

# FDA FOOD SAFETY MODERNIZATION ACT



## FSMA—What You Need To Know An online informational session

### Final Rule on Facility Registration

Docket Folder (FDA-2002-N-0323)

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# Important Notice

- Because sections were abbreviated for this presentation, the information provided is only an overview and should not be relied upon as a substitute for reading the final rule, or obtaining legal advice, or as a summary of all regulatory requirements.
- Every company must conduct its own detailed review of the final rule.



# Public Health Security and Bioterrorism Preparedness and Response Act of 2002

- Also called the Bioterrorism Act
- Directs the FDA to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies
- Effective December 12, 2003, requires food facilities
  - To register with FDA
  - To give advance notice to FDA on shipments of imported food



# Food Facility Registration

- On July 14, 2016, food facility registration was finalized as part of FSMA implementation.
- Effective July 14, 2016, food facilities engaged in manufacturing, processing, packing, or holding food for consumption in the U.S. are required to submit additional information to FDA including
  - Registrant's email address
  - Registration renewal every 2 years on even-numbered years
  - Assurance that allows FDA to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act
  - Electronic records submission by January 4, 2020
  - Use of unique food facility identifier (UFI) beginning October 1, 2020



# Food Facility Registration (cont'd)

- A UFI ensures that companies' correct information is being registered
  - Incorrect information will cancel the food facility registration
- Final rule also expands the number of establishments considered as retail food establishments that are not required to register as food facilities



# Final Rule On Food Facility Registration

- Improves the accuracy of the food facility registration database in the U.S. and overseas
- Reduces the potential for food fraud
- Helps FDA
  - To efficiently use its resources for inspections
  - To quickly respond to food-related emergencies



# For Technical Assistance

- Visit the website *FDA Unified Registration and Listing Systems (FURLS)*

<https://www.access.fda.gov/>



# References

FDA. July 13, 2016. FDA Issues Final Rule under FSMA to Update Food Facility Registration.

[http://www.fda.gov/Food/NewsEvents/  
ConstituentUpdates/ucm510037.htm](http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm510037.htm)

FDA. July 13, 2016. FSMA Final Rule: Amendments to Registration of Food Facilities.

[http://www.fda.gov/Food/GuidanceRegulation/  
FSMA/ucm440988.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm440988.htm)

FDA. July 13, 2016. Registration of Food Facilities.

[http://www.fda.gov/Food/GuidanceRegulation/  
FoodFacilityRegistration/default.htm](http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)





# References (cont'd)

Food Safety Tech Staff. July 14, 2016. FDA Finalizes Rule on Food Facility Registration. Online article of online news magazine FoodSafetyTech.

[https://foodsafetytech.com/news\\_article/fda-finalizes-rule-food-facility-registration/](https://foodsafetytech.com/news_article/fda-finalizes-rule-food-facility-registration/)

Siegner, Cathy. July 14, 2016. FDA amends facility registration rule to limit fraud, ease inspections. An online article of the online news magazine Food Safety News.

<http://www.foodsafetynews.com/2016/07/fda-amends-registration-reg-to-cut-food-fraud-ease-inspections/#.V49oOpMrKqA>



# If You Have A Question, Ask:

- FSPCA Technical Assistance Network

[http://www.iit.edu/ifsh/alliance/resources/  
technical assistance network inquiry form.sht  
ml](http://www.iit.edu/ifsh/alliance/resources/technical%20assistance%20network%20inquiry%20form.shtml)

- FDA Technical Assistance Network

[http://www.fda.gov/downloads/Food/  
GuidanceRegulation/FSMA/UCM467582.pdf](http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM467582.pdf)



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