

Please note that this material is primarily intended for use by FDA guests and interpreters during February 2016 seminars in Japan.

FDA Food Safety Modernization Act

~Where should we start first when preparing for FSMA?~

- ① PCHF (Preventive Controls for Human Food)
- ② Produce Safety Standards
- ③ FSVP (Foreign Supplier Verification Program)

February, 2016

JETRO (Japan External Trade Organization) – Chicago

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I. FSMA 101 – Basic Facts

- FSMA (Food Safety Modernization Act) / Passed through the congress on January, 2011/
Since then, FDA is establishing FSMA rules / The most sweeping reform of the U.S. food safety laws in more than 70 years
- The Core FSMA proposed rules have been published since January, 2013
/ Public meeting & Public comment / Final Rules have been published since September, 2015
/ Some of them go into effect in September, 2016
- A phased approach to FSMA implementation – FDA Q&A assistance – FDA website / FSPCA

【Rules finalized in 2015】

- Preventive Controls for Human Food (Sep, 2015)
- Preventive Controls for Animal Food (Sep, 2015)
- Foreign Supplier Verification Program (Nov, 2015)
- Rule on Accreditation of Third Party Certification Bodies (Nov, 2015)
- Produce Safety Standards (Nov, 2015)

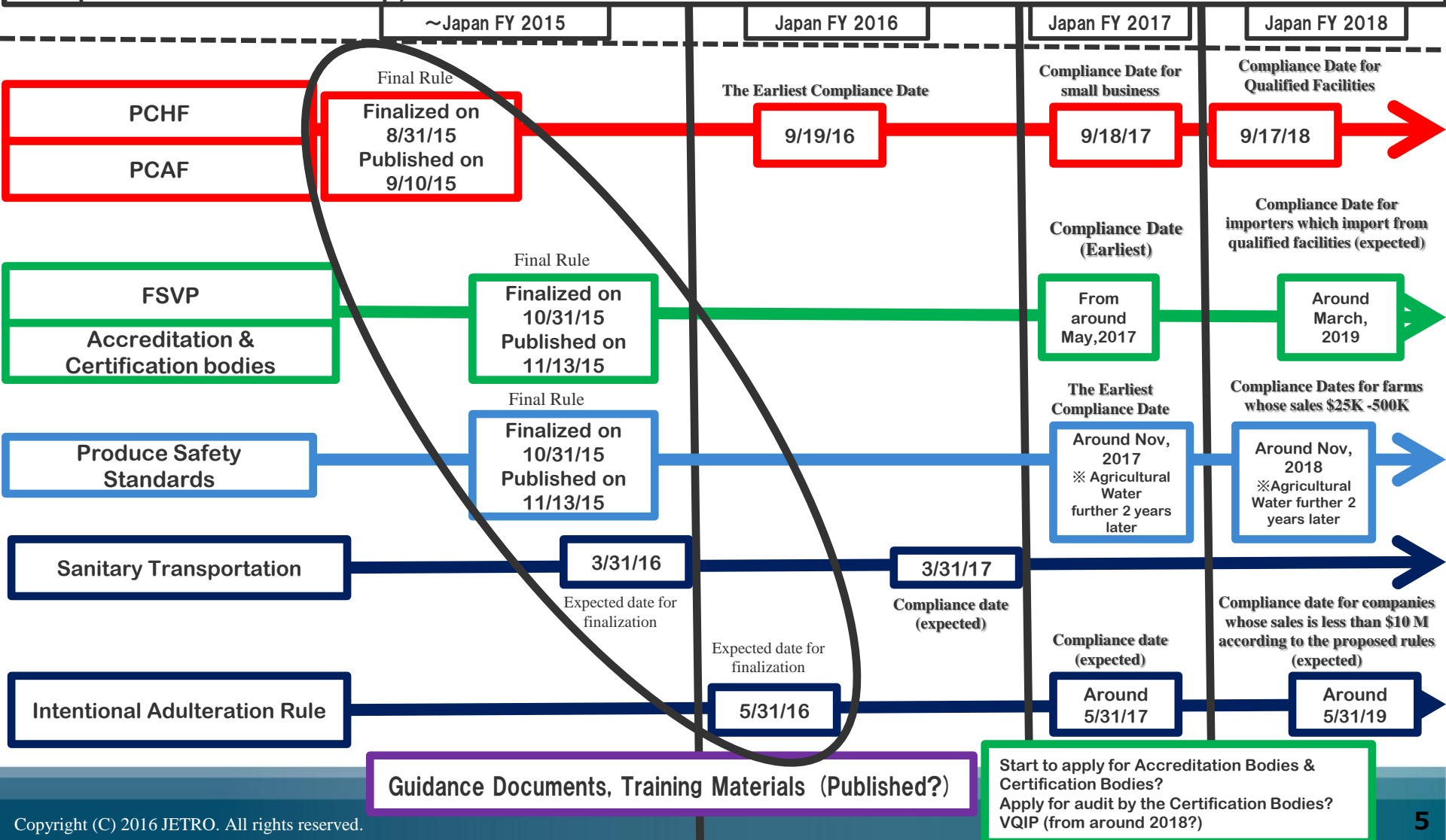
【Not yet finalized】

- Intentional Adulteration Rule (may apply to seafood, juice according to the 2013 proposed rule)
- Sanitary Transportation Rule (may only apply to domestic transportation according to the 2014 proposed rule)

【Other documents】 (including the ones which may be made by FSPCA (Food Safety Preventive Controls Alliance))

- Voluntary Qualified Importer Program, User-Fee Programs for Accreditation and Certification Bodies
- Guidance documents related to each final rule
- Training materials for the industry

Some of core FSMA Rules was already finalized in 2015. You don't need to wait to prepare until all the rules & guidance documents are published if you want to be in time for its implementation. The earliest compliance date will be Sep, 2016 while the latest one will be around 2020 for farm activities.



Record Keeping (two years)

	Who is covered?	Examples of what to do	Memo
Preventive Controls for Human Food (PCHF)	Facilities engaging in Food (Beverage) Manufacturing, Processing, Packaging, Holding (subject to facility registration) (※1)	Hazard Analysis and Risk-based Preventive Controls	New, Comprehensive Food Safety framework (HARPC) / Need to analyze Hazards requiring controls & to document it
		Develop & Manage Food Safety Plan (includes recall plan if necessary)	Conducted / Overseen by PCQI - Training, Job experience
		Supply Chain Program as one of PCs (e.g., onsite audit, sampling, review)	Supply Chain Program will be included in Food Safety Plan if there are any hazards requiring such controls. (Evaluation, Verification)
		Training for all employees engaging in these activities	Sanitary/ Food Safety / Farms engaging in low risk activities NOT exempt from training
Produce Safety Standards	Establishments engaging in Farm Activities (※2)	Sanitary, Training, Agricultural Water, Soil Amendments, Tools & equipments	Some RACs are NOT subject to this rule. (e.g., grains, green tea leaves, rarely consumed RACs) / (Focusing on biological hazards requiring controls)
Foreign Supplier Verification Program (FSVP)	Importers (※3)	Approval of foods & suppliers	Evaluate the risk of each supplier & each food / Approve suppliers & foods (Matrix alone is NOT sufficient)
		Verifications (e.g., onsite audit, sampling, review)	Onsite, Review, ... (※)In the "worst" case, your food may not be imported to the U.S..

(※1) Facilities with average food sales (including non-U.S sales) during the previous 3 calendar years of \$ 1M are exempt from the requirements for food safety plan. Also, not only grain elevators & facilities but also facilities solely engaging in storage of unexposed packaged food are exempt from the requirements for food safety plan (including Hazard Analysis and risk-based preventive controls if there are no hazards requiring time/temperature control for safety).

(※2) Farms include a primary produce farm as well as Secondary Activities farm a majority interest of which is owned or jointly owned by Primary farms which grow/raise/harvest majority of those RACs at the Second one. /Exempt farms no more than \$25K (average produce sales during previous 3 years) / Modified requirements farms no more than \$500K (average food sales during previous 3 years) / Mixed Type Farm subject to PCHF

(※3) Evaluation of Hazards, Verification Activities Vary depending on the nature of food, compliance of suppliers, which rule apply to./ Record retained in foreign languages is permitted. /Translation within reasonable time / Submit records to FDA upon request

Image of Food Safety Plan

※Reanalysis at least 3 years or so/Retain onsite

Perform & Record Keeping (2years)

- ※Original/True Copy/Electronic records
- ※Permit to be stored off site so long as they can be retrieved and provided onsite within 24 hours upon FDA's request

1. Hazard Analysis & Identification (Written)

- * Whether there are any hazards requiring controls & what type of hazards are (Still Need to document hazard analysis in case there are no hazards requiring controls)
- * Based on Scientific reports, past occurrence of incidents and so on (known or Reasonably foreseeable hazards)
- * Physical(contamination of glasses),Chemical(post pesticide, radioactive residue),Biological(microorganism, pathogen)
- * Consideration of severity & probability
- * Determine whether there are any hazards requiring controls under supply chain program

(Hazard Analysis & Identification / Approval of suppliers list)

(FYI) Examples of cases in which there may be no hazards requiring controls

(Still Need for Written Hazard Analysis depending on the situation)

- ①Low Risk Activities (Milling Grains, Making dry pasta/jams/soft drinks from sugar/syrups and so on)
- ②Foods which can not be consumed without the application of appropriate controls (e.g., coffee beans, grain)

2. Preventive Controls if there are any hazards requiring controls (Written)

- * Based on science reports and so on
- * Process, Food Allergen, Sanitation, Supply Chain, Recall plan
- * NO need to set Critical Limits at CCPs (⇒ HARPC : significantly prevent / minimize hazards)
- * Supply Chain Program (Use approved suppliers/ Determine appropriate verification activities / Conduct programs / Onsite audit in case there are hazards which may cause SAHCDHA.)

3. Management Components (Written Procedures)

- * Monitoring PCs
- * What type of & frequency of verification activities (e.g., product testing / environmental monitoring if contamination of RTE foods with an environmental pathogen is a hazard requiring PCs)
- * Corrective Actions (how to identify & correct problems)

[Cases where there are hazards requiring PCs]

- Monitoring
(e.g. temperature records)
- Verifications
(Verification of monitoring & corrective actions & supply chain program/ Calibration of process monitoring)
- Corrections

Training curriculums for all employees (QI) / PCQI (if necessary)

Trainings

- ①Qualified Facilities / attestation / average food sales / preventive controls / Oct- Dec from 2018
- ②Farms engaging in low risk activities / No food safety plan / Need training for all employees (QI)
- ③Not only Grain warehouse & elevator but also warehouse solely engaging in storage of unexpected packaged food are exempt from the requirements for food safety plan (including Hazard Analysis and Risk based Preventive Controls) if there are no hazards regarding time/temperature controls. Storage facilities with any hazards requiring time/temperature controls, procedures of monitoring, corrective actions and verifications for time/temperature controls need to be included in their food safety plan.
- ④Food safety plan & various verification activities need to be conducted / overseen by PCQI (Preventive Control Qualified Individual).

【Image】

(This varies by case)

F D A
(Food and Drug Administration)

PCHE

**Inspection
(possibility)**

**Inspection/
Request for records
(possibility)**

Farms

**Suppliers
of
ingredients**

- ① Evaluate risks/ Use approved suppliers
(according to the nature of hazards and so on)
- ② Conduct Verification Activities

↓

Manufacturers

- ③ Develop & Manage Food Safety Plan
- ④ Record Keeping

- ① Evaluate the risk/ Approve suppliers
- ② Verification activities

Warehouses
(e.g., Holders, Exporters)

PCHE
(※) Depending on whether
time/temperature control is needed.

FSVP

**Importers
in the U.S.**

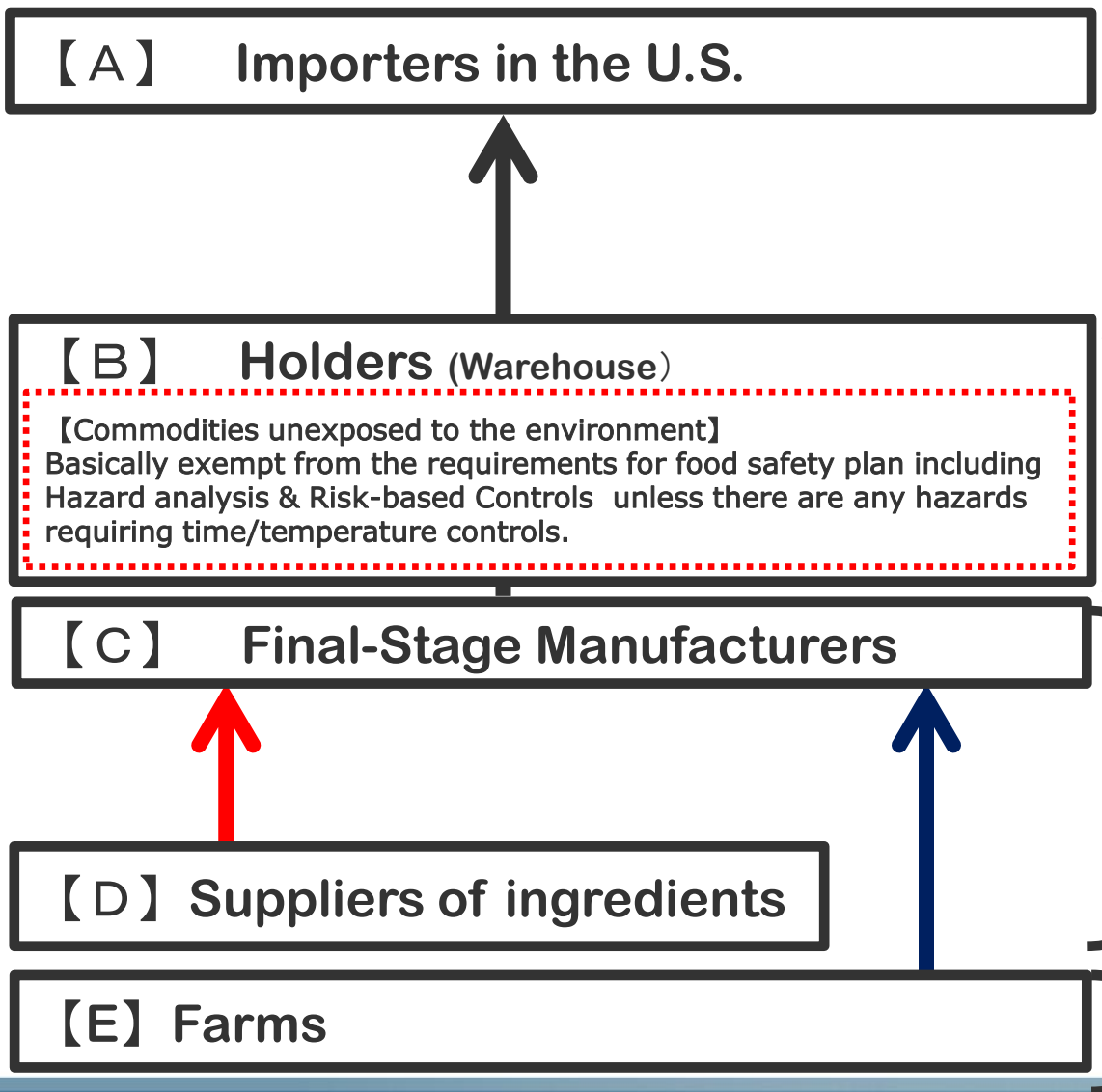
**(Record Keeping
/ Can be retained in
foreign languages)**

Farms
Certain farm activities / Record Keeping

Produce Safety Standards

(*) RACs exempt from food safety standards / Food grade chemicals / Samples for trade shows May NOT Exempt from the requirements for FSVP.

Food Chain



【FSVP (301)】

What to do

- ① Firstly, Analyze Hazards / Evaluate the compliance of suppliers
- ② Verifications / Record Keeping (2 years)
- ③ DUN Number
 - (※1) Basically annual audits are appropriate verification activity for hazards that may cause SAHCDHA.
 - (※2) May assess evaluation of hazards conducted by manufacturers(C) or wholesalers(B).
 - (※3) In case that manufacturers conduct supply chain program when importing ingredients under PCHF, they are deemed in compliance with FSVP.

【PCHF(103)】

- ① If there are any hazards requiring time/temperature controls, food safety plan & the plan management will be focused on time/temperature control issues.
 - Monitoring, corrective actions and verification for temperature controls
- ② Record Keeping (2 years)

【PCHF(103)】

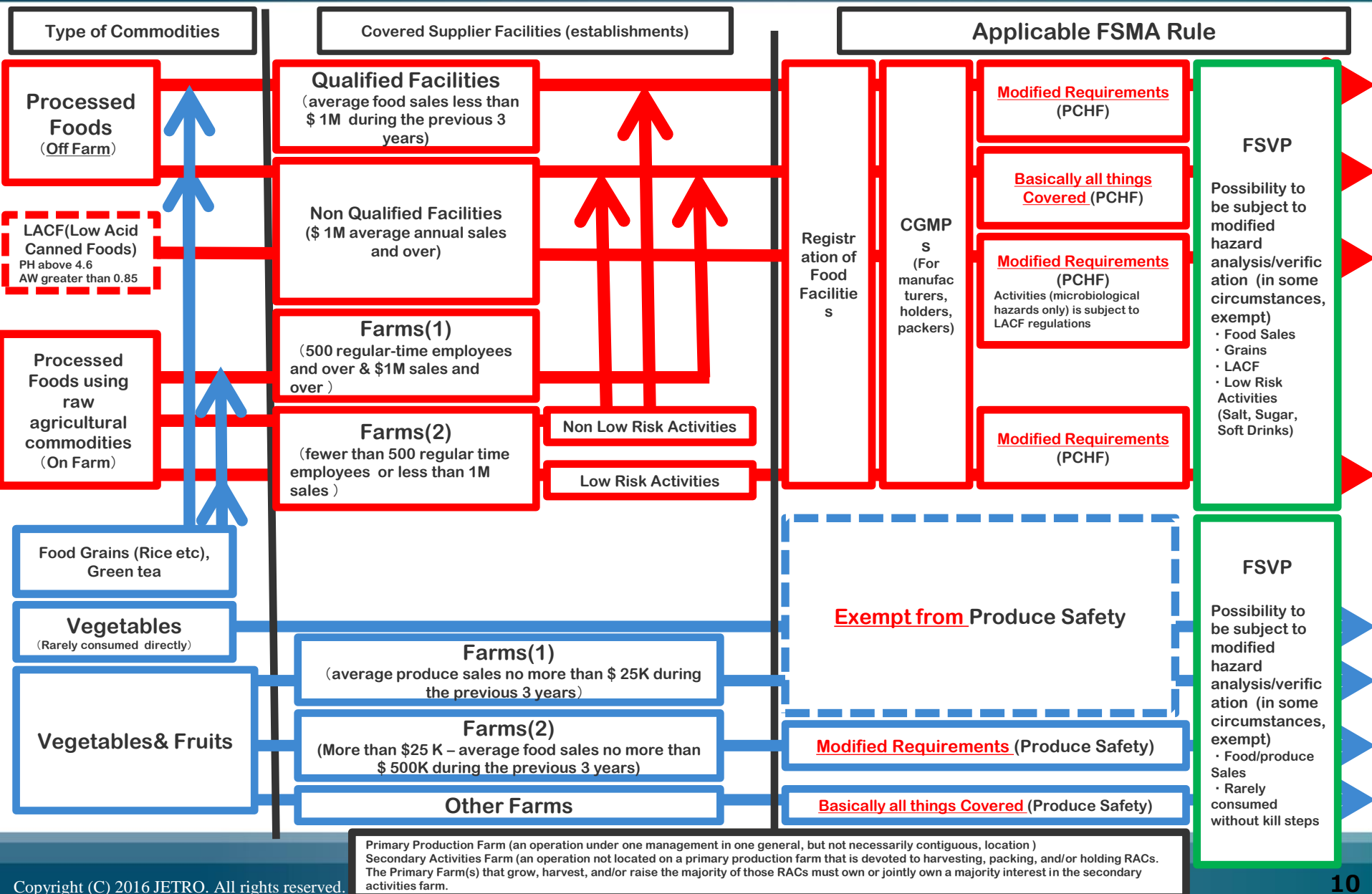
- ① Develop Food Safety Plan (includes written Hazard Analysis)
- ② Management / Record Keeping (2 years)
- ③ (if necessary) Supply Chain Program
 - (※) Basically annual audits are appropriate verification activity for hazards that may cause SAHCDHA.

【Produce Safety Standards (105)】 etc.

Any Food Safety Plan is NOT needed.
 Farm Activities following by this rule (Record Keeping 2 years)
 RACS that are not covered by this rule may be subject to other FDA rules.

JETRO Coverage Image by product, facility type

(※) Seafood (NOT include seaweed), juice ,alcohol beverage and ingredients that can be used for manufacturing these are exempt from PCHF, FSVP.



Primary Production Farm (an operation under one management in one general, but not necessarily contiguous, location)
 Secondary Activities Farm (an operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
 The Primary Farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.

II. Tips to prepare for FSMA

- Where should we start? How should we prepare for FSMA?

Importers	1. Confirm which rule will apply to each commodity & supplier & to what extent the rule will be applied to them.
	2. Assign QI(Qualified Individual) - considering job experience, knowledge, training
	3. Evaluate the hazards requiring controls based on scientific reports, illness data and so on. Document hazard analysis. If you assess the hazard analysis conducted by suppliers, you need to obtain the analysis from them in the future.
	4. Evaluate the compliance of suppliers, transportation/distribution/sanitation, etc.
	5. Document the evaluation of risks posed by each food & supplier. Make a list of approved suppliers from whom you import. Making a matrix alone won't be sufficient.
	6. Determine how to verify suppliers' activities. You may obtain documents from distributors (e.g., exporters prior to importation) indicating verification activities conducted by such distributors.
	(※)Until GFSI organizers prove their recognition satisfies FSMA requirements as well, importers obtaining GFSI audit reports ONLY from suppliers is NOT sufficient. Importers need to prove the validity of those reports by themselves until then.
【After compliance date】 Document verification activities. (Check Food Safety Plan - onsite audit)	

Food Manufacturing, Processing, Holding, Packaging

1. Confirm which rule will be applied (PCHF or Produce Safety Standards) and to what extent.
2. Confirm whether you qualify as very small businesses or small businesses under PCHF. (This will affect your compliance date)
3. Assemble all the necessary evidence of annual food sales by July, 2018 if you apply for “Qualified Facilities” status (very small businesses)
4. Assign PCQI(Preventive Control Qualified Individual) / Document training curriculums if necessary.
5. Evaluate Hazards requiring PCs based on scientific reports and so on. Written hazard analysis is needed even if there are no hazards requiring PCs.
6. Develop a supply chain program & a recall plan if there are any hazards requiring PCs(*).
 (*): Supply Chain Program : At least written Hazard Analysis of ingredients & evaluation of suppliers’ food safety history in cases where hazards of ingredients & RACs are controlled by suppliers.
7. Determine what is an appropriate control for each identified hazard and document it.
 (Holding) Whether time/temperature control is required for safety
 (Others) Commodities that cannot be or are rarely consumed without an application control / Low Risk Activities / Activities subject to low acid canned food regulations
8. Determine & document monitoring, verification activities, corrective actions.
9. Determine & document training curriculums for employees. Even farms engaging in low risk activities are required to have this training.

RACs Growing, Harvesting, Holding, Packaging	1. Confirm whether or not your RACs are covered by Produce Safety Standards.
	2. Confirm whether you qualify as an exempted farm or qualified farm. (This will affect your compliance date and so on)
	3. Assemble all the necessary evidence of annual food / RACs sales if you are an exempted farm or qualified farm.
	4. If you are an agricultural cooperative, then confirm whether your activity falls within the definition of farm under the Produce Safety Standards.
	5. Confirm whether your activities go beyond the definition of farm which are exempt from PCHF. If part of your activities don't fall into the definition of farm, you will be subject to PCHF & facility registration. In such cases, you need to check whether your activities fall within the definition of low risk activities under PCHF.

III. Other Information

- **Outreach activities, training curriculums / Gradually Main focus on FSMA / Since Apr, 2015**
(e.g., Public Meeting in D.C. on Apr,2015, Public Meeting in Chicago on Oct, 2015, Roundtable in MD on June 2015)
- **Work on development of training curriculum along with Private & Public sectors**
(※) FSPCA (Food Safety Preventive Controls Alliance) established in 2011 / IL science and technology institute, Food industries, Agencies
- **Public meeting / Open to any individual companies / Precious opportunity to share comments/thoughts**

【New Online Form for submitting questions】 (Interpretation of rule)

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

Need : Name, Email address, Pull down menu (attribution)

No Need : Company name

Filling in the what is behind your questions in a concrete way may be recommended.



【FSPCA】 (Science / Technology)

<http://www.iit.edu/ifsh/alliance/>

Develop training curriculums for industry

~What we have been working on with government and so on~

【Comment to FDA】

Since 2013

- ① Submitted our comments to FDA / 5 times so far
(loosen the restrictions regarding qualified facilities, permit companies to retain records in foreign languages and so on)
- ② Shared our thoughts at every possible opportunity

【Gather Information】

- ① Ongoing communication with law firm, food industry
- ② Attend Public Meetings & Webinars hosted by FDA
- ③ Examples of how to address this issue (Canada, Mexico / Sep, 2014)
- ④ Examples of how to address this issue (Other countries / Aug, 2015)

【Outreach】 (held by JETRO)

- ① Annual seminars in Tokyo and so on
- ② Local seminars in Japan (increase seminars since FY 2015)
- ③ U.S. conferences, seminars in LA, SF, NY

(※) Presentation at June Roundtable, Aug APEC Workshop & Oct Public Meeting in 2015

~Our Future Focus~

Continue to gather updated information about FSMA + conduct outreach

【Guidance / Training Curriculum】

Don't wait to prepare for FSMA until all the Guidance & Training Curriculums are published so you can be in time for compliance dates.

【Disclaimer】

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