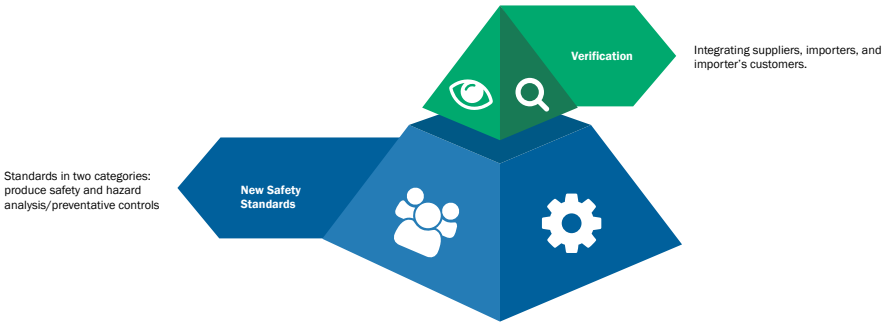
FSMA's Foreign Supplier Verification

The FDA's Food Safety Modernization Act (FSMA) rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is now final, and compliance dates for some businesses begin in 18 months following the publication of the final rule.

What is FSMA's Foreign Supplier Verification Program?

FSVP provides greater oversight in the products coming into the U.S. to ensure that "importers would be required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of domestic food producers."



Essentially, the FDA is asking who has financial stake to ensure the food coming in will be up to the standards that the FDA expects. If you are the U.S. owner or co-signing at the time of entry, you are the importer for purposes of this rule. If there is no owner or co-signer at the time of entry, then the FDA will look at the U.S. agent or representative for the foreign owner or co-signer.

To answer some of the questions surrounding the FSVP rule, TraceGains enlisted the help of Marc Sanchez, FDA Attorney, who provides the following details regarding FSMA's FSVP and breaks down some of the confusion with a few examples we've listed out in the following pages.

TraceGains, Inc., 1333 W 120th Ave, #209, Westminster, CO 80234 USA | www.tracegains.com | info@tracegains.com | 720-465-9400

"Does FSMA's Foreign Supplier Verification Program apply to me?"

This is probably one of the first questions to ask yourself regarding the FSVP rule. There can be a lot of different parties that might have hands on a shipment as it comes into the U.S., so how exactly do you define who the importer is for the purpose of this rule?

Since the importer is ultimately the responsible party under the FSVP rule of FSMA, you must first start the process by determining who the importer is. Is it the party who purchased the food, the owner, or the consignee?

When in doubt, look for the party that has financial interest, or the party that has the ability to control or interact with a foreign supplier. You're not really going looking at the intermediaries, but more so at the consignee, the owner, or the U.S. agent.

A Few Exemptions...

It's important to note that there are a few exemptions to the FSVP rule. Some of these are exemptions because there are already systems in place in which manufacturers rely on. These exemptions include:

- Juice – Subject to HACCP
- Seafood – Subject to HACCP
- Research Use Only – Research and evaluation purposes only
- Personal Consumption – Transshipped foods
- Alcoholic Beverages – ATTB currently retains jurisdiction
- Low Acid Canned Foods (LACF) – Micro hazards only

It's important to point out that there are additional details within each of these exemption categories, and in reviewing whether or not you are exempt, you need to make sure you fully fit the exemption description and fit the description regularly.

Modified Requirements

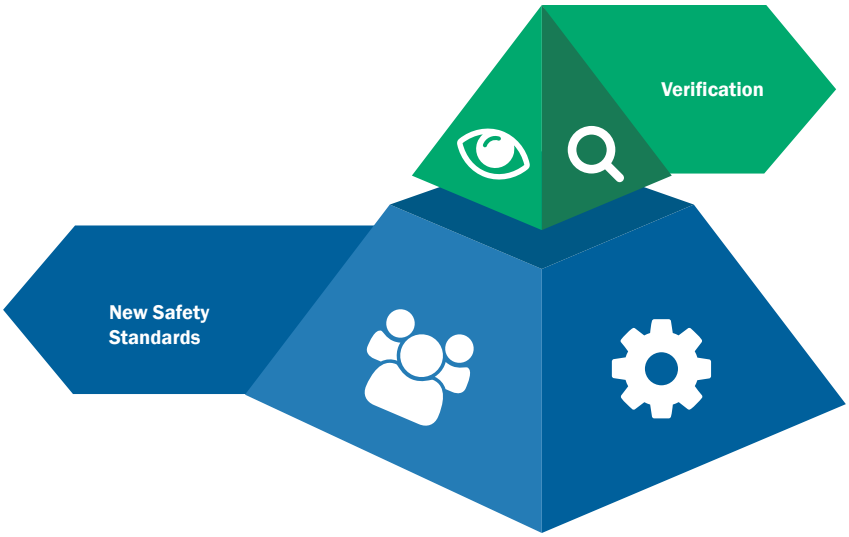
There aren't quite exemptions within in these categories listed below, but there are some modified requirements that are, again, narrow and really require analysis. You will need to make sure these apply continually, and not just at one time. These exemptions include:

- Dietary Supplements (Finished vs. Bulk) – Finished dietary supplements are subject to most of FSVP, whereas bulk/components are subject to Part 111 with a little FSVP.
- "Very Small" Supplier or Importer – Documented annually qualification (<$500K food sales)
- FDA Approved Country – This refers to a list of approved countries that have an equivalently robust food safety system (approved countries have not yet been determined).

Contents of a Verification Program

When looking at the FSMA framework for any rule, it basically—and at its most basic—is a two-tiered system. What FSMA is essentially doing with each of these rules is setting new safety standards (in two categories: produce safety and hazard analysis/preventive controls), and relying on industry verification of compliance.

FSMA Framework



Integrating suppliers, importers, and importer's customers.

Standards in two categories: produce safety and hazard analysis/preventative controls

Manufacturers will not be relying on FDA to be the primary body to enforce these new standards. For FSVP specifically, the FDA is saying that you, as the importer (or party within the supply chain), have to verify that either up or downstream suppliers are meeting the new safety standards. There is now deeper integration between the two parties, and the paradigm of buying from either the best quality or the cheapest cost is changing. Now, a party that will engage with manufacturers in the compliance activities required to bring a particular product into the U.S. is what Industry is ultimately going to be looking for.

Contents

Looking at how the verification process works, there is, at its core, a program that requires you have a verification program that consists of:

- Compliance Review
- Hazard Analysis
- Verification Activities
- Corrective Actions
- Periodic Assessment
- Recordkeeping

And at the heart of these pieces is the hazard analysis, which consists of the identification of and assessment around any physical, biological, or chemical hazards that are likely to occur. One of the really unique pieces to the FSVP rule is, and often times not unlike other parts we see in FSMA, recordkeeping. But because we're talking about *foreign* bodies, the FDA has a few specific items outlined in this rule and even almost goes to the point of saying electronic records are required. FDA states this in a couple of ways:

- FDA want records easily and quickly retrievable. FDA doesn't want to wait for your supplier, wherever they may be, to try and mail you needed records.
- FDA wants records in a form that won't deteriorate. If you have to go back and pull sampling data from within the year, you need to make sure the integrity of that data is going to be available for that timeframe and even longer.

Control and Type of Hazard

There are two key points to a verification program: hazard type and control.

The hazard type is going to inform you what the verification activity will need to be. If you identify a hazard as Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA) that's reasonably likely to occur, then you're looking at the highest level of verification activities—on-site audits either from the importer or from accredited third-parties. If you don't have a SAHCODHA hazard then there are more options available (sampling, testing, etc.).

Once identified, who controls the hazard? Depending on who (importer, customer, or foreign supplier) controls the hazard, you can then determine the steps needed for verification activities.

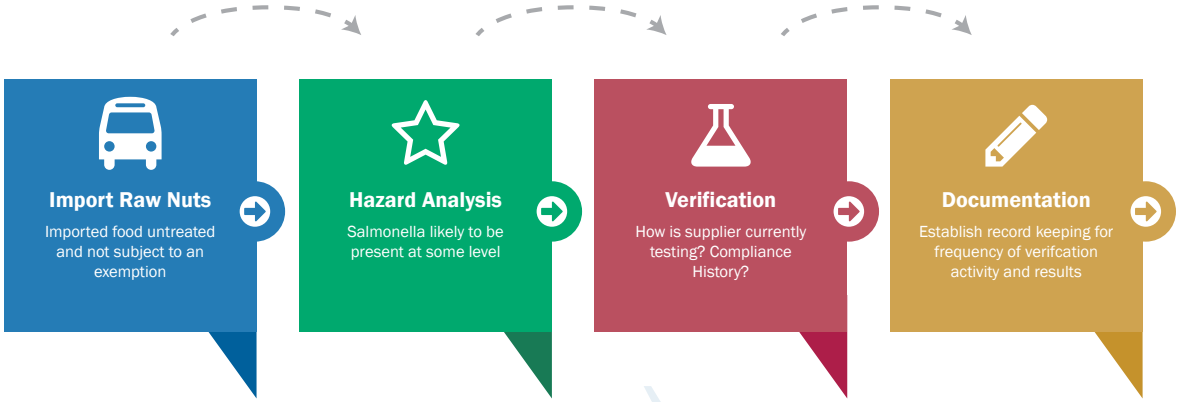
Hazard Type + The Control = Verification Activity

So as mentioned above, if the hazard is determined to be SAHCODHA, you will most likely conduct an on-site audit. But if not, there are other methods available. For example, looking at a supplier's compliance history to ensure the supplier is adequate at controlling the identified hazard.

If you determine the history to be unsatisfactory, you will need to factor that in to then determine the appropriate verification activity. In some instances, you might want to even escalate it to an on-site audit.

FSVP in Action: Importer Controls Risk

To help illustrate the FSVP rule, we provide a couple of scenarios. For example, say you are a company that imports raw, untreated nuts. In this situation, the importer is bringing in the raw nuts for bulk sale, either in retail outlets or for additional steps like mixing, which might be used for variety packs. This defines the importer, therefore, you control the hazard. You can then do a hazard analysis on what could potentially be a health consequence from this import. You can identify salmonella as a possible micro contaminant and maybe certain pesticides as a chemical hazard. But for this example, we'll use salmonella.



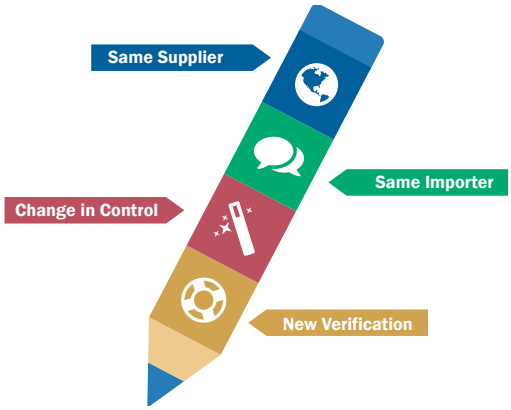
The salmonella will likely fit into a serious health consequence, which might require an on-site audit as a verification step. Again, you will need to look at the supplier's compliance history. Do they currently have a kill step, or do you need to implement a new kill step? Will this meet your requirements?

The final step in this process is the documentation. You will need to establish recordkeeping practices and identify the frequency of verification activities and results.

All of this is done by the importer in coordination with the foreign supplier to verify that the imported raw nuts and the hazard (salmonella) are controlled and documented.

FSVP in Action: Customer Controls Risk

As another example, you can take the same scenario as listed above and simply change the control. Now the importer (you) above is simply passing the raw nuts on to a retailer that will use them in additional products. We have changed the control to say that the customer is now in control of the hazard.



Same Supplier
We Can assume the same supplier of the raw/untreated peanut or other tree nut

Same Importer
We can even assume the same importer ingredient.

Change in Control
BUT if there is a change of control where the ingredient will be used by a customer for further processing then...

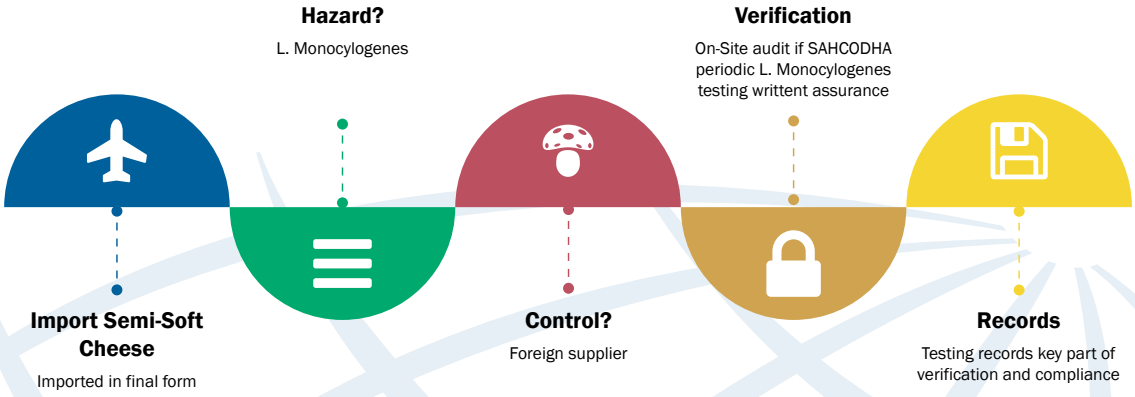
New Verification
Importer now not responsible for hazard analysis and verification BUT myst still maintain annual documentation of customer's compliance.

This means the customer is now having the risk of salmonella with the raw, untreated nuts and will have to do something to control that hazard. This also means the verification has changed.

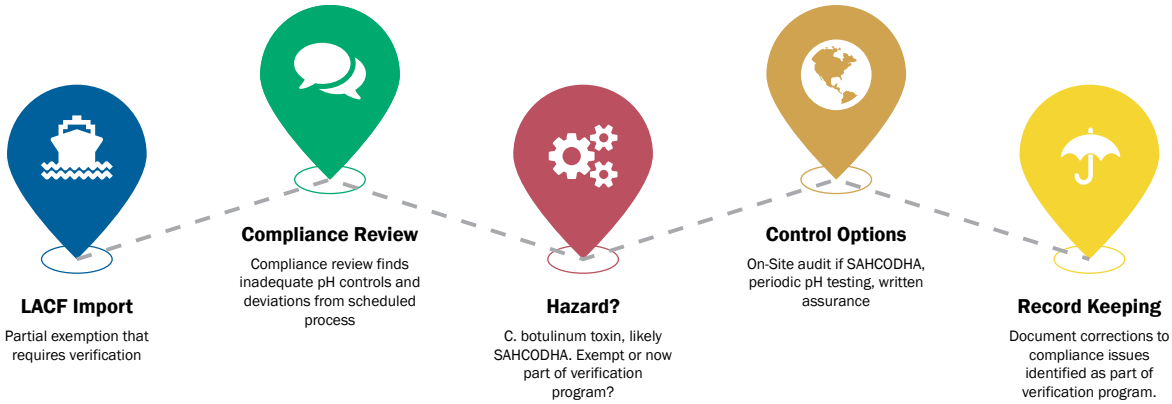
Instead of doing an on-site audit at the foreign supplier or introducing a new kill step at the foreign supplier, you have to make sure you're doing annual documentation of the customer's compliance. It's kind of like passing the baton and saying, "You're in the U.S. and subject to the preventive controls rules. We're expecting you to comply with those rules, and we're going to document your compliance with them." Documentation is really important at this point, however, there are some situations—like not agreeing with how your customer is controlling the hazard—that are still unclear.

Example of Serious Hazards

Should you do an on-site audit?



An example of foreign supplier's compliance history when the supplier has had issues of controlling the hazard:



At the end of the day, the basics should be very familiar.

Review and Strategize: The hazard analysis must be robust and avoid the path of least resistance. It's also important to look at compliance history.

Establish Frequency: Hazard control is on-going and must be evaluated for adequacy. Records on how it's doing is as important as records of establishment.

Verify, Adapt, Verify…: How is the supplier performing? The customer? Adverse events change the analysis? These are all important questions to ask.

About Marc Sanchez

Marc Sanchez is an FDA and USDA regulatory attorney in private practice (http://fdaatty.com/) representing FDA-regulated companies in the food, dietary supplement, beverage, cosmetic, medical device, and drug industries. He also teaches part-time at Northeastern University on regulatory topics including U.S. and international food law and regulation.

About TraceGains

TraceGains (www.tracegains.com) cloud-based SaaS solution provides food and CPG companies with an integrated quality, supplier, compliance, and regulatory document management system that eases compliance with FSMA, GFSI, and HACCP. By automating, innovating, and streamlining Food Safety and Quality Assurance, TraceGains' customers are 365 Audit Ready™ and the system typically pays for itself in only four to six months.

TraceGains is among the Food Logistics Top 100 software and technology providers and a Top 20 Information Technology Firm by Coloradobiz magazine. Learn more about TraceGains products at www.tracegains.com. Follow TraceGains on Twitter @TraceGains.