

MOV

from Uneasiness under the Sanitary

By Pam Young

Most food companies have been diligent in developing and implementing food safety plans to ensure compliance with the Food Safety Modernization Act (FSMA). And yet, when talking to people working in various management positions in these companies, it is not uncommon to hear them express concern about whether their plans are adequate to protect them if a problem should arise.

And while the level of stress and strain that people are feeling over the uncertainty of compliance may vary, individuals holding executive positions are eagerly looking for a greater sense of confidence that their companies are truly compliant with FSMA requirements.

One area that seems to be causing a great amount of uneasiness is food transportation.

The ink on the U.S. Food and Drug Administration (FDA)'s Sanitary Transportation rule (STR) has long dried, and while the specific requirements have been defined and discussed in countless webinars and food safety trainings, it seems as though there continues to be confusion about what compliance with the rule should actually look like in practice.

Now well into the second year after its publication, it is time to drill down on the issues that have become barriers to full, satisfactory compliance with the STR.

WINNING

to Confidence Transportation Rule

Now in the Same Corner—Mutual Compliance

A primary contributing factor to this lack of clarity seems to be that in its effort to ensure food is safe and secure throughout the supply chain, FDA has created a critical relationship between two industry groups that, while historically coexisting in typical business arm's-length professional transactions, must now work much more closely together toward mutual FSMA compliance.

One group regulated under the STR consists of food industry members that grow, store, load, process, ship, and/or receive foods that are dry, fresh, and/or require temperature control for food safety. The other group that is now responsible for compliance under the rule is the trucking companies that actually transport the food. These are typically owner-operators, which range from those having a fleet size of fewer than five tractors and trailers to large carriers with fleet sizes in the thousands using employee drivers.

Previously, food companies needed their products transported, and they did not get involved in the actual process of transportation other than to select a carrier and make sure that pertinent pick-up and delivery information was properly dispatched. FSMA compliance now essentially requires food companies to become liable partners with their carriers.

Members of the food industry know that their products need to move, but the details and nuances of how that transportation happens are typically managed by one group in their company: the logistics department. Today, over a year since the rule became enforceable, there are employees in these logistics roles who have

little to no knowledge of the STR.

Many people have asked whether the rule is actually being enforced, and if so, what should a company expect if and when it is asked to produce proof of compliance. While published reports of actual investigations relating specifically to the rule are difficult to find, shippers and truck drivers have informally referred to instances when, during an inspection for FSMA or Department of Transportation (DOT) compliance, an inspector informally asks questions specifically related to compliance with the STR. A closer look at enforcement is discussed later.

The State of the Transportation Industry

In the transportation industry, knowledge of and compliance with the rule depend on the character of the company. Carriers that identify themselves as progressive and/or innovative are typically the companies that have participated in a food safety training, know the rule and its requirements, and have protocols that align with the rule's requirements. But only about 25 percent of the largest fleets in the nation would be part of this "progressive" group.

Many of these are contracted carriers for some of the largest foodservice, retail, and wholesale companies. Driving through fresh produce-growing regions, such as California's Salinas Valley, one can find quite a few of these fleets loading or waiting for a pickup at a shipper's facility that supplies these food companies. Often, when asked why compliance is not a priority within their organization, a carrier's response is that "no one," meaning their customers, is requiring compliance yet.

What does a carrier mean when it says no one is "requiring" it to comply with the STR?

Typically this comment refers to a contractual obligation with which a carrier has agreed as part of its transportation contract. When the rule was first published and food shippers began to understand that FDA had placed primary responsibility for specifying food safety protocols on them, they contractually shifted the burden for compliance onto the carriers' backs. In many cases, food safety personnel relied on the company's legal department to create, via a contract, the compliance required to meet FDA's expectations.

This shift was anticipated by FDA in the rule, as they made it clear that while the shipper knew best how to take care of its product, it was acceptable for the shipper to specify how that should be done and then require the carrier to bear the shipper's burden for FSMA compliance.

The reality of the situation is that the food companies that are depending on their food safety departments to ensure FDA compliance are assuming (or hoping) that this is happening on the basis of contractual agreements. Unfortunately, these carriers are operating under a few of their own assumptions, such as the fact

that if they have signed a contract, that alone is proof that they have adequately complied with the rule. Actual compliance pieces, other than making sure their drivers have seen the 1-hour FDA video, may or may not be written and implemented in their company's safe food transportation plan.

It seems that many carriers don't even have a food safety plan.

And worse for food companies, particularly shippers, if they do not have a contract in place with a carrier or haven't implemented a safe food transportation plan, the chances are real that the carriers supplying their company with transportation for its food products may not have any idea that the STR exists and that legally they are responsible for compliance (see "A 'How-To' Carrier

A "How-To" Carrier Guide for a Food Safety Plan

While putting a food safety plan in place is necessary, it does not need to be complicated but does need to be completed. It does not need to be perfect, but it should be a work in progress and will change as you start implementing your procedures. It will need to be prepared and performed. "Prepared" refers to the procedures that are planned out, written with achievable outcomes, and focused on preventing problems that happen in transportation. "Performed" refers to the actual implementation of your plan. Build in methods, including documentation, that ensure that your employees and your company partners (customers, suppliers) are able to consistently and completely comply.

Here are three simple steps to start:

1. Assign a person to supervise and manage the process. This is the Competent Supervisory Person (CSP) required in Section 1.908(a)(2) of the STR who should be skilled, knowledgeable, and experienced in all relevant areas like food safety and transportation.
2. Make a bucket list. The "buckets" will help organize all the responsibilities required in the rule. Use the rule to make the buckets: CSP; Vehicles and Transportation Equipment; Transportation Operations; Training; and Records.
3. Under each bucket, start listing your company's activities that fall into each group. Make a table or chart that can be helpful in knowing how your compliance is going and what you need to get done. In each group (e.g., Vehicles and Transportation Equipment), the rule has defined areas of responsibilities. Under each area, using labels such as Doing, Not Doing, and To Do, write the activities that your company is already doing and what you are missing: The latter becomes your To Do list, which should include dates and people responsible for making sure a task gets finished and moved to the Doing list.

If you have signed a contract with a shipper or another party named in the rule for specific compliance requirements, those requirements become your bucket list. If and when your customer asks for your compliance records to show you are meeting your contractual obligations, your plan will be complete.

Remember, cross your t's and dot your i's. It's one thing to have a plan, but it is not truly complete unless it is implemented. Your CSP is responsible for ensuring that the plan has moved from preparation to performance!

Guide for a Food Safety Plan”).

This apparent disconnect between the food and transportation industries is a problem in that it exposes both groups to the risk of being noncompliant with FSMA.

Achieving STR Compliance

One solution might be to demonstrate to the stakeholders in these groups that they can each benefit from a mutually compliant alliance. This will help them see how their investment in the process will ultimately protect their companies from undesirable and potentially disastrous consequences that accompany noncompliance with the STR.

So, if a trucking company carries out its responsibilities under the rule, the shipper and receiver who are depending on that carrier to pick up and deliver the load both receive the benefit of the carrier’s compliance. Looking at it from the shipper side, if a shipper, either in a written contract or in instructions stated on their bill of lading, requires a carrier to meet the shipper’s specifications, the carrier that fulfills those obligations will have also fulfilled its own compliance responsibilities.

But merging interests alone will not solve the overall compliance challenge. There is another issue that needs serious attention before the real work of meeting the STR’s requirements can get under way.

At the core of this marginal compliance lies some confusion about the rule so that not only do the parties lack significant appreciation for each other’s roles under the STR, but there are also some foundational questions about the rule’s requirements.

Several of the “mis-” words that may apply in this situation may have slightly different meanings, but ultimately, they seem to end at the same place. Misinterpretations, misunderstandings, and misconceptions could all lead to misguided attempts at satisfactory compliance and perhaps even to costly mistakes.

While this is not an exhaustive list of the misunderstandings at play, the following may be a few of the most significant.

Misunderstanding #1: The Rule Itself

Back in the early 1960s, Peggy Parish wrote a series of books for children about a goofy housekeeper, Amelia Bedelia, who had a knack for misinterpreting common-sense instructions. Amelia managed to misconstrue tasks like planting lightbulbs instead of flower bulbs into clay pots and cutting holes in her boss’s dress when asked to “remove the spots.”

Interestingly enough, and somewhat similar to how people misunderstand the STR, Amelia routinely charged ahead down the wrong path without any misgivings that something was amiss as a result of her actions. So too in the food and transportation industries, people are apparently confident in their choices related to food transportation. Some of these decisions are probably not what FDA envisioned as “safe and secure,” and worse, these decisions may be contrary to what should make sense.

Speaking of FDA, the writers of the STR intended that the rule be flexible and nonprescriptive. The reason for this method of rulemaking was that in the transportation segment of the supply chain, a vast number of companies grow or make numerous types of products, and they need some flexibility to best move those products as well as to accommodate the needs of their customers.

The rationale makes sense, but for the many companies that need to participate in the supply chain to transport or receive product, there are that many different interpretations of “safe and secure” transportation activities. Once the rule was published and the reality of enforcement began, the questions ensued: What is “clean”? Does our company’s “food” fall under this rule? Who is a shipper when there are more than two people involved in securing a truck to haul a load? What is a “material” deviation, and how will this affect cargo insurance?

A simple approach to managing this problem is to use the STR’s goal, consistently stated throughout the text, as a primary qualification in important decisions. STR’s clear objective is to transport food in a way that does not make the food unsafe.

Therefore, procedures regarding cleaning/sanitizing, preventing cross-contamination, temperature control, training, etc. all should have a “risk prevention” evaluation process that serves as a guideline supporting the STR’s goal. The procedures should be described and written into a company’s food safety transportation plan.

In questions that are not “practice” related and more specific to a definition in the rule, such as whether a company is in the shoes of a shipper, it is better to assume that a company has a specific role. Write a protocol for that role rather than ignore the requirement. Definitely have a company attorney review the food safety plan.

Misunderstanding #2: Best Practices

Not only did FDA intend to incorporate flexibility into the STR, but it also relied on industry “best practices” to help provide the framework for transportation protocols and procedures. The assumption was that these accepted means of managing freight movement are consistently incorporated and implemented by all parties specified in the rule, whether or not the practices are embodied in a written food safety plan.

This too was a good idea, except that in food transportation, a multi-faceted and historically ignored industry (in relation to food safety rules), companies have been moving food products in patterns and with procedures that best accommodate their operations and customer needs. Safe food transportation may be a consideration but not always a priority.

The STR is activity-based, so FDA expects that stakeholders will know and actually practice these guidelines. However, one of the criticisms of established best practices that has surfaced since the rule’s publication is that while they make sense on paper, the outcomes fall short when actually executed. This can happen because

there is insufficient scientific support for the quality of a practice or because of inadequate training of the people responsible for understanding it.

Here is an example that demonstrates both reasons.

In regard to science, the STR requires transportation equipment to be “clean.” This means that when, for instance, a driver pulling a refrigerated trailer arrives at a cooler, at a minimum, the trailer should be free of debris and should not have past cargo odors.

Unless the carrier is contracted to wash out the trailer after every load or every type of cargo, “clean” refers to making sure that visibly there is no dirt, substance, or product/pallet pieces remaining on the floor or stuck to the walls.

Any bacterial material, invisible to the naked eye, could still be in the trailer. Washouts are not regulated, so some surfaces do not even get rinsed and at times can be cross-contaminated because of the washout method used by a facility.

How does inadequate training affect the quality of a washout? Many companies tell their drivers to get washouts, but they do not necessarily give them instructions

on how a washout service provider should clean a trailer or how often a trailer should be cleaned.

Many carriers that are hauling dry freight in a refrigerated trailer get a washout only if they are contractually required to do so. Drivers and dispatchers tend to focus only on the type of prior cargo, which disregards other problems such as potential contamination from forklift wheels or loaders/lumpers who are moving in and out of a trailer without considering the cleanliness or sanitary condition of their shoes.

This “dirty” discussion will be broad-

STR Flight Plan

The U.S. government has strict rules that govern planes, pilots, and passengers. Anyone who travels via air knows that these Federal Aviation Administration rules are nonnegotiable. Just like air travel safety requires preparation and following a process, so too must a driver navigate through the critical stages of food transport by following a procedure that will help a carrier stay STR compliant. These checklists are intended to be a guide only. Companies should work with their legal and food safety departments to develop checklists specific to their operations.

Reservation Stage: Pre-trip equipment status checklist

Trailer: Check that refrigeration unit, floor, walls, ceiling, doors, and chute are

- Designed to properly haul the food described in the dispatch
- Inspected to ensure good condition (no holes, rips, tears)
- Free of debris and odors, with completely clear floor grooves, a refrigeration unit that has been tested and is working properly, and load locks that have been cleaned and made available before pickup begins

Plan for problems. In fact, a “Plan B” is critical to have in place and practiced. Identify the person to contact and/or protocol to follow to engage the start of alternative compliance protocols.

Security Stage: Pre-trip information and product status checklist

For food products, check that

- Compatibility is confirmed (temperature and ethylene sensitivity)
- Pickup and delivery purchase orders, locations, and times are confirmed
- Shipper’s precool specifications are confirmed and set
- Transit temperatures are specified on bills of lading (BOLs), temp recording device locations noted on BOLs
- Transit temperatures are confirmed with a reliable pulp thermometer
- Product is segregated and protected from nonfood product
- Cartons, boxes, packaging, etc. are confirmed in proper condition (no tears, crushes, etc.)
- Loading patterns are designed to maximize airflow

- Products are securely stowed with adequate numbers and correct positions of load locks

This is a critical food safety stage that is often compromised because a driver wants to get on the road. Many delivery problems can be avoided or mitigated by careful attention to a checklist of this type.

Board-and-Go Stage: In-transit checklist

Monitor and report

- Deviations in prescribed temperature recordings in trailer to specified food safety contact
- Instructions given by shipper, receiver, or food safety contact regarding the temperature issue
- Any delays that potentially threaten a scheduled delivery date and/or time
- Location updates if required and/or not available, other than driver communication
- Any events that threaten the safety and/or security of the food product
- Problems with delivery appointment (discrepancy in purchase order, date, location, etc.)

Arrival Stage: Destination and delivery checklist

Confirm and/or document

- Load arrived as ordered per dispatch
- BOLs are accurate and signed by the receiver (correct product count received)
- Correct temperature recording device is located and retrieved
- Shipper is notified of delivery outcome: Either a “clean bill” or, if a problem occurred, further instructions

Drivers should stay on-site until given a green light to leave, unless the shipper/dispatcher has communicated that “clean bills” warrant permission to leave without further instructions.

Documentation of these activities is like a boarding pass. An air passenger goes nowhere without one. The STR requires accurate and thorough record keeping, and the ability to produce these documents will prevent serious noncompliance issues.

ened in the next section, but for now, it is important to use the “clean” equipment example as an area where best practices may fall short of what the STR seeks to accomplish.

Misunderstanding #3: Focus on the Wrong Question

As mentioned above, the issue of “clean and sanitary” may need some clarification. But this area is indicative of a larger potential point of contention that is frequently raised during a discussion with both food and transportation industry members. A common objection from both sides is that there is not a published instance of a foodborne illness related to a food transportation incident.

The STR is designed to prevent practices that create food safety risks during transportation. The rule generally refers to types of risks, mostly in three areas, which are cleanliness of equipment, cross-contamination, and temperature abuse in foods that require temperature control to keep them safe.

But outside the obvious risks such as visibly dirty trailers, extreme transit temperatures, or dangerous exposure of unprotected food to various sources, there is a very limited factual basis from which more substantive and thorough transportation practices can be defined and incorporated into food safety transportation rules.

Therefore, the question should be, “If there is a possibility of bacteria, an allergen, or even insects in a trailer due to prior cargo, an inadequate trailer washout, or because the doors of the trailer were left open for a time, what will we require to ensure that this trailer is actually clean and sanitary?”

The above question is specific to Section 1.906 in the STR, but the analysis and careful consideration of a company’s protocols and procedures are the same for each section of the rule. A true best practice would be to encourage a company to ask the correct questions that apply to each section so that in the end, a company develops a reasonable and effective plan.

Misunderstanding #4: Risky Assumptions

Amelia Bedelia seemed completely unaware of the potential consequences of her actions, almost as though she was so certain that her choices were spot-on that she would ultimately be immune to unfortunate outcomes. Getting fired didn’t cross her mind, and some of her stunts were downright dangerous!

It is interesting to talk to different company representatives from both the food and transportation industries about the likelihood of strict enforcement and its subsequent consequences. In certain industries such as fresh produce, people are very much aware of the seriousness of complying with the STR. In the transportation sector, as mentioned previously, there are some companies that are investing time, money, and whatever else is necessary to make sure that all aspects of food safety are covered in their organizations.

While published instances of STR enforcement are scant, similar to documented cases of transportation causing foodborne illness outbreaks, this should not be the basis for ignoring FDA’s express intent to ensure compliance. In Response 19 in the text of the STR, FDA details its obligation and possible means of enforcement.

The Department of Justice has also made public its intent to use criminal prosecutions in some instances to enforce regulations such as the STR to protect the public from wrongdoing. It is common knowledge now that several large legal cases have been heard and decided that individuals holding executive positions could be held liable for actions of their employees.

The question then becomes one of opportunity. What are some of the ways that FDA might investigate questionable transportation practices?

Coming from the produce transportation industry, two common situations, if improperly managed, could lead to unwanted scrutiny.

The first instance could happen with a questionable delivery. This very topic could be lengthy and involved, so for purposes of this article, it is probably sufficient to say that it is a very short period before red flags start waving when a load arrives hot, cold, late, damaged, and/or missing product.

A second instance involves a DOT inspection. Carriers know that a small infraction can quickly roll into a serious problem. Something simple such as a malfunctioning light can attract the wrong kind of attention. In the rule itself, FDA states (Response 19) that it intends to follow up on DOT issues that suggest unsafe food transportation practices.

Sustainability and the Steps toward Compliance with STR

Driving along the foothills in the Salinas Valley, one sees signs posted at the edges of the vineyards that say “SIP [Sustainability in Practice] Certified.” By being SIP certified, the growers and winemakers in this region have committed to a high level of business practices that ensure the best outcomes for their people, their profits, and the land they depend on to produce quality wines.

Wine consumers traveling these country roads see these signs and know that SIP certified means that the wines they drink from that vineyard have been produced by people who believe in the value of meaningful best practices.

The STR produces mixed reactions among its stakeholders, but more often than not, people who are now required to comply consider it a necessary evil rather than an opportunity to increase food safety and sustainability.

But what would happen if companies began to view this regulation as one of their key paths to sustainability? What would the effect be if the stakeholders revised and improved their best practices, so that consumers would be assured and confident that food products were transported safely and securely?

Using the rule as another way to invest in their employees, improve their financial strength, and steward their respective areas of natural resources, these businesses can turn something seemingly cumbersome into a true and lasting investment.

While the following are not new ideas, applying them to STR compliance efforts

may re-center current efforts in companies that are somewhat lost in their implementation process, and perhaps these suggestions will encourage others to get going on their plans.

Communicate

Have serious and open discussions with all the company's employees. Insist on candid conversations about what STR compliance is and what it should look like in practice.

One common characteristic of organizations that do not have food safety plans is that they have chosen the "ostrich" route. Their heads are in the sand; they are clearly comfortable with not knowing, sometimes willfully ignoring, how the rule applies to their company.

And then there are a few companies that are telling the "emperor" that he is dressed and ready for a compliance inspection. It can be a challenge to point out to the leaders of some companies that serious gaps exist in food safety plans. These leaders may be setting themselves up for exposure of the worst kind if they choose not to give serious attention to this regulation.

Culture

To facilitate the level of communication discussed above, a change in the overall atmosphere of a company may be needed to achieve the best results. People need to know that it is OK to ask questions, seek advice, and report problems.

Sometimes, a salesperson in a food company may not have had any transportation experience, so it is important to train and support that individual in complying with specific protocols. Or the situation could be turned the other way around, where a logistics person knows nothing about why a specific product should be transported a certain way. Everyone in the organization needs to understand how their job affects the overall food safety compliance of the company and those eating the food they transport.

Actually, STR compliance should be integrated in all areas of all companies. Sales, logistics, marketing, legal, and food safety are all part of ensuring compliance throughout the company; creating an open and encouraging atmosphere will make employees more willing to contribute in valuable areas.

Partnerships

Some families or friends have code words to use when they are around each other in a difficult or uncomfortable situation. For example, a husband or wife may say "parsley" in a conversation when they see their spouse with something scary in their front teeth that may be embarrassing if not removed.

Companies that buy and sell from each other in some capacity need to be willing to help their company's partners avoid a problem. Ignoring something potentially risky is not what good partners do. This starts with communication but should move quickly to collaboration so that both entities' food safety plans can withstand scrutiny.

Dispatchers and drivers are often put in the hot seat when a problem arises at a customer's or supplier's dock. For example, a driver may have been careful to get a trailer cleaned and properly prepared, but once backed in and ready to start loading, the driver notices mud, debris, or sometimes blood on the forklift tires or on product boxes. Perhaps in a situation where a load that requires temperature control for safety, the product has not been properly cooled to the correct shipping temperature.

If this happens once or twice, it is probably not a serious risk. However, continuous disregard for a customer's or supplier's requests to use safe food transportation practices might indicate that it is time to make a change. Of course, this is easier said than done, but it is a better alternative than hoping that a lucrative relationship stays lucky and does not lead to a fine, making someone ill, or something even worse for the CEO.

And those drivers and dispatchers stuck making the decisions about whether to load or not load? Insisting that they look the other way opens the door for other areas of noncompliance.

Look Inside and Out

In building a plan, a good starting point, especially for food safety personnel, is implementing what these folks are already good at, namely, using objective scientific testing in trailers, typical functions like employing audits and corrective actions, and for sure, putting to use all the food safety vocabulary words so that your transportation food safety plans align with other areas of the company's food safety initiatives.

Carriers may need to work on understanding food safety language, but using that language and applying it to the procedures that are working and align with the STR will help the transportation company write a solid, complete plan that will satisfy their customers' food safety departments.

But perhaps just as useful for either a food or transportation company is to look outside their industry to learn how other transportation sectors accomplish compliance.

Examine maritime or aviation systems. Each of them has a high level of risk management because of the dangerous results of noncompliance (see "STR Flight Plan").

Conclusion

In closing, and speaking of the field of aviation, there is a retired colonel that told his freshman class of aviation majors, "Taking off is optional, landing is mandatory." This is a great summary of the responsibility the STR has placed on the food and transportation industry members. If a company is involved in the movement of food, compliance is mandatory. ■

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