **Who is Required to Register?**

Following the terrorist attacks against the U.S. on September 11, 2001, the U.S. Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which directs the Food and Drug Administration (FDA) to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. This law established a new requirement that all “food facilities” that produce food for consumption in the U.S., whether domestic or foreign, must register with FDA. A “food facility” is a facility that is “engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States.” This requirement applies regardless of whether the food remains within the state in which it was produced or enters interstate commerce. For example, a manufacturer of ice cream, custard, sorbet, ice cream mix and/or other frozen desserts that sells food to local retail food establishments, foodservice establishments (scoop shops, grocery stores, convenience stores, restaurants, etc.) or other commercial customers, would be considered a “food facility” and be required to register.

Like many regulations, there are, of course, exemptions, including restaurants, certain retail food establishments, private residences, farms, food banks and other business locations where food may be produced, packaged, held or sold. Ice cream shops that make their own ice cream in-house for sale directly to consumers would typically be classified as a “retail food establishment” and be exempt from having to register with FDA. However, due to the criteria for meeting FDA’s exemption from registration for retail food establishments, the shop could be required to register if it also is selling food to other *commercial* customers (i.e., not consumers). Specifically, FDA facility registration IS required if the annual total dollar amount of food sales made to commercial customers exceeds the total dollar amount of food sales made directly to consumers.

### **Preventive Controls and CGMPs**

It is important to keep in mind that whether or not you are required to register with FDA affects whether you are subject to FDA’s Hazard Analysis and Risk-Based Preventive Controls for Human Foods (PCHF or “Preventive Controls”) regulations (21 CFR 117 subparts C, F & G). FDA registered facilities must comply with these rules. They also must comply with FDA’s Current Good Manufacturing Practices (CGMPs) (21 CFR 117 subpart B).

Food safety practices in retail food establishments are generally regulated under the Food Code, which is adopted and applied on the state level. The Food Code addresses a range of food safety practices, including employee health and hygiene, protecting food from contamination, equipment and utensils, water and plumbing, physical facilities, and poisonous or toxic materials.

Additionally, retail food establishments bear responsibility under the Federal Food, Drug and Cosmetic Act (FFDCA), including the adulteration provisions of the statute. For example, they cannot introduce into interstate commerce food that is adulterated, such as if it bears or contains a poisonous or deleterious substance which may render the food injurious to health (e.g., *Listeria monocytogenes*) or if it was prepared, packed, or held under insanitary conditions. Using its authority under the FFDCA, FDA has taken regulatory and criminal action against restaurants that have been linked to foodborne illness outbreaks (e.g., [Chipotle and norovirus](#)).

## **Registration and Renewal**

Any company that is required to register must do so *before* it begins to manufacture/process, pack or hold food. Once you have registered initially, FDA requires all registered food facilities to [renew their registration](#) between October 1 and December 31 of each even-numbered year (meaning this year—2020—is a renewal year, if you are already registered). If you fail to renew your registration, FDA considers the registration expired. Food facilities that sell food without a valid, current registration can be subject to Federal civil or criminal penalties. Facilities that fail to keep required information updated or don't cancel their registration following FDA procedures may also face FDA action.

If you are simply an ice cream retailer and don't make ice cream yourself, but utilize the services of a co-packer, co-manufacturer, private label distributor or a supplier, then you may want to confirm they are in the process of renewing their registration with the renewal period; otherwise, you may face delays or have to find other suppliers. Imported products or ingredients generally cannot enter the U.S. without a valid facility registration number because this information needs to be provided as part of the entry process.

## **Suspension of Registration**

Under certain circumstances, FDA also has the power to suspend a food facility's registration when there is a real or likely serious food safety problem that could cause serious adverse health consequences or death. This is an extreme remedy, so FDA has only used this authority in limited situations when it is unable to drive voluntary compliance. Once a facility's registration is suspended, it would no longer be able to enter food into inter- or intra-state commerce or import/export product into or out of the U.S., as applicable.

## **Disclosure of Registration Number**

One question that comes up every now and then is whether registration numbers must be shared with business customers. Although on occasion, a commercial customer may ask or demand that a supplier's registration number be shared, there is no requirement to list the registration number (or numbers) on the food label or share it with business customers. In fact, FDA discourages food facilities from publicly disclosing their registration numbers to prevent others from using the registration number for improper purposes, so be very cautious about sharing such information, if asked. However, bear in mind that imported food needs to provide the registration number at entry as part of the Prior Notice process, so you may need to share your registration number in this context in order to facilitate imports.

To wrap up, even though we are still in the midst of the COVID-19 pandemic, FDA has not announced any plans to postpone this year's renewal period, which is just around the corner. So, be sure you review FDA's guidance and make sure you are registered properly, if required, and all information is up-to-date and completed before the end of the year. For additional reading, see FDA's guidance on Food Facility Registration:

- [Guidance for Industry: Questions and Answers Regarding Food Facility Registration \(Seventh Edition\)](#)
- [Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide](#)
- [Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories](#)

More information from FDA is available [here](#).

*John Allan is Vice President for Regulatory Affairs and International Standards at the International Dairy Foods Association (IDFA), based in Washington, D.C. [www.idfa.org](http://www.idfa.org)*

*Rich Draper is the CEO and Co-Founder of The Ice Cream Club, Inc., in Boynton Beach, Florida. [www.icecreamclub.com](http://www.icecreamclub.com)*