Questions and Answers from
Foreign Supplier Verification Program

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Questions:

1. **Q: So is seafood still subject to the same rules as before?**
   A: Correct. Seafood will still be subject to the Seafood HACCP. The importer will have to 1) review such HACCP Plan for completeness, 2) review the compliance history of the supplier, and 3) undertake the appropriate verification activities and frequencies to assure compliance by the foreign supplier.
2. **Q: What about further processing? What is the definition of this exception?**
   A: If the question is related to the definition of a foreign supplier, then "further processing" implies that the supplier is that entity which ships a product that will not underdo any other processing by another entity before it is exported. The only exception is the "minimis" kind of additional handling such as labeling for retail at a later stage. That is allowed since such activity will not change or alter the product.
3. **Q: What about cans and acidified foods? Are those exempt?**
   A: These products are not exempt from the FSVP. The importer is not required to undertake a hazard analysis related to biological hazards since manufacturers of such products have already done so to satisfy existing regulations applicable to such products. What the importer has to do is make sure such facilities have also addressed chemical, physical hazards as well.
4. **Q: If a grain such as wheat, canola, beans, peas, lentils, soybeans are shipped into the US for further processing (cleaning, packaging) is it exempt?**
   A: Under Subpart B – Hazard Analysis and Risk-Based Preventive Controls, of Part 117 – Current Good Manufacturing Practices, Hazard Analysis and Risk-Based preventive Control for Human Food , raw agricultural commodities such as cocoa beans, coffee beans, and grains are exempt if you determine and document that the type of food could not be consumed without an appropriate control. Since the FSVP is the equivalent of the Subpart B for domestically sourced materials, I would think that such exemption applies to imported commodities sited in your question. After all, we do not grow cocoa nor coffee in the USA.

5. **Q: Are suppliers from foreign suppliers expected to follow HARPC or FSMA as well? We are exported to the U.S… Are our suppliers expected to be HARPC compliant as well?**
   A: All foreign supplier are subject to FSMA. HARPC is one of the rules under FSMA. The importer in the US is responsible to assure that their foreign suppliers have undertaken a HARPC analysis in order to establish if there are "hazards needing a preventive control" and if so who will control such hazard, the foreign supplier, the local supplier to the foreign supplier, or the importer. In short, the importer is responsible for assuring that all foreign supplier have undertaken a HARPC analysis to define want preventive controls will be applied and by who in the food supply chain. The importer is also responsible for reviewing the compliance history of its foreign supplier in order to approve or disapprove supplier.
6. **Q: What is the difference between HARPC and HACCP?**
   A: HACCP is a voluntary food safety approach based on the Codes Alimentarius. It is recognized and used worldwide. HARPC is a regulation of the US, applicable to all manufactured food products and food contact substances consumed or used in the US, regardless of the origin of such food products and substances. HARPC and HACCP have some aspects which are identical, others which are similar and other which are unique to HARPC, which are additional to HACCP.
7. **Q: Hazard Analysis exceptions? – What about frozen vegetables?**
   A: Frozen vegetable are considered a processed food and would be subject to hazard analysis as per HARPC.
8. **Q: If my supplier is SQF certified, does it comply with the FSVP?**
   A: Yes, as long as the SQF scheme addresses all the requirements of FSMA, and the auditor is a "qualified auditor". It would to wise to address this question with your certification body and obtain such assurance in writing.
9. **Q: Do you have hazard analysis guidelines fix for fresh fruits and juices or how to conduct?**
   A: Fresh fruits to be consumed as such, as "raw agricultural commodities" such as a mango, banana, strawberry, blueberries, etc., are subject to the Produce Rule of FSMA. Juices are subject to the regulated HACCP for juice and juice pulp. The guidelines for the Juice HACCP can be obtained from the FDA. The guidelines for the Produce Rule are being developed by the FDA.
10. **Q: Can a questionnaire be sent that covers food safety issues to answer food safety issues to answer and return for evaluation?**
    A: AIB has developed a FSMA Readiness Assessment consultative template to be used to assess the HARPC rule and the FSVP rule. A person knowledgeable with these two rules such be able to apply such assessments and identify needed improvements, in order to meet the requirements of these 2 regulations.
11. **Q: Do U.S. importers need to go and do facility audit?**
    A: The audit can be done by the importer, or the importer can rely on an audit done by a third party. Regardless of who does it, the auditor must be a qualified auditor as defined in the rule. If the importer relies on a third party for the audit, the importer must review the results of the audit, assess the outcome make decisions and sign the review.
12. **Q: Whether I as a third party auditor in my country could help clients? I meet the FSMA reg by audit services or only FDA auditor can do this?**
    A: Yes, a third party auditor can carry out the audit of a foreign supplier as long as the auditor is a "qualified auditor" and the importer assesses the results of the audit and signs off on them. If a FDA audit happens within 12 months of when the private audit was supposed to happen, such FDA audit can substitute for the private audit.
13. **Q: Are there some third party companies certified to do this risk based hazardous analysis? Some third party companies to do risk based hazard analysis for importers?**
    A: The answer is yes. However, the rule does not require that the person doing the risk analysis or doing the audit of the food safety plan of the foreign supplier be "certified". The rule requires that such professional be a "qualified individual". If such a professional works for a certification body doing work in food safety, such professional could demonstrate his/her qualifications based on his/her training and experience.
14. **Q: If a supplier is on an import alert "green list" such as soft cheese from France, can that serve as proof of a supplier evaluation and that the supplier is compliant?**
    A: My thoughts on this is that the "green list" applies only to the product and not the supplier of such product, the foreign supplier would still be subject to the FSVP. This is a question worth sending directly to the FDA.
15. **Q: What is the difference between FSVP and VQIP?**

A: The FSVP applies to all imports of food products, raw materials, ingredients and food contact substances. The Voluntary Qualified Importer Program (VQIP) is a program that importers can "voluntarily" participate to mainly make it easier and faster the import process. In order to participate the importer would have to apply, pay an annual fee and have its foreign supplier "certified" under FSMA/FDA.

16. **Q: We have A LOT of suppliers. We will need to utilize third party auditors in some cases. What auditing companies are approved by the FDA?**
    A: I have a lot of empathy for you. As already indicated in other answers the use of third party auditors is fine as long as such professionals are "qualified" as defined in the rule. FDA does not approved such companies, except for the Voluntary Qualified Importer Program (VQIP), which has not yet been finalized.
17. **Q: Does FSVP apply to food contacts substances (resins, films, flexible plastic packaging?)**
    A: Yes. Under the FSVP the definition of food in the FD&C Act includes such substances.
18. **Q: Are GFSI recognized scheme comply on the requirements of FSMA?**
    A: I am sure all of them will comply with FSMA requirements, otherwise their value will be diminished. Make sure your certification body provides you written evidence how its scheme meets all applicable FSMA requirements.
19. **Q: If Radiological and EMA is added to my HACCP plan, will that suffice as a HARPC/HACCP plan?**
    A: The short answer is no. HARPC requires a few more items such as the documentation of the "knowing or reasonable foreseeable hazard", that is the scientific evidence, identification of who will control the hazard in the food chain, transport practices, environmental hazard analysis for RTE foods as defined in the rule, cross contact controls for allergen, and supplier compliance history valuation. A good way to find out what more is needed beyond your current HACCP food safety plan is to undertake a FSMA Readiness Assessment as discussed before.
20. **Q: What about the qualification of the people doing the verification? Do they need official training? Any kind of approval?** Could it be done by a food consultant? He/She needs to be from the USA? And if the foreign food embellishment is already approved by the USA authorities, is verification still necessary?
    A: Great many questions. The Preventive Controls Rule for Human Food contains a definition about "Qualified Individual". This definition states that each employee must be qualified to undertake his/her duties to assure the production of safe food. So each position needs to be evaluated and personnel trained accordingly. This applies to line personnel, supervisory personnel and to the Preventive Controls Qualified Individual (PCQI) who will be responsible for the development, implementation, management and reanalysis of the plan. The PCQI does not have to be an employee of the plant, does not have to be from the USA. Verification will still be necessary since this is an internal requirement of the foreign supplier to demonstrate the Food Safety Plan is being carried out as designed and is effective.
21. **Q: If I attended such a session then will I be certified or qualified? (I think this was right after the polling question wanting qualified professional as the answer)**
    A: FSMA does not apply the "certified" criteria but is does the "qualified individual". As per such definition, and employee will be considered qualified for his/her position when the appropriate training and experience can be demonstrated. The training qualifications will depend on the position of the employee, such as line personnel, supervisory positions and the PCQI. One way of getting the training qualifications is to be trained for the specific food safety competencies required for a given position. This applies to line positions and supervisory roles. For the PCQI you can opt to take the FSPCA/FDA course or show proof that you have taken training from other sources which is equivalent. As to the experience, this depends of your accumulated experience throughout your career.
22. **Q: Would this be handled differently if the importer is also a food manufacturer in the US?**
    A: No. In this case the food manufacturer would be the importer and would have to establish and manage a written FSVP.
23. **Q: Can electronic records just be scanned copies?**
    A: You can scan a printed record and submit it as a true copy. You can print an electronic record and submit it.
24. **Q: What about packaging that your product goes in? Do these rules apply?**
    A: As discussed earlier, food contact substances are included in the FSVP and must be subject to the hazard analysis.

25. **Q: Do original records need to be sent to importer by the manufacturer?**
    A: No. However, true copies of such records must be made available for verification activities such as record reviews. Or, the importer must have access electronically to such records. For example, the importer has to review the Food Safety Plan of his foreign supplier. Such plan can be submitted electronically, or electronically to the importer for review and assessment. Or it can be reviewed by a third party, however the importer must assess the results of such review and document such activity.
26. **Q: Are English translations required to be done by qualified parties? Can the company do it on their own?**
    A: The rule does not state that translation have to be done by "qualified parties".
27. **Q: So the unique ID is the ID of the importer? Including the number of the consignee, agent? Is this then equivalent of the license that was used to import the product? Still trying to understand how the importer is determined. Also assume it is based on each entry at port?**
    A: The importer can the 1) the owner of the product (the person who bought the product for import into the USA), 2) the consignee (he person who will be officially receiving the imported product in the USA), or 3) the agent of the foreign supplier in the US who is legally representing the foreign supplier. By unique number it is implied that such ID is related to a specific person/location where the product can be traced to. I would suggest you ask the FDA whether the import license can be such specific ID
28. **Q: If you import from exporters thank pack fruit/vegetables, you must check all growers? (Could be hundreds), or rely on gap certifications obtained by the exporters for their operations? The definition could be interpreted several ways.**
    A: As an importer you would have done a HARPC or requested such analysis from your foreign supplier for review and assessment. In it your supplier will have identified the hazards needing preventive controls. Assuming, we are talking about "produce" (fruits and vegetables to be eating in their raw state), then the growers of your foreign supplier are subject to the produce rule. You, as an importer will need to verify that your supplier is verifying compliance with the produce rule by all his local suppliers. GAP certifications, as long as they contain all the requirements of the Produce Rule would be an acceptable verification activity.
29. **Q: Does radiological and EMA risk assessment added to my current HACCP program suffice?**
    A: This questions was answered previously.
30. **Q: We import maca that is processed they sent to us in powdered form, is this under the produce safety?**
    A: From your description, I understand that you are importing a "processed" form of maca. In other words, the roots are harvested, selected, cleaned, dried, and milled to obtain the right powdered consistency, and then packed for shipment. If m description is correct, then it would not fall under the produce rule which applies to raw agricultural commodities which are consumed in their raw state. Your supplier should be subject to the FSVP, and the farms supplying the raw maca should be applying gaps. Finally, I do have a question. Are you selling the maca product as a food, or as a food supplement? If it is considered a food supplement it would be subject to the appropriate regulations for such food supplements.
31. **Q: If there is a food product produced in the US, exported and then turned around without extra process…does it need to go through the same FSV program?**
    A: No, as long as you document the reasons why the product is being returned to you in the US and you provide auditable and verifiable written information, which demonstrates that the product did not undergo any changes.
32. **Q: Our supplier is organic certified, does this help?**
    A: No. Organic is not a criteria covered under FSMA.