2016 SQF Conference
Session Questions and Answers

The Best Defense Is a Good Defense: Risk, Readiness and Resiliency in Protecting the Food Supply

By Jeff Moore, Director of Science, United States Pharmacopeial Convention
Tuesday, October 25, 4:15PM – 5:15PM

Could your recommend some recall coordination best practices.

I would review the U.S. FDAs recommendations for conducting recalls, but be sure to include a mock recall for an INTENTIONAL event as these are handled somewhat differently than an unintentional event.

Would you recommend physically detaining suspicious persons until law enforcement arrives?

No, I would not recommend physically detaining a suspicious person. I do recommend getting a very good description of the person, the type of vehicle they may be operating and the direction of travel that they embark. Be sure to provide this information to your local police security personnel immediately.

You profile certain races as terrorist in your slides while in every race there are terrorists. I condemn terrorism in any form.

Thank you for your observation. Race and ethnicity is not a factor in identifying potential terrorist as terrorist and criminals come in all shapes colors and sizes. Behaviors and actions are factors, as this has been demonstrated over the course of history.

LTL(less-than-truckload) loads generally do not have a seal because they stop at multiple locations, is there something that can be put into place to counter this?

Excellent question. LTL's are difficult to protect. My recommendation for years to this issue is to at least require the driver of the LTL to use a padlock in between stops to secure his/her load.

Is the BARED listing covered by the fair credit reporting act?

No! There is no "credit information" associated with the Barred listing thus, it is not covered or regulated by the FCRA Fair Credit Reporting Act.

How do you suggest ensuring only authorized personnel have access to particular areas for a facility with limited access control?

Create what I call, RED ZONES! These areas should be well sectioned off from other parts of the plant and signage clearly indicating that the area is off limits to all unauthorized persons.

Piracy and counterfeiting is a growing concern for food companies in the US and around the world. What can companies do to combat these growing threats?

I would utilize the services of a Food Defense / Food Fraud expert to do an assessment of the areas your products are most likely to be targeted for this type of crime. Next, the food defense expert should follow up to make sure the holes are plugged making it difficult for someone to carry this out.

Is the food defense vulnerability assessment a confidential document or can it be reviewed by an auditor?

The document should be considered confidential, and only those that have a qualified reason to review it should be allowed. Be sure to keep a record of every person who reviews your plan and assessment in case needed for latent investigation.

Is a mock food defense exercise required as part of the US Food Safety Modernization Act (FSMA)? Will it also be required in the new SQF Code?

No. A mock food defense exercise is not a required part of FSMA however it is a good idea to conduct such an exercise. It is important that all elements of your program and plan are tested in advance to insure they will work when needed.

What's your opinion of FDAs Food Defense Plan builder software?

The FDA Food Defense Plan builder is not a bad tool to use. Plus, it's free! It is a good product for a facility that may not have the resources to hire a professional to come in and write a food defense plan for them.

Would you agree that Customs–Trade Partnership Against Terrorism (CTPAT) is strong program for the supply chain? If not, where do you see opportunities for improvement?

I concur that CTPAT is a strong program! Actually, CTPAT provided the framework by which the Food Defense elements of the US Food Safety Modernization Act were built. I've been involved with CTPAT since its inception and it has always been one of my favorite government programs.

What is a best practice to manage multiple vendors who are in your facility daily/weekly when you do not have the manpower to escort?

It's a good idea to use a badge-type system. The vendor/contractor should be required to wear this badge visibly the entire time while at your facility. The badge should contain his/her name, company name and photo.

Do you recommend any tools for vulnerability assembly?

There are several tools available to use to conduct assessments. The US FDA actually has some "freebees" on its website that can help you with your assessment. I suggest looking around before deciding on which tool to use as some are better than others.

Best Practices for a Supplier Approval Program for Foreign Supplier Verification Program (FSVP) and SQF Compliance

By Jennifer L. McCreary, Technical Manager Training and Education Services, NSF International

Wednesday, October 26, 10:00 AM – 11:00 AM

Is HACCP training and being an experienced SQF practitioner sufficient to meet the PCQI requirement of the US Food Safety Modernization Act?

The definition of a Preventive Controls Qualified Individual (PCQI) is a qualified individual who has successfully completed training in the development and application of risk based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Can you provide some details on radiological risks and what are the expectations?

Please check out the US FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food.

I am a flavor manufacturer and most of my ingredients are "chemical single molecules" or essential oils produced by chemical manufacturers in Asia or India. They are most often ISO certified but don't have food safety program. Does FSVP apply to me? If yes, how do you recommend I implement an FSVP?

If the chemicals meet the definition of food, you will need to implement an FSVP program. Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u).

Are there any exemptions to the Foreign Supplier Verification Program?

There are a number of exemptions for FSVP. You can find out full details in the FSVP Final Rule. Some exemptions include if you are not the US importer or consignee; you only import any of the following: Certain fish and fish products, juice products, food for research or evaluation, certain alcoholic beverages, certain meat poultry and egg products; food for personal consumption; food that is transshipped; food that is imported for processing and export; dietary supplements; you are a very small importer; or you import food from a country with a recognized or equivalent food safety system.

Next year, under the Safe Food for Canadians Act, will all foods be required to comply (i.e. maple syrup)?

Yes - the following is copied from the Safe Food for Canadians Act: "It is expected that, where applicable, food businesses involved in the following activities would need to obtain a license: importing food; manufacturing, processing, treating, preserving, grading, packaging, or labelling food for export or trade across provinces; exporting food that requires an export certificate—even if you are not involved in its preparation; slaughtering food animals where the meat product is exported or traded across provinces; or storing and handling a meat product in its imported condition, if a further inspection is needed."

Can or will third party audit (e.g. an SQF audit) be accepted as a supplier verification audit instead of sending an employee abroad?

Definitely-this is one of the advantages of requiring that your foreign suppliers are SQF (or any other benchmarked GFSI scheme) certified.

In your presentation you mentioned that FSVP does not apply if company only imports "certain fish and fish products" and "certain alcoholic beverages." Please provide the specific products within these two categories that FSVP applies for.

Answer copied from FSVP Rule Exemption for alcoholic beverages. (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions: (i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and (ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

Is the date of VQIP enforcement still 2016 or has this been moved to 2018?

VQIP (Voluntary Qualified Importer Program) is a voluntary program and there is no deadline for implementation.

Can we accept verification audits conducted by our suppliers' customers on the supplier?

You might be able to accept this as a verification audit but you will need to do some confirmations first. You will need to ensure that the auditor conducting the audit is qualified as defined by FSMA. As well, some items to consider: will you supplier release the full report of the audit so that you can ensure that the process/product that you are purchasing is included in the audit - the scope of the audit, i.e. is it looking at regulatory compliance or just Good Manufacturing Practices (GMPs).

If I receive product samples from foreign companies do I need to be registered with the FDA?

You may be exempt if you fit the following. Text copied from FSVP Rule Exemption for food imported for research or evaluation. This subpart does not apply to food that is imported for research or evaluation use, provided that such food: (1) Is not intended for retail sale and is not sold or distributed to the public; (2) Is labeled with the statement "Food for research or evaluation use"; (3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and (4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

I heard that FSVP applies to primary packaging-is this true?

Yes, please see answer to FSVP and packaging above.

With the requirement of registering every food facility through the FDA, how is this verified? And, that each location has been registered and is current?

Text copied from FSVP Rule (if the item does not meet the following, it will not be allowed into the US). How must the importer be identified at entry? (a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection. (b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of "importer" in § 1.500.

Are you aware of food manufacturers offering training to their foreign suppliers to learn their new obligations under FSVP?

I am not aware of food manufacturers who are offering this training, but many foreign suppliers are taking the FSPCA Preventive Controls Rule (PCQI) training. Many of these courses are being offered in the US and elsewhere. If you are looking for a course, please check out www.nsflearn.org, or the FSPCA website lists training courses that are publicly available.

What is our obligation to FDA regarding notification if a pathogen is found in a container of imported ingredients? What is the responsibility of FDA, the importer and the broker to assure the ingredients are destroyed and that there is follow-up with import supplier.

Finding a pathogen in a container of imported ingredients falls under the Reportable Food Registry. C.1 Who is the "responsible party" that must submit a report regarding instances of reportable food to FDA through the Reportable Food electronic portal? The responsible party is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. Persons who are required to submit a facility registration under section 415 of the FD&C Act are the owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. "Person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations.
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm212793.htm

Can we accept a third party Food Safety certification from a foreign supplier that exports into the US?

Yes. You will want to ensure that the third party auditor conducting the audit is qualified, as defined by FSMA. In addition, confirm that the site where the audit is conducted is the site where your product is being sourced from and the audit covers both record review and that audit observations address the hazards that may be associated with the product.

If foreign raw materials are received through a broker, is the broker responsible for foreign supplier approval?

Under the FSVP Rule, the importer is defined as the U.S. owner or consignee of the food offered for import (i.e., owns the food, has purchased it, or has agreed in writing to purchase it). The definition of importer for FSMA/FSVP differs from the definition used by the CBP (Customs and Border Protection). If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent/representative of the foreign

owner/consignee, as confirmed in a signed statement of consent. The key is that there be a FSVP importer in the United States who takes responsibility for meeting the FSVP requirements. By specifying the U.S. owner or consignee, the definition helps to ensure that the person responsible for meeting the FSVP requirements has a financial interest in the food and has knowledge and control over the food's supply chain. The ''U.S. owner or consignee'' of a food, as we have defined the term, is more likely to have knowledge of food safety practices and control over the supply chain of an imported food than a customs broker, who often is the importer of record of a food for CBP purposes. However, a manufacturer who already has supplier controls in place as part of the Preventive Controls Rule does not have to duplicate their program.

You mention a very small importer is defined as one with $1 million in sales or $2.5 million in sales for feed. Is the amount for imported food only or company-wide sales?

Taken from FSVP Rule: Very small importer means: (1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and (2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

How should we determine a foreign supplier's risk if they have never conducted a mock recall?

For a company that has never conducted a mock recall, I suggest that you can examine whether they have a system in place that would permit them to carry out the recall in a timely fashion, i.e. do they have key contacts for customers in the event they need to contact you, do they have a recall team in place and does the recall team know their role, do they track product codes and know which customer received which code. Even if they have never conducted a mock recall you will want to ensure that they are able to connect with you quickly in the event that there is a problem with any ingredient that they supply to you.

What is an acceptable importer identification at entry? Is there a list?

Copied from FSVP Rule: 1.509 How must the importer be identified at entry? (a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection. (b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of ''importer'' in § 1.500.

Where can I find a food safety risk assessment by country? Does the FDA or CFIA have it? Is it accessible?

Both FDA and CFIA track food recalls which can be used as part of the food safety risk assessment. As well in the presentation you will find a European website which lists product detentions. I am not aware of a food safety risk assessment tool.

If you are buying vitamins or minerals here in the US, but the supplier obtains them from another country, which country of origin should be used?

Sorry I am not a labeling expert and not qualified to answer this question.
SQFI: FDA's Technical Assistance Network (TAN) provides technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN addresses questions related to the FSMA rules, programs, and implementation strategies after the rules are final. The TAN is available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm498163.htm

What should we do if we find out that our foreign raw material food contact substance (FCS) supplier does not have a food safety plan?

As the importer, it will be your responsibility to conduct a hazard analysis to determine what hazards are likely with the FCS. You may determine that there are no hazards of significant risk or your facility has internal processes in place to control all the hazards.

Using the rice example, how would a US company find out if a company is using the exhaust from trucks to dry the rice?

In the case of the rice, it was a supplier's supplier. As part of your supplier approval program, you should ask how they approve their own suppliers.

How do you assess the risk of radiological hazards for a foreign supplier?

This is something that you could include as part of your supplier questionnaire.

Is the FSVP applicable for my chemical supplier? Do I need to control the company that provides my hand soap, for example?

For the purposes of FSVP, it refers to food. Food has the meaning given in section 201(f) of the Federal, Food, Drug and Cosmetic Act, except that food does not include pesticides. Your chemical supplier for hand soap is exempt from FSVP, but is still considered a supplier by SQF so will need to be approved.

Is a scorecard to the foreign supplier required by FSVP?

No, it can be useful as part of an ongoing supplier verification program but it is not required.

Why are Food Contact Substances such as the raw material (resin) used to manufacture food packaging considered "food?"

Copied from FSVP Rule Comment/Response 5: The term "food" is defined in section 201(f)(3) of the FD&C Act to include articles used as components of food, and the case law interpreting the definition makes clear that many substances that meet the definition of food contact substances under section 409(h)(6) of the FD&C Act also meet the definition of food (see, e.g., Natick Paperboard v. Weinberger, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food); U.S. v. Articles of Food 688 Cases of Pottery (Cathy Rose), 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food)). You will need to confirm with FDA but I believe that they have included the raw material to ensure that there is nothing in the components of the raw material which will do harm if it comes into contact with food.

Will Canada's food safety regulations be recognized to the same standards as in the US to avoid the need to audit them?

May 4, 2016 (copied from FDA Constituent Update) The U.S. Food and Drug Administration (FDA) signed an arrangement with the Canadian Food Inspection Agency (CFIA) and the Department of Health Canada (Health Canada) recognizing each other's food safety systems as comparable to each other. The arrangement was signed at a meeting of the FDA-CFIA Health Canada Joint Committee on Food Safety. This is the second time that the FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012. A similar system recognition process is underway between FDA and Australia and the European Commission.

If you are buying an ingredient from a supplier who has their sales office in the US but with manufacturing facilities overseas, how is that handled? Do we have to audit the overseas plant or would the supplier be responsible for conducting internal audits for compliance? Would this supplier fall under a foreign supplier or treated as a broker as they are directly importing the product and selling it to us.

Please see the answer to question 1 above. It depends on who is the owner of the ingredient when it reaches the US.

Does FSVP apply to imported food packaging?

FSVP does apply to imported packaging. The following is taken from the FSVP Final Rule comment section (6): FSVP applies to food and the term ''food'' is defined in section 201(f)(3) of the FD&C Act to include articles used as components of food, and the case law interpreting the definition makes clear that many substances that meet the definition of food contact substances under section 409(h)(6) of the FD&C Act also meet the definition of food.

As an importer, can we accept our supplier's HACCP plan to satisfy the hazard analysis requirement of the FSVP? If they don't have one who should conduct it?

Yes you can accept your supplier's HACCP plan, but you should confirm that it is an effective program, i.e. is the team qualified who developed it, did they conduct a thorough hazard analysis, are the CCPs well managed, etc. If they do not have a HACCP plan and you require one, it is the supplier who needs to conduct it since the individual(s) conducting the hazard analysis must be familiar with the facility and the process.

Are manufacturing companies who purchase items from a broker responsible for verifying they have a FSVP program on items we purchase from them?

Please see the answer to question 1 above. I suggest confirming that the broker has a FSVP for the item you are importing. Otherwise, the item may be detained or rejected at the border the next time it arrives and this has the potential to disrupt your production schedule.

How is FDA approaching foreign supplier approval?

FDA will be overseeing any FDA regulated food products being imported into the US to ensure that they are in compliance with FSVP and FDA now has the authority to detain or deny entry to any FDA product not in compliance.

How do we know what contaminants to look for?

FDA has published a draft guidance document on Hazard Analysis and Risk Based Preventive Controls for Human Food and chapter 3 has information on potential hazards. As well FSPCA (Food Safety Preventive Controls Alliance) has several references on their website.

What is a supplier external to the US's role with meeting FSVP requirements? Or is this the US importer's responsibility?

While it is the US importers responsibility to ensure that they are meeting FSVP requirements, it is good business practice for a foreign supplier to cooperate by providing the necessary documentation and if necessary, allowing access to their facility, to demonstrate that the foreign supplier is operating under GMPs and a food safety management system e.g. SQF, which demonstrates that the foreign supplier is producing under conditions equivalent to product produced domestically in the US.

A Recall Plan: Be Prepared or Be Sorry

By Roger Roeth, Executive Technical Officer, EAGLE Certification Group
Wednesday, October 26, 11:00AM – 12:00PM

If you are SQF level 3 certified, do you need to notify SQF when having a quality recall?

No. As per SQF Code, Part A section 5.3, notification of the certification body and SQFI is only required for food safety events that require public notification, such as class 1 and 2 recalls in the US.

How to you decide if there's a risk enough for recall for physical hazards? For example, a thin metal wire (25mm ss metal) that is hard for a metal detector to detect.

The FDA has standards defined as 7 mm to 25 mm. I would base the decision for a recall on your specific hazards for metal. It may be tighter than what is required by the FDA standard and if it is, that is what you should base it off of.

If you are certified to the SQF Code at level 3 and have quality recall, are you are mandated to let SQFI know. Please clarify.

No it is only required for food safety events that require public notification such as class 1 and 2. See section 5.3 of Part A in the SQF Code.

Is there a difference between food service and retail related to recall?

Food service is generally easier as you rely on the food service customer to return the suspect product. If it is retail, then the product could have gone out into the consumer's home and that adds another entire level of risk and communication.

With a mock recall, is there a standard for scoring the effectiveness of the exercise?

There is no standard or any requirements in the SQF Code. It is common for the customer to identify targets. The two main targets often used are percent recovery and the time it took to complete.

When doing a mock recall, how do we capture and record product recovery and effectiveness of recovery? In other words how far do your take the mock exercise?

There are many ways to document the mock recall. Many use a checklist, which I feel is best practice. The checklist lists each step that you have defined in your recall process. Key information to collect for a mock recall is percent recovery, time it took to complete the trace, the customers and external parties communicated with, the destination of the affected product, a recall team sign in sheet and any associated documents records from the trace exercise.

Please expand on your thoughts regarding communication with an external lab. Who at the lab would confirm a pathogen and verify a finding?

I would confirm with the lab, if possible, prior to initiating a recall based on your test results. If it is regulatory test results, it is assumed their results are acceptable and you probably will not have the opportunity to contact them.

What is the best source or template for a mock recall checklist and mock recall letters.

You may create mock letters using the information you have received from your customer. For a regulatory letter, look at other companies' letters, as they are posted whenever there is a recall. Also, a template may be available on the USDA site. My suggestion is to create a checklist template using your own recall procedure and flow chart.

What is the proper method of FDA notification: calling the recall coordinator or a Reportable Food Registry report through the safety portal?

You should do both.

Does a recall mean losing SQF certification? Is it the same for voluntary withdrawal?

Communication between the site and the certification body (CB) is very important during a recall. The CB may ask the site to provide evidence that the recall is being addressed and corrective action in place. Ultimately, the decision is up to the certification body. A lot of information and discussion goes into this type of decision. If your situation has involved a death or is a repeat of a previous issue, or there is no evidence that the site is reacting to the situation, then your certificate may be withdrawn, but again it is a decision of the CB.

Do you have tips for working with retailers to gather their inventory information in order to ensure accurate product destruction recovery status?

Identify the right person to contact at the retailer. If they are close to your facility, send an employee over to observe and work with them. Developing partnerships up front with your customers goes a long way to making this part of the process go smoothly.

Are we required to have a different scenario for each annual mock recall? Can you do a mock recall for metal each time?

Base your scenarios on what your actual hazards are. If metal is your only hazard, then yes, you can do only mock recalls for metal, but if you also have allergen hazards and pathogen hazards, you need to also practice those scenarios.

Why would a multiple shift company not have trace and mock recall practices on late shifts? Recalls don't sleep.

I agree. Most recalls happen late Friday afternoon so that is when I usually did my unannounced mock exercise. That is why it is important to have your plant contact information current and also have backups identified for each position on the recall team.

If the site does not conduct a tracing exercise as required by 2.6.2.1, what will be consequences during the re-certification audit?

This is typically assessed as a minor non-conformity.

In your presentation, you suggested the site should practice a mock recall based on the phone call from the supplier that the ingredient may undergo a recall within the next 48 hours - did you mean notification within 24 hours of indication of recall possibility notification of FDA that recall will be issued or recall notice issued?

Notification that you have decided to do a voluntary recall.

What measures should be taken when it comes to microbial and spoilage organisms testing to prevent a possible outbreak?

The only advice I will state here is to develop a testing program to be aggressive and to try to actually find those areas which could be a potential hiding place for your pathogen of concern. If you are aggressive in the number of samples taken and locations then you can find and eliminate it from your operation.

How much notice should you give your recall team? Should the mock recall be scheduled in advance or is a surprise drill the better route to take?

The best practice would be to do both. The sites I have visited that want to have the process down perfectly perform both during the year. The first one is typically announced, after which they review their performance, then the next exercise can be unannounced and hopefully address those issues identified in the announced recall.

Is public notification required for class 2 or 3 or just class 1?

The SQF Code requires notification for a food safety event that requires public notification. In the US, this is most typically class 1 or 2 recalls.

To prove that the site has tested the full recall and traceability program during the mock recall, what do auditors look for beyond evidence of a trace exercise?

As an auditor, I look for any evidence that might support that you performed all the steps in your recall plan. For example, did you identify who you had to contact and did you create any mock communication to them (e-mail, notification letter)? Was there a sign-in sheet for the recall team which demonstrates to me, as the auditor, that more than just the logistics team or QA manager conducted the mock recall.

When requiring your customers to dispose of any product on hand, what is considered acceptable proof of destruction?

A disposal slip and photos of disposal and inedible process.

What should we expect from our raw material or primary packaging suppliers on recall withdrawal programs?

At minimum, they should meet US Food Safety Modernization Act (FSMA) standards. If it is a high risk item then it should meet the requirements of the SQF Code.

Are there any templates available online (such as via the FDA or another site) that can be used to document mock recalls?

The USDA website might have a template, as they have a very detailed guidance document available. My suggestion for a template is to look at your recall plan or flow chart and develop a checklist using the steps in your recall process.

What are industry best practices for customer notification, when required?

Best practice is to ask your customer prior to any issues and determine exactly what information they need. Document their requirements in your plan and then when the decision is made to have a recall, give them the information they want.

Who is required to make the decision within a company to initiate a recall? What if the company's policy states this is the responsibility of someone outside of the site's food safety group? What are the implications if the SQF practitioner would disagree with the decision?

Generally it is the decision of the highest ranking person at the site or that of a member of the corporate group. If your plant is part of a corporation then it is likely to be a corporate decision. As far as what to do if you disagree with the decision - find some way to document it. If you meet as a recall team, suggest the scribe document those types of challenges.

If your supplier does a voluntary recall, must the manufacturer also do a recall? What if your company doesn't think there's a food safety risk and believe the supplier conducting the voluntary recall is extreme precautionary?

As I mentioned in the session, it is your decision, but in today's environment I would err on the side of precaution and safety. What is the risk if it does end up being a food safety risk and your company did nothing?

The What, Why and How of SQF Retail/Wholesale Grocery Certification

By Gina R. (Nicholson) Kramer, RS/REHS – Executive Director, Savour Food Safety International, Inc

Wednesday, October 26, 10:00AM – 11:00AM

Does the SQF certification and audit work in conjunction with FDA Food Code and State Foodservice rules and inspections; or replace it?

The SQF Retail/Wholesale Grocery Code works in conjunction with regulatory requirements per location of the organization and its stores.

Leveraging The Power of Your SQF Assessment Database

By *Neil Bogart, SQF Practitioner, Assistant Vice President Quality Systems, Red Diamond, Inc.*
Wednesday, October 26, 1:45PM – 2:45PM

How much do vendors have to pay for the SQF assessment database?

There is no charge to utilize the SQF functionality of the ReposiTrak database. To expand use of ReposiTrak to automate the collection and management of internal or ingredient upstream supplier documents, there is a small nominal charge based on number of vendors. For more specifics, I would reach out to ReposiTrak directly at www.repositrak.com.

Can you generate a COA from this system?

Yes.

What are other options that might be nice to have that is not currently in ReposiTrack?

ReposiTrak does not yet do Product Lifecycle Management.

What if there's an error in input by the QA team? In other words, how are corrections made?

Site employees are assigned privileges. Only those allowed to make changes are able to. The changes are also tracked.

Is this compatible with other programs such as MP2?

No.

Intentional Adulteration of Food: What Would YOU Do?

By Rod Wheeler, Founder and CEO of the Global Food Defense Institute, Senior Law Enforcement Contributor/Crime Analyst, Fox News Channel
Wednesday, October 26, 1:45PM – 4:00PM

In the first exercise with the ABC Bakery company, when was the investigation declared closed?

Excellent question! The case was declared closed when we sought an indictment against the accused and after all products were discarded and machinery cleaned.

If you have noted in your employee handbook and have signs posted that random lockers checks will be conducted and are company procedure, does cutting off an employee lock still apply?

It really depends on the governing laws of your jurisdiction. I would recommend that you check specifically what the laws are in your area by checking with your corporate attorney and being guided by his/her counsel.

Where can I find information on your two-day course?

Please visit www.myfooddefense.com. You can also contact us directly for more information via e-mail at info@myfooddefense.com.

Effective Supplier/Retailer Partnerships

By David Guilhaus, Supply Chain Food Safety Manager, Publix Markets;
Holly Mockus, Senior Product Manager, Alchemy Systems;
LeAnn Chuboff – Senior Technical Director, SQFI;
Neil Bogart, SQF Practitioner, Assistant Vice President Quality Systems, Red Diamond, Inc.
Thursday, October 27, 9:30AM – 10:30AM

What vendor portals are recommended based on ease-of-use?

ReposiTrak is my recommendation - Neil Bogart

Measuring Business Culture – The BCA Approach

By Bill McBride, Former Chair, Auditor Competence Scheme Committee, GFSI – SQFI Asia Pacific Representative, SQFI
Thursday, October 27, 9:30AM – 10:30AM

During the annual re-evaluation do you re-evaluate the aspirational values, or do the values stay the same?

Re-evaluate the aspirational values. The aspirational values should be reviewed as part of the re-evaluation process, and may need to be tweaked, but the benchmark for the assessment should always be the aspirational values.

How can you avoid department, corporate, and facility goals from conflicting with each other or not aligning with company values?

The first thing to recognize is that this is not a short-term fix-it is a medium to long term strategy. The reason to focus on overall business culture is to work towards everyone pulling in the same direction and break down the barriers between departments and separate fiefdoms.

During Step 2 how do you sort between what executive management wants the culture to be and what it is really?

Always base it on aspirational values. Executive management will always have a say in the aspirational values, and may even establish or mandate the aspirational values. Aspirational values are not always established democratically. However once they are defined and communicated, all staff then knows what is expected.

How can you balance improving culture versus improving the survey responses and focus on business objectives?

Business objectives are often financial and short term. Identifying and measuring culture changes the focus and (eventually) business performance measures are established that are more holistic and aligned with business culture.

How would I get senior management to see the need in assessing and improving the culture?

Sometimes difficult. All you can do is start the dialogue and provide facts of where business performance can improve if culture is recognized, defined, communicated, and measured.

Is it more important to change behaviors or attitudes?

In general, change attitudes and behavior will follow. However in some cases, where the attitudes are well entrenched and staff are resistant to change, the reverse may be initially necessary to “break the mold.”

Getting Ahead of Food Fraud: Practical Tools and Solutions

By Dr. Jeff Moore, Director of Science, United States Pharmacopeial Convention
Thursday, October 27, 10:45AM – 11:45AM

Does food fraud apply to food packaging materials? Do we need to make the assessment and plan?

The concept of "food fraud" is generally understood to encompass the deliberate adulteration or mislabeling of *consumable* food products for the purpose of economic gain. Food packaging supply chains also may be susceptible to economically-motivated activities with a negative impact on safety or quality, e.g., deliberate substitution of inferior-quality materials. However, such activities typically are not described as "food fraud."

Why is it not considered food fraud with 90% + of wasabi we buy being horseradish rather than actual wasabi?

Many foods are not subject to "standards of identity," i.e., requirements that specifically prescribe appropriate names and compositional criteria. In the absence of clear requirements, determining the appropriate name or composition of a food product in the marketplace can be complicated. Such decisions can take into account a variety of factors, such as national and local laws and requirements, marketplace norms, and consumer expectations, among others. There are cases in which whole or partial substitution of food products would constitute "food fraud," but it is not possible to develop a bright-line rule or general definition to describe all such cases.

Food fraud has been around for a long time and is a global problem, to combat it requires collaboration between governments, global trade organizations, manufacturers and the public. What are some of the actions or initiatives being taken to combat this problem?

A number of organizations around the globe have undertaken initiatives to combat food fraud. The following are some examples, but this is not intended to be a comprehensive list.

- **Q:** In the U.S., regulations developed to implement the FDA Food Safety Modernization Act include new provisions for the prevention of food fraud-related hazards.
- **Q:** The European Commission has recently held a series of high level meetings with different stakeholders and has founded a new group with a focus on Food Authenticity, and the Food Integrity project is funding research on food fraud. Professor Chris Elliott at Queens University was commissioned by the UK government to publish a report on food fraud following the horsemeat scandal. The European Commission's Joint Research Centre (JRC) has also started publishing a monthly report on food fraud at https://ec.europa.eu/jrc/en/news/new-monthly-report-food-fraud-and-authenticity
- **Q:** The Chinese Food Safety Risk Assessment Center (CFSA) has established an expert group to address food fraud and to administer the "black list" of substances that are not allowed for use in foods (created as a result of the melamine scandal).
- **Q:** The Global Food Safety Initiative (GFSI) formed a food fraud think tank and recently added to its Guidance Document the requirements for food fraud vulnerability assessments and control plans.
- **Q:** The U.S. Pharmacopeia (USP) has brought together collaborative panels with experts from industry, government, and academic stakeholders to develop solutions to combat food fraud (e.g. databases, vulnerability assessments, mitigation guidance, testing standards, and training programs).

What would be a best practice to investigate food fraud?

The work to deal with food fraud often does not end once you uncover potential food fraud, and organizations may find it useful to enlist the help of forensics labs and other organizations that specialize in investigating food fraud in supply chains.

How can we look at fraud when auditing our suppliers? Isn't this a highly skilled forensic-type of audit we are not skilled in?

Auditing is one of many strategies that can play a critical role in mitigating food fraud vulnerabilities. To be most effective in dealing with food fraud, auditing should include anti-fraud measures such as those outlined in the USP Food Fraud Mitigation Guidance. Examples include conducting a "should cost" analysis and using unannounced audits. Sometimes fraud is easily uncovered if the records don't match (e.g., product "volume" coming into the factory doesn't agree with "volume" produced). Auditors are now trained to look more specifically for indicators of food fraud in documentation, but there is a recognized need to enhance the training available to auditors to uncover food fraud, and to review food fraud mitigation plans to include criteria to ensure that audits are robust.

Are there examples of food fraud that are considered acceptable because it's been used for a long time… way before we coined the phrase food fraud?

Food fraud is not acceptable in any form, as this term necessarily describes the purposeful *adulteration* or *mislabeling* of food products for the purpose of economic gain. The definition is premised on the notion that buyers or consumers will not be getting what they expect. Marketplace norms and consumer expectations frequently overlay applicable legal requirements as they relate to what is considered "acceptable" in the marketplace. Where products comply with applicable laws and requirements and also adhere to established marketplace norms, these cases are not encompassed in the definition of "food fraud."

To be effective should we make the purchasing department responsible for doing the vulnerability assessment?

Dealing with food fraud should be approached from a multidisciplinary perspective involving different departments and different management levels within an organization. It is up to individual companies to determine how best to allocate resources to their vulnerability assessments, taking into account their own structure and the expertise that different parties in the organization may contribute to the process.

Where can we find a database of foods or ingredients that are more likely to be adulterated?

The USP Food Fraud Database (FFD 2.0) is one such resource that is accessible online (www.foodfraud.org) and that contains over contains over 5000 records, 3600 ingredients, 1100 adulterants, and 2200 primary source references.

Is it considered food fraud if product is labeled as champagne or tequila and is sold as such but not from that region?

Not all foods are subject to requirements expressly governing appellation of origin, i.e., requirements restricting the use of specific terms to specific areas of production. In the absence of clear requirements related to geographical indication, determining the appropriate name or composition of a food product in the marketplace can be complicated. Such decisions can take into account a variety of factors, such as national and local laws and requirements, marketplace norms, and consumer expectations, among others. There are

cases in which the use of label terms to mislead consumers as to the origin of a food product would constitute "food fraud," but it is not possible to develop a bright-line rule or general definition to describe all such cases.

If a company declares an allergen that is not present in the product, is it considered labeling food fraud?

Companies are responsible for labeling their products in compliance with applicable legal and regulatory requirements, including those related to declaring the presence of allergens. In some cases, companies may determine that it is appropriate to notify consumers of the *potential* presence of allergens, even where such allergens are not intentionally added to the food product. Such determinations are fact-dependent, and it is not possible to generalize about their appropriateness or permissibility. The decision to include voluntary or "precautionary" allergen labeling on a food product does not necessarily constitute "food fraud."

How do you properly handle incidents of food fraud to ensure no recurrence in the industry (other suppliers, even worldwide repercussions)?

Unfortunately, the risk of food fraud cannot be eliminated entirely because the complexities of the food chain make it susceptible to fraudulent activities carried out in unpredicted and innovative ways. Food fraud prevention should be a dynamic system that is continuously evaluated and validated, in which new data are fed back into the system and used to help identify gaps, improve vulnerability assessments and optimize mitigation strategies.

What's the difference among all the available assessment tools?

There are various tools in the market that can help companies assess their vulnerability to food fraud and that provide guidance on mitigation strategies. Some examples are:

(1) Databases containing historical data, such as the USP Food Fraud Database 2.0, Food Protection and Defense Institute Database and HorizonScan. The information extracted from the databases is used, for example, to evaluate the susceptibility of food ingredients to food fraud.

(2) Vulnerability Assessment tools, such as SSAFE/PwC, EMAlert and USP's Food Fraud Mitigation Guidance. These allow the industry to identify vulnerabilities in the supply chain. The USP Food Fraud Mitigation Guidance also includes a framework for performing an impact assessment and creating an EMA risk mitigation plan.

How do we access the USP database to assess vulnerability? Is there a cost associated with it?

The USP Food Fraud Database (FFD 2.0) is a tool containing a collection of historical data and data analysis tools that are used in an entity's vulnerability assessment. For example, the information extracted from the database can be used to evaluate the susceptibility of food ingredients or product formulations to food fraud, and to assess the risk of associated potential hazards. To access the FFD 2.0 go to www.foodfraud.org or contact USP at foods@usp.org. Yearly subscriptions are available for purchase.

Does the USP website have a list of suppliers who were involved in food fraud?

The USP Food Fraud Database (FFD 2.0) does not include information about company names in the data extracted from primary source documents. Although every record in the FFD is linked to a primary source reference, company names are often not reported and can change over time. USP believes an assessment of the overall food fraud history of a given ingredient is one useful indicator of potential future risk, and we have structured the data in FFD to provide this information. For evaluating supplier-related risks, we suggest the organization-specific approach outlined in the USP Food Fraud Mitigation Guidance (available at www.foodfraud.org).

What were the fraud issues associated with salt in your example?

Examples of fraud issues associated with salt include the substitution of food-grade salt with non-food grade salt.

Why is it not considered food fraud with the truffle oil issue? Most truffle oil being passed off as authentic is a chemical reaction of several oils?

Many foods are not subject to "standards of identity," i.e., requirements that specifically prescribe appropriate names and compositional criteria. In the absence of clear requirements, determining the appropriate name or composition of a food product in the marketplace can be complicated. Such decisions can take into account a variety of factors, such as national and local laws and requirements, marketplace norms, and consumer expectations, among others. There are cases in which whole or partial substitution of food products would constitute "food fraud," but it is not possible to develop a bright-line rule or general definition to describe all such cases.

How much can we rely on government to catch fraud?

Dealing with food fraud effectively requires all stakeholders (industry and government) to work together in a collaborative effort. As examples, governments can:

(1) Support activities aimed at uncovering and responding to existing food fraud incidents, such as developing training, inspection, and enforcement protocols that are specific to food fraud.

(2) Establish a legal framework that includes compliance requirements specific to food fraud and that imposes appropriate penalties for food fraud infractions.

(3) Facilitate the establishment of preventive measures through the publication of guidelines and the provision of training opportunities.

Ultimately, the government is one entity among many that must work together to address the threat of food fraud.

The EMP Challenge: Taking Your Environmental Monitoring Program to the Next Level

By Timothy A. Freier, Division Vice President of Scientific Affairs, Mérieux NutriSciences;
Brent Wallen, Director Business Development, Enviromap

Thursday, October 27, 12:45PM – 1:45PM

What are your thoughts on all the quicker "DIY" tests now available, for example hygiene Listeria swab that purports to save on lab costs?

I would recommend looking very carefully at how some of these easy rapid methods have been validated. *Listeria* can be stressed and at low numbers we have found that even with AOAC validated methods there can be false negatives if everything is not controlled very carefully. Also, the confidence in using an ISO 17025 lab with experience and expertise with no perception of bias and able to work with you through issues can be extremely valuable.

For a low moisture item like chocolate in a dry cleaning environment would you still recommend swabbing in zone one for Listeria?

In this situation it would be highly unlikely to have *Listeria* growth niches in zone 1 so would recommend more attention on zone 2 and 3 similar to *Salmonella* recommendations. May want to test finished product on a quarterly or yearly basis to provide the added verification that there are no zone 1 issues.

You mentioned using thousands of swabs in order to reach a root cause if needed, but at what point does that look bad to an auditor?

Hopefully the auditor has enough knowledge and background that they would understand that environmental contamination issues can be extremely difficult to sort out and may require many, many samples taken over a long period of time.

Can you elaborate on how you define a lot using the belt example? For example we define a lot from sanitation to sanitation?

For *Listeria* a lot would be all the product that contacts a defined packaging line from complete sanitation to complete sanitation. The key is to be able to prove that there is no crossover between defined packaging lines. Need to look at equipment personnel maintenance tools etc. Air is not typically considered a factor that can connect packaging lines but certainly product contact brine chillers for example would join.

What if Listeria dies off in your product after 2 days due to acidity, pH etc.?

If using chemical pasteurization as a preventive control would need to validate and be able to hold product as long as it takes for the die-off to occur. A low-stringency EMP would probably be in order would want to make sure that high levels of Listeria do not contaminate the product that could overcome the intrinsic antimicrobial capabilities.

Our product has a pH of 3, water activity is 62; we have a validated kill step and challenge studies and per our environmental monitoring plan take twice monthly 2030 samples and yet our customers request a higher frequency of testing. Where do we draw the line?

This is a great question as food safety programs mature and become more effective we need to continuously ask ourselves if we are applying the right resources to the priority areas. Our customers don't always understand how the whole system works together and may have standardized requirements and may push us to do more EMP samples than our own risk evaluation would indicate. Only recommendation is try to communicate how EMP is a verification of all the other programs and as we demonstrate excellence in control of these other areas we should be able to decrease the stringency of our EMP.

Is Salmonella present in salmon?

Salmonella would be pretty rare in raw salmon, however it has been more of an issue in shrimp and shell fish. The name comes from Dr. Daniel Elmer Salmon, not the fish.

If Zone 1 is positive for Listeria, does that mean that there is potentially Listeria in zone 2 or even 3? Should I take a more preventive approach and begin sampling in zone 2 or 3 on a more frequent schedule than zone 1?

Yes, typically there are not very many zone 1 sites available and typically these sites need to be tested over and over. Effective programs will have more zone 2 and zone 3 sampling sites and these sites can provide more proactive and preventive results and can help find problems before they get to zone 1.

What procedures do you recommend for Listeria testing on zone 1 with a short shelf life product that you cannot test and hold?

There are several rapid methods commercially available with a 1 day turn-around time. One of the key ways to increase TAT is to work out the logistics of getting the sample to the lab. Options for onsite labs managed by a professional lab group are growing. Other options include courier routes to the lab. Use of a very specific and sensitive test such as PCR or VIDAS UP can give you confidence in the screen result allowing taking action without doing a full cultural confirmation.