

FDA FOOD SAFETY MODERNIZATION ACT



FSMA—What You Need To Know An online informational session

Module IV. Third Party Accreditation and Certification

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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.



C/T/A/H/R

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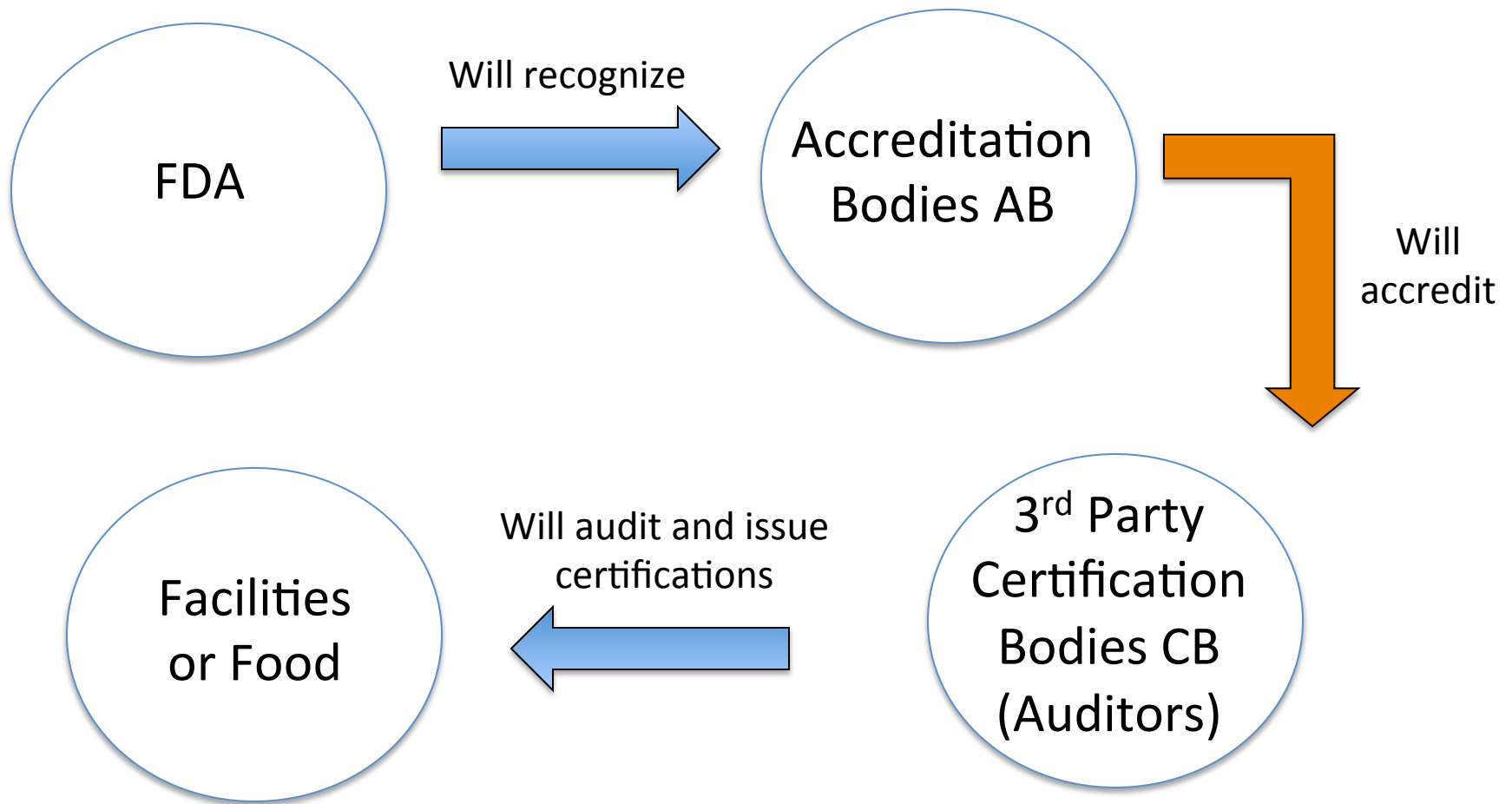
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MODULE IV. THIRD PARTY ACCREDITATION AND CERTIFICATION

Final Rule issued November 27, 2015



FDA 3rd Party Certification Program



Accreditation of 3rd Party Certification Bodies

- Voluntary program
- To conduct food safety audits and issue certifications of foreign facilities and the foods they produce for humans and animals
- May be required by the FDA to accompany a food in specific circumstances

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm>



When Are Certifications Needed?

- Importers will generally NOT be required to obtain certifications.
- Certifications will be used for two purposes:
 1. Facility certifications will be used by importers to establish eligibility for participation in the **Voluntary Qualified Importer Program (VQIP)**, which offers expedited review and entry of food.

When Are Certifications Needed? (cont'd)

2. Food or facility certifications will be used for admissibility of a food subject to a risk-based determination by FDA.
 - Requires a specific determination by FDA under Section 801(q) of the FD&C Act
 - Factors include consideration of the capability of the regulatory system of the exporting nation to ensure compliance with U.S. safety standards for the food.
 - Exemptions for certain alcoholic beverages and products subject to USDA oversight at import



Recognized Accreditation Bodies

- May be a foreign government, foreign agency, or private 3rd party

3rd Party Certification Bodies (CB, Auditors)

- May be a foreign government, a government employee, foreign agency, private 3rd party entity or individual
- Or an audit agent of an accredited certification body
- Qualified auditor (21 CFR 117.3)
 - A qualified individual with technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function

3rd Party Certification Bodies (CB, Auditors) (cont'd)

- Kinds of audits
 - Consultative
 - **In preparation for a regulatory audit**
 - Not used as a basis for certification
 - For internal use only
 - Also considers compliance with federal standards, and meeting industry standards and practices
 - Regulatory
 - Used as a basis for certification



Exemptions

(Accredited 3rd Party Certification)

- Foreign facilities manufacturing alcoholic beverages
- Meat, poultry, and egg products subject to the USDA oversight at the time of importation



Implementation

(Accredited 3rd Party Certification)

- As soon as the final Model Accreditation Standards guidance and final User Fee rule are published
- Accreditation bodies could begin to apply when the program goes into effect
 - 3rd Party CB could seek accreditation after one or more FDA- recognized accreditation bodies begin accepting applications

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)



END OF MODULE IV

