U.S. FSMA Seminar: Practices

Case Studies

Registration of Food Facility

Q1

Company A contracts out production to Company B and Company C.

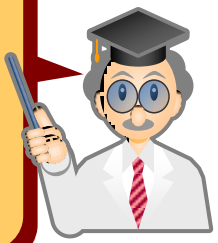
1. Which company is responsible for applying to a facility registration?
2. If only Companies B and C are required to make a facility registration, is it also their responsibility to prepare and implement a food safety plan? Is there any measure to be taken by Company A?
3. If Company A finally undertakes quality assurance and inspection of the final product, what is the responsibility of Company A?
4. Companies which made the facility registration (i.e. Company B and Company C) would be different from the manufacturer to be indicated on the food labeling. Would this be a problem?

A #1: It depends. If Company A receives and holds the packaged product produced for it prior to export to the U.S.; then it and the producing companies would need to be registered. If Company A conducts further manufacturing or processing of more than a *de minimis* nature on product produced for it; the company that initially produced the product would not need to be registered.

A #2: If A and B are producing product for export to the U.S.; both will need to implement a food safety plan. If A holds unexposed packaged product, it will at minimum need to implement at least current Good Manufacturing Practices (cGMP) and have written training documentation for those. If packaged product is held at refrigeration temperatures; it may also need to meet modified requirements of preventive controls addressed n 21 C.F.R. §§ 117.7 and 117.206.

A #3: Company A must be registered as it will be "holding" product. It will also have a written hazard analysis . However, unless this identifies a hazard requiring a preventive control, it must only have written documentation of training of cGMPs. And, if applicable, the modified requirements discussed above if product requires refrigeration for food safety.

A #4: If product is produced for Company A; the label on the product would generally indicate in the signature that the product is "Distributed by "Company A name." The information that it was actually produced at Company B or C does not need to be declared on the actual product label.



Q2

For Sites A to G below, please advise us of whether a facility registration is required, the details of such registration, and the applicable regulations for each site.

(*)

Exporting to U.S.

Manufacturing site D in Japan (individual packaging)

Customs broker & warehouse G in Japan (holding)
*temperature control not required

C is making end product

Manufacturing site C in Japan (processing)

Warehouse F in Japan (holding)

Manufacturing site B in Japan (processing)

Manufacturing site E in Japan (packaging)

Farm A (growing, harvesting, packing and holding)

(*) Sites C-G must all be registered. PCHF is applicable to sites C – G. Sites F and G will at minimum need to meet the CGMP part of the regulation. See response on Q #3 for information on "farm." 21 C.F.R. §§ 1.225(a) and 1.226(a)

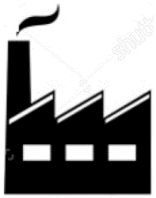
Q3

For Sites A to H below, please advise us of whether a facility registration is required, the details of such registration, and the applicable regulations.

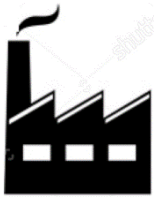
To U.S.

Export

Warehouse H in Japan (holding)
*temperature control required



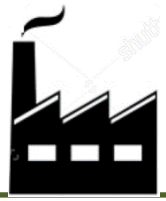
Manufacturing site G in Japan (final processing and packing)



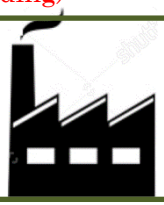
Brand owner

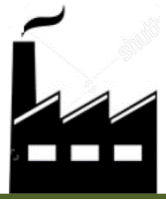
contracting out manufacturing by instructing specifications, designs and forms

Manufacturing site F in Japan (manufacturing and processing) (holding) (Quality assurance of final product)



Manufacturing site E in Japan
(Manufacturing/processing of raw materials, packaging, and holding)





Farm A
(growing, harvesting, packing and holding)

Chicken Farm B
(growing and holding)

Manufacturing site C in Thailand
(Manufacturing/processing of raw materials, packaging and holding)

Manufacturing site D in Japan
(Manufacturing/processing of raw materials, packaging and holding)

Answers to Question #3

- Farm A:
  - Would need to register ***if*** the product from this farm was exported directly to the U.S. as the slide indicates the farm is "packing." FDA considers activities such as sorting, grading, wrapping or boxing harvested food for be "packing." Unless all product was consumed on the farm or another farm under the same ownership, the farm would need to be registered. (*See* 21 C.F.R. § 1.227(b)(3) and 1.227(b)(3)(i) and comment 41 in preamble to Interim Final Rule (70 Fed. Reg. 58905))
  - ***However***, as the product is going to several other manufacturing sites in Japan where it is further processed into an end product; the farm ***would be exempt*** from registration even if "packing." (*See* 21 C.F.R. § 1.226(a))

Answers to Question #3

- Chicken Farm B:
  - If farm B is producing shell eggs and has 3,000 or more laying hens at a particular farm and does not sell all their eggs directly to consumers, and that produces shell eggs for the table market in the U.S., it would be required to register the farm with FDA (*see* 21 CFR 118.11 (a)).
  - If this farm is producing shell eggs for use by manufacturing site E, the farm is exempt from registration as it will be considered a "Farm." In addition, as the product (eggs) are receiving more than a *de minimis* process at site E and are ***not*** being produced for the table market in the U.S. even if the eggs are "washed" at the farm as part of harvesting – there is no need to register. (*See* 21 C.F.R. § 1.226(a))
  - If farm B is producing poultry meat; it is not permitted to be exported to the U.S. as Japan is not on the list of approved countries for export of poultry – raw or cooked. (*See* list of eligible countries and products at: https://www.fsis.usda.gov/wps/wcm/connect/4872809d-90c6-4fa6-a2a8-baa77f48e9af/Countries_Products_Eligible_for_Export.pdf.pdf?MOD=AJPERES)

Answers to Question #3

- Manufacturing site C and D:
  - If site C and D provides raw materials to site E or F which *only* receive *de minimis* processing at site E or site F, or further in the manufacturing chain; then site C and site D and all subsequent sites would need to be registered. (*See* 21 C.F.R. § 1.226(a))
  - If site C and site D provides raw materials to site E and F and the raw materials undergo further processing; site C and site D do not need to be registered. (*Id*.)

Answers to Question #3

- Manufacturing Site F:
  - Site F is exempt from registration *unless* the further manufacturing / processing (including packaging) at site G is of a *de minimis* nature.
  - If subsequent activities are of a *de minimis* nature; this site (site F) as well as all subsequent sites in the process must register.

(*See* 21 C.F.R. §§ 1.225(a) and 1.226(a) and comments 17, 21, 25, 26 in Interim Final Rule (70 Fed. Reg. 58900-902)

Answers to Question #3

- Manufacturing Site G:
  - Site G must register as it appears it is the final site where processing and packaging occurs. (*See* 21 C.F.R. §§ 1.225(a) and 1.226(a))
- Warehouse H:
  - Site H must register as it is "holding" product prior to export to the U.S. (*See* 21 C.F.R. § 1.225(a))

Company Size

Q4

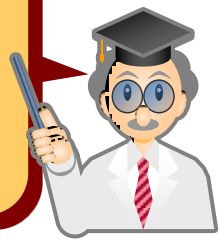
For the purpose of PCHF regulation, are the following companies "very small business," "small business" or other business?

Company A : Average Annual Sales of all food for 2016, 2017 and 2018 (or 3-year period preceding the applicable calendar year): <$1,000,000/year, adjusted for inflation, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale: **Very Small Business** (*See* 21 C.F.R. § 117.3)

Company B :Number of full-time equivalent employees *(Headquarters /Subsidiaries) = fewer than 500: **Small Business** (*See* 21 C.F.R. § 117.3)

Company C : Number of full-time equivalent employees* (Headquarters /Subsidiaries). 500 or more : **Other Business**

***Full-time Equivalent employees:** number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of work in one (1) year, 2080 hours (i.e., 40 x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.



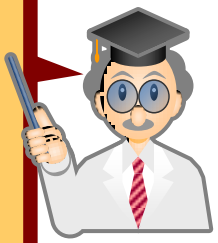
Parallel import

Q5

(1) Currently, there is a potential problem of parallel import foodstuff product (i.e. product not imported by licensed importers) not initially intended for distribution in the U.S., of which the suppliers are not aware. If an importer is required to verify foreign suppliers under FSVP, the importer will be primarily responsible; however, after this FSVP starts to apply, if an importer makes a recall or receives an FDA action of import alert for such reasons as food adulteration, non-compliance of food allergen labeling or incorporation of ingredients prohibited in the U.S., is only the name of such importer publicized in the import alert? Or, is the name of the foreign supplier (including manufacturers and brands) also publicized?

(2) As mentioned above, parallel import product (i.e. product not imported by licensed importers) cannot be regulated, and it is difficult for a foreign supplier to take appropriate measures. Please advise about effective preventive measures against the above situation, and effective response measures in case of the occurrence of such situation.

A. #1: It depends. The FSVP only applies to the importer. If there is an issue with compliance to the FSVP regulation – it is the importer who is affected. An import alert, however, can be issued for a particular type of product, all products from a certain manufacturer or supplier, or even all products from a particular country or region – no reasons that are due to compliance by the importer with FSVP. In these cases, the import alert listing could be by product, manufacturer, or even country and not list the importer of record. However, if the importer of record is involved with the reason why a product is adulterated or misbranded; it is possible they could be named as well. If FDA determines a person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of SAHCODHA; that person may be debarred from importing food.
A. #2 While a product not intended for export to the U.S. may be offered for importation; that does not mean that the manufacturer is at fault. Part of compliance with PCHF is that distribution of food is considered. When doing so, determine whether or not you understand how your product is distributed and whether it is being offered for export to the U.S. and take appropriate measures to notify your customers that it does not comply with standards for export. If you determine there is an issue; contact appropriate authorities to put them on notice so that an import alert is not issued.



About PCQI

Q6

(1)PCQI required in accordance with PCHF and QI required by FSVP could be the one from outside of the entity.
Accordingly is this understood to be proper and appropriate when a manufacturer who intends to export its food to US may ask PCQI to be conducted by the same QI of the US importer, or not?

(2)And in the event that a manufacture, exporter, and importer are affiliated by the same capital stock forming up a group entity, the QI who establishes the food safety plans for the group would have to be in a position to perform the verification of his own plan, and is this proper and appropriate, or not?
We would like to know if there is points where we should be aware and careful in his practical conducts and performances.

A．#1: The FSVP regulation specifically addresses that "you may not rely on the foreign supplier itself or employees of the foreign supper to perform supplier verification activities…." (*See* 21 C.F.R. § 1.506(e)(2)(ii)) Based on this, a manufacturer would need to "employ" its own PCQI to oversee its food safety plan who is independent of the Qualified Individual employed by the importer of record used to conduct the foreign supplier verification. This was also commented upon in the preamble to the final rule, "In addition, as a general matter, the final rule does not allow foreign suppliers to perform verification activities of themselves because of the potential for a conflict of interest (codified in § 1.506(e)(2)(ii))." (*See* 80 Fed. Reg. 74283, column 1)

A. #2: As discussed in the above response, it would be expected that at the oversight level of preparing the food safety plan at the foreign manufacturer as well as then developing and completing foreign supplier verification in the U.S. that those individuals would not be the same. Moreover, while the regulation and preamble is silent on when there is common ownership; a "best practice" for this would be that these individuals do not report directly to the same person. In fact, the more reporting levels between the QI in the U.S. and the PCQI at the manufacturing site the better – even if several levels up, they report to the same "Global V.P." for example. It is expected that this will be addressed in the FSVP training module available at a later date.

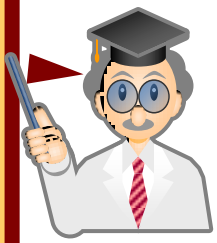
Scope of Application to Agricultural Cooperatives

Q7

1. Please explain the important points relating to application of regulations to agricultural cooperatives.
2. In calculating annual sales, should sales of individual cooperative members' farms be included when to determine whether the business is "small business" or "very small business" or other business?

A．#1: "Agricultural cooperatives," while not defined in the regulations, are discussed in the preamble to the Produce rule (See 80 Fed. Reg. 74396, column 3) in discussion of the definition of "farm" and that it should reflect "modern business models" as it was revised to in 21 C.F.R. § 1.227. Moreover, in the "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry;" question B.2.7 (page 14) that discusses the revised "retail food establishment" definition indicates that FDA recognizes that "some farms are *members of cooperatives* that pool RACs grown, harvested, or raised by member farms for value-added processing. The phrase "one or more farms" in the explanation of the meaning of "farm-operated business" allows cooperatives comprised of multiple farms performing certain manufacturing/processing activities to be eligible for the *retail food establishment exemption* from registration. (See Comment 9 in the Registration Final Rule, 81 Fed. Reg. 45921, column 2). It is important to understand what the "cooperative" is doing with regards to sales to make a determination as to whether or not it is exempt from registration and therefore many aspects of FSMA or if it must register and would then be subject to compliance with many of the FSMA regulations such as PCHF.

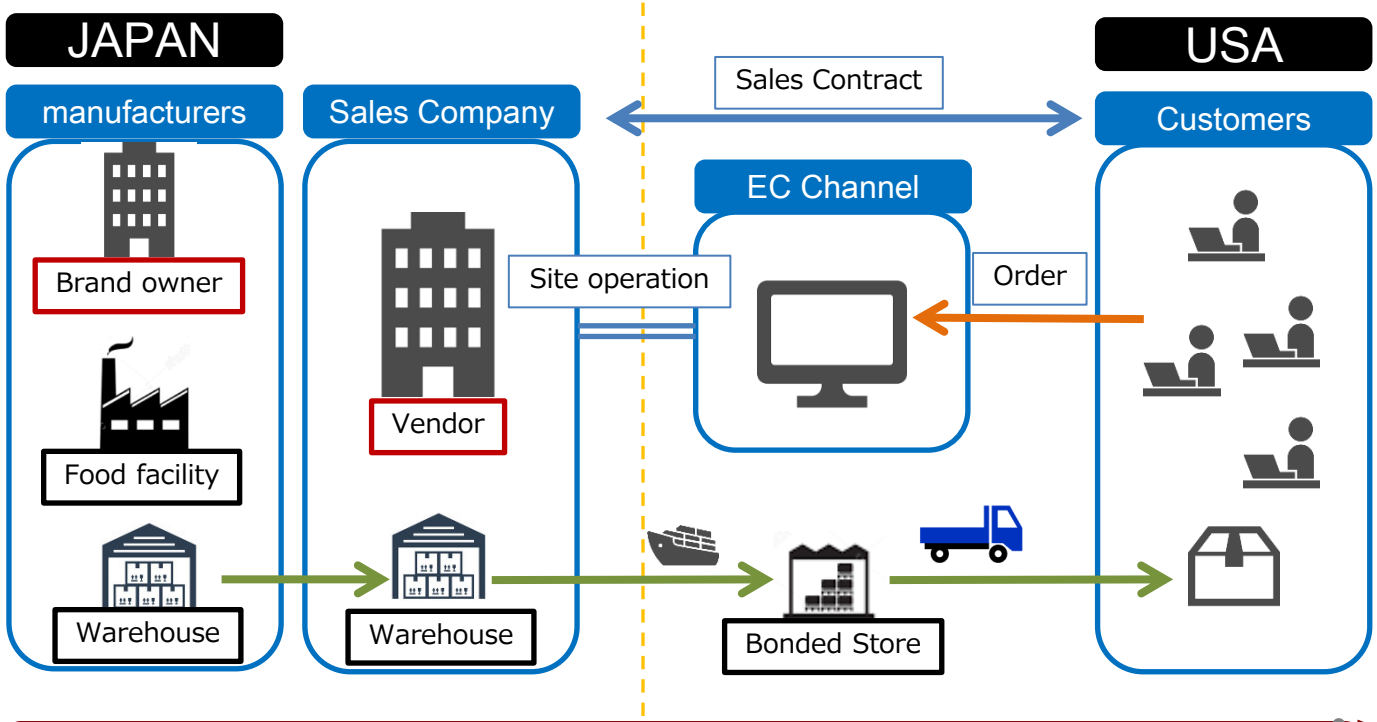
A. #2: Whether or not sales of individual farms should be considered will be determined on how the cooperative is set up. A cooperative generally is considered as "pooling" their products. If the cooperative meets the definition of a "farm" or a "retail food establishment," they would be exempt from registration regardless of size. Even if not exempt, a determination would need to be made of how the cooperative is set up to determine what is part of sales.



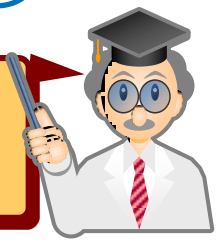
Cross-border EC Transaction

Q8

Questions on online e-commerce transaction(Cross-border EC)
1. Is any facility registration required?
2. How is FSMA to be applied?
3. Is there any condition or category for application of FSMA? Please explain.



A. See next slides.



Cross-border EC Transaction

A. #1: The need for registration of any of the facilities "depends" on if an exemption applies. Beginning on who the final product sales are to – it would appear that the food facility and its warehouse, the independent warehouse, and the bonded store would require registration as you indicate that the internet sales are to "customers." FDA uses the term "customers" to refer to sales to businesses as compared to sales to "consumers." (*See* 62 Fed. Reg. 58913, column 3, comment 76). If the manufacturer meets the definition of "retail food establishment" – meaning its primary function is to sell food directly to consumers, it would be exempt from registration. If its warehouse was co-located with and part of the "retail food establishment," it also would be exempt from registration. (21 C.F.R. §§ 1.226(c) and 1.227). As it appears that the warehouse for the vendor is separate, it would be required to register whether or not sales were to customers or consumers as would the bonded store.

Cross-border EC Transaction

- A. #2: Whether or not any of the regulations implementing FSMA apply will depend on if an entity must register with the FDA. If sales are directly to consumers and the entity is considered a "retail food establishment," there would be no regulatory requirement related to FSMA. At minimum, it appears that at least the vendor warehouse and the bonded warehouse would need to be registered and that CGMPs would apply and possibly modified PCHF requirements depending on the products being stored. Moreover, the importer of record ("customer") would need to comply with FSVP if "customer" is not a consumer.
- A. #3: With regards to FSMA application; if a facility or warehouse is required to register, it would need to meet applicable parts of the PCHF. If "customer" is not a consumer; the importer would need to comply with FSVP in the U.S.

Foreign Supplier Verification Program and Confidentiality

Q9

We do not wish to disclose our food safety plan, as it contains some of our confidential information.

On the other hand, in order to comply with FSVP for importers, we may be required to submit and disclose such plan.

Considering the requirements of FSVP and the protection of the company trade secrets, do we really have to disclose such information or, what kind of information may we provide to importers, or what measures should be taken for this case ? Please advise.

A. FDA has made clear in responses to comments regarding concerns with importers requesting what may be confidential information from foreign suppliers that "How foreign suppliers and importers choose to handle the issues surrounding the sharing of any confidential information with each other is between those parties. While we recognize that there might be some suppliers who are reluctant to provide information relevant to the kind of verification activities required by this rule, we believe that many suppliers will agree to such activities in order to facilitate the exportation of their products to the United States and access new customers. (*See* FSVP Final Rule preamble, 80 Fed. Reg. 74275, column 3)

If information to be shared is confidential or trade secret, those documents should be marked as such and the importers should be made aware of what information provided is considered confidential or trade secret. It will be up to each foreign supplier to make its own decision on whether or not requests for certain information that an importer has deemed necessary will be provided – as it will be up to the importer of record in the U.S. to determine what information they must receive to determine if a food is "safe" for import.