

Amendments to the Registration of Food Facilities

Presented by David Lennarz

Vice President

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About David Lennarz


Vice President and Co-Founder

- David Lennarz is a graduate of the University of Virginia and has worked for nearly 22 years in FDA-regulated industries in the U.S. and Europe. Mr. Lennarz has conducted seminars on U.S. Food and Drug Administration regulations for Food & Beverages, Drugs, Medical Devices, and Cosmetics for trade associations, trade shows, and governments in more than 30 countries around the world. He served as a Technical Expert for the U.S. Food and Drug Administration's Foreign Facility Registration Verification Program operated by FDA's Division of Field Investigations. He co-founded Registrar Corp in 2003 and is based at Registrar Corp's headquarters in Hampton, Virginia.



Overview

- The Bioterrorism Act and Food Facility Registration
- The Food Safety Modernization Act and Biennial Food Facility Registration Renewal
- The Final Rule for Food Facility Registration and the 2016 Biennial Registration Renewal Period
- Summary / Questions & Answers



To prevent, prepare for, and respond to
bioterrorism and other public health emergencies.



Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Food Facility Registration

- Registration required under the Bioterrorism Act of 2002 for facilities that manufacture, process, pack or store food (including beverages and dietary supplements)
- Foreign facilities must designate a U.S. Agent

Food Facility Registration Exemption

- Trading companies
- Personal residences
- Transportation only
- Farms
- Retail Food Establishments
- Fishing Vessels
- USDA-regulated facilities

Food Facility Registration Information

- Facility Information (name, corporate entity type, physical location, trade names used to do business)
- Contact Information (telephone, email address, emergency contact, preferred mailing address)
- Product Information (general product categories)



Shifting the focus of federal regulators from responding to contamination to preventing it.

The Food Safety Modernization Act of 2011

Food Facility Registration Renewal

- Every two years, on even-numbered years
- Facilities must consent to FDA inspection
- Failure to renew results in invalidated registration, is a “prohibited act”

2016

JANUARY	FEBRUARY	MARCH	APRIL
1 2	1 2 3 4 5 6	1 2 3 4 5	1 2
3 4 5 6 7 8 9	7 8 9 10 11 12 13	6 7 8 9 10 11 12	3 4 5 6 7 8 9
10 11 12 13 14 15 16	14 15 16 17 18 19 20	13 14 15 16 17 18 19	10 11 12 13 14 15 16
17 18 19 20 21 22 23	21 22 23 24 25 26 27	20 21 22 23 24 25 26	17 18 19 20 21 22 23
24 25 26 27 28 29 30	28 29	27 28 29 30 31	24 25 26 27 28 29 30

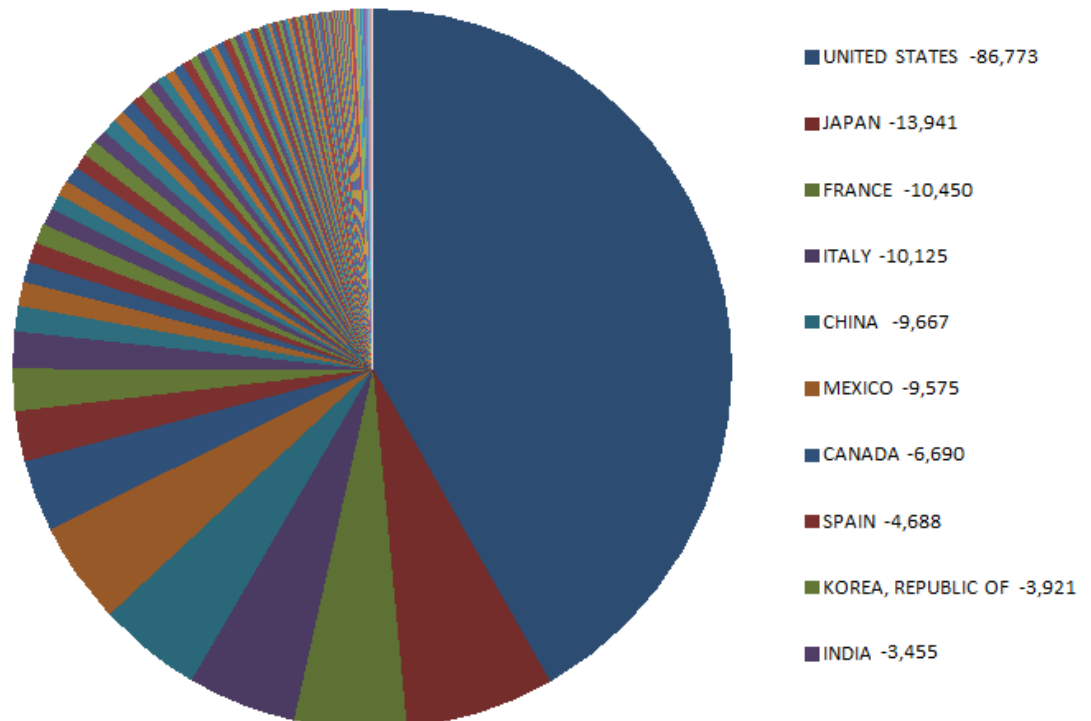
MAY	JUNE	JULY	AUGUST
1 2 3 4 5 6 7	1 2 3 4	1 2	1 2 3 4 5 6
8 9 10 11 12 13 14	5 6 7 8 9 10 11	3 4 5 6 7 8 9	7 8 9 10 11 12 13
15 16 17 18 19 20 21	12 13 14 15 16 17 18	10 11 12 13 14 15 16	14 15 16 17 18 19 20
22 23 24 25 26 27 28	19 20 21 22 23 24 25	17 18 19 20 21 22 23	21 22 23 24 25 26 27
29 30 31	26 27 28 29 30	24 25 26 27 28 29 30	28 29 30 31

SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
1 2 3	1	1 2 3 4 5	1 2 3
4 5 6 7 8 9 10	2 3 4 5 6 7 8	6 7 8 9 10 11 12	4 5 6 7 8 9 10
11 12 13 14 15 16 17	9 10 11 12 13 14 15	13 14 15 16 17 18 19	11 12 13 14 15 16 17
18 19 20 21 22 23 24	16 17 18 19 20 21 22	20 21 22 23 24 25 26	18 19 20 21 22 23 24
25 26 27 28 29 30	23 24 25 26 27 28 29	27 28 29 30	25 26 27 28 29 30 31

Registration Statistics

- **FOIA Request:**
207,655 food facilities registered with FDA as of January 1, 2016
 - 120,822 of those located outside of the United States
 - [See full statistics on our website.](#)

FDA Registered Food Facilities (2016)



Registration Statistics

- FDA purges its database of non-renewed registrations early the next year.
- Number of FDA registered food facilities dropped 14% from January 2014 to January 2015
 - Likely due to facilities failing to renew during the 2014 renewal period.



Final Rule for Food Facility Registration

- Unique Facility Identifier required for 2020
- Electronic submissions only in 2020
- Third Party Submission Verifications
 - If the registration submission, update, renewal or cancellation is not made by the owner, operator, or agent in charge, FDA will verify the third party was authorized to act on behalf of the registrant.
- Agent Assignment Verification
 - FDA will verify that the person designated as the U.S. Agent for foreign facilities has agreed to serve in that role.
 - FDA will not provide the facility with a registration number or confirm the registration renewal until that person confirms they agree to the designation.

Facility Food Product/Activity Categories Expanded

Human Food Product Categories and Activity Types:

- Warehouse/Holding facility will be divided into three categories:
- Ambient, Refrigerated and Frozen.
- Low Acid/Acidified Food Processor will be divided into two categories: Low Acid Food Processor and Acidified Food Processor.
- Farm “Mixed-Type” Facility will be added to the list of activities.
- Shellfish: Molluscan or Other?

Animal Food Product Categories:

- New Product Categories: Botanicals and herbs; direct fed microbials; forage products; and technical additives.
- Old categories replaced with new ones: Animal derived products → Animal protein products
Food processing byproducts → Human food by-products not otherwise listed
Recycled animal waste products → Processed animal waste products.

Registration and Renewal Assistance

- Registrar Corp can register and renew food facilities with U.S. FDA
- U.S. Agent Benefits
 - Registration Renewal: Registrar Corp will renew FDA registrations biennially as required by FDA
 - Mock FDA Inspection (*free of charge other than travel and lodging when FDA sets an inspection date*)
 - Certificate of Registration issued by Registrar Corp
 - Registration Updates
 - FDA Compliance Monitoring
 - Prior Notice (*three free per year*)
 - Detention Assistance
 - DUNS Assistance



Questions & Answers

