THE ACHESON GROUP

XL Group Insurance

TAG Intel

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In this issue:

Welcome to the first issue of TAG Intel brought to you by Response XL – a collaboration of The Acheson Group, LLC (TAG) and XL Group. Each quarter we will bring you news you can use for keeping up on industry happenings and reducing your recall risk. In this introductory issue, we take a dive deep into the seven pillars of FSMA, introduce you to Response XL and what it means for you, relate recall provisions of FSMA, discuss the challenges of GRAS, and provide a few Hot Topics and an overview of TAG.

The Seven Pillars of the Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) was signed into law in January 2011 and as soon as it was signed, there were various new authorities that the US Food and Drug Administration (FDA) received immediately. There were also a wide range of other new authorities that the FDA received from FSMA that required a full rulemaking process.

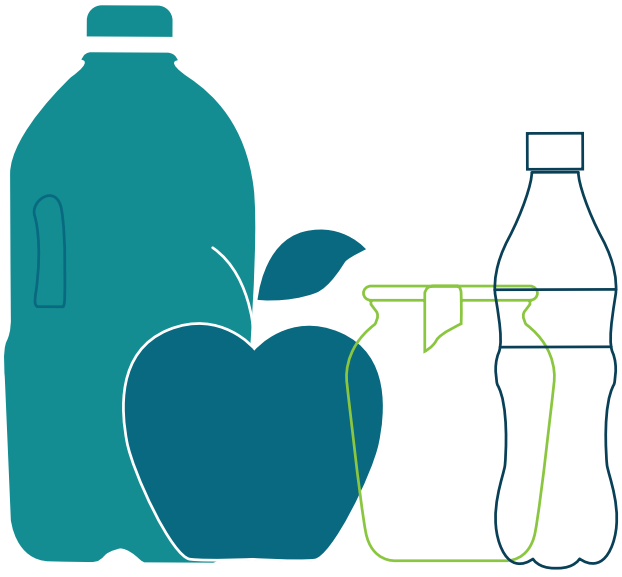
Today, three plus years on, we have seen seven new, very robust and complex proposed regulations come out from FDA for comment. It is these seven proposed new regulations that we call the “Seven Pillars of FSMA.” But before spending time discussing the seven proposed rules in more detail, we should spend a moment to focus on what passed as soon as FSMA came into law.

Of the various new authorities that came into effect immediately, I want to focus on a few that are potentially very impactful to FDA-regulated facilities. The first is the new records inspection authority. Pre-FSMA, the FDA needed credible evidence that a food would cause a serious adverse health event before they could look at your records. What this meant was that the evidence that food was contaminated with an agent that would lead to a Class I recall had to be solid. In other words, finding a pathogen like Salmonella in food would be credible evidence. What FSMA did was to lower that bar significantly to the point where FDA today only needs a reasonable probability that the food will cause a serious adverse health event. So this is a much less clear standard to my way of thinking, and it makes it easier for FDA to see your records. When FDA does ask for your records they can get pretty much anything, other than your personnel and financial records and your recipes. They can access all your records related to production, supply chain, distribution, testing etc. as well as your consumer complaint records. Further, if they don’t like what they see with the food that triggered the records request in the first place, they can expand this request for records to other foods you produce and even into other facilities. So what this means is that you need to keep your records current and accessible so if the FDA does come for them you can put your finger on them quickly and easily.

The second major new authority is FDA's ability to suspend your registration. So if you are an FDA-registered facility and you get into serious trouble, the FDA can suspend your registration which means that you can still produce products – but you cannot ship them. So this effectively closes down your business. To date, FDA has exercised this new authority twice, and the company they did this to the first time has subsequently gone out of business.

Other new authorities of the FDA are the ability to mandate a recall, the ability to require certificates for what they consider to be high-risk foods imported into the US, and the ability to detain food when they believe there is a reasonable probability that the food is either misbranded or adulterated. The FDA also has the authority to collect a fee for a re-inspection. This means that if you have an inspection and the FDA finds a problem and issues a Form 483 and then has to come back to make sure you have followed up – that second inspection can carry a fee. To date, they have not actually used this authority, which is somewhat of a surprise since they need the money rather badly, so we have to assume it is only a matter of time before this one kicks in too.

So we are now in an era where the FDA has some significant new tools, and they have certainly used both the suspension of registration and the administrative detention authority. As we move forward from here, we should anticipate that the Agency will continue to use these tools and at a greater rate than they are currently, and that they also will leverage the records inspection authority more.



As noted above, FDA has now issued seven proposed rules – the Seven Pillars of FSMA. The seven rules include preventive controls for human foods; preventive controls for animal foods; produce safety rules; foreign supplier verification program; third-party auditor rules; food defense rules; and, most recently, the sanitary transportation rule.

One of the insights from all these proposed rules is that we see some clear common themes. The most important theme is that they are all heavily focused on prevention. Most require food companies to determine their food safety risks and, if those risks are reasonably likely to occur, to control those risks. There is a heavy emphasis on writing plans (more on that in a moment) along with the need to show that you know what you are doing with regard to food safety and following through on what you should be doing. These proposed rules are much more about being able to demonstrate to FDA, through appropriate recordkeeping, that you are actually controlling the risk and not just saying that you are controlling the risk – hence the need for much more ongoing monitoring and recordkeeping.

There has been much written about the various proposed rules, and I lack the space to go into details on each one, so I will instead pull out some highlights of the way in which these rules fit together as well as some common themes. This is important to understand, because many food companies will be impacted by a fair number of the rules once they are final. To give an example, if you are medium-sized company (over $10m in sales annually) that makes food using a few ingredients that you import, and then ship that food to a distribution center, you will likely be impacted by at least six of the seven new rules. The only one that would not pertain to you would be the produce rule. So let's look in a bit more detail at these seven pillars of FSMA.

1 Preventive Controls for Human Foods

This rule is a cornerstone of FSMA and will push food companies to go beyond basic Hazard Analysis and Critical Control Points (HACCP) to Hazard Analysis and Risk Based Preventive Controls (HARPC). This means that a registered food company will need to look at risks beyond basic HACCP. These may be risks that are typically controlled using prerequisite programs – like environmental controls, allergen controls, or, in some situations, even hand washing that would be under GMPs.

Food companies are going to have to build a food safety plan that will identity all the potential risks, then focus in on those risks that are reasonably likely to occur (RLTO). For the RLTO risks, preventive controls will need to be put in place to control those risks; these controls will have to be monitored; corrective actions have to be documented; the systems have to be verified; and, periodically (once every three years at a minimum), the whole plan has to be reassessed. A critical part of this will be to maintain records. FDA expects you to put a plan together, but more than that, they expect you to execute on that plan and will hold you accountable for doing that during routine inspections.

2 Preventive Controls for Animal Foods

This rule is very similar to the preventive controls for human foods. It has the same structure and requirements but, for the first time, it will require companies producing food for animals (pets and livestock) to put good manufacturing practices in place. It will also impact companies producing human food that send scraps for animal feed. This rule has had a lot of comment and FDA has already said they are going to make significant changes to it.

3 Produce Rule

The produce rule is essentially the regulatory implementation of good agricultural practices. The focus of the rule is exclusively on microbial contamination, not chemical.

The FDA expects those who grow produce that is not further processed to put a variety of controls in place to control microbiological risk. Some of the areas of control include: the safety of the water being used – especially if it is being sprayed directly on the produce; control of animal encroachment; the personal hygiene of those harvesting or handling produce; and cleaning and sanitation of equipment used to harvest or carry produce. There are exceptions in this rule for small farms, but it will impact many that grow fresh produce that is being shipped into interstate commerce.

4 Foreign Supplier Verification Program

The Foreign Supplier Verification Program (FSVP) will require those who import food into the United States to implement a program that assesses risk with regard to the food they are importing and control that risk in a variety of means.

This rule will require firms to develop a written plan and, while the FDA has offered two options in the proposed rule around controlling suppler risk, the final rule will provide only one way to do this. Likely it will involve an assessment of the risk in the imported foods and then a level of oversight through either on-site audits, lot by lot testing, certificates of analysis, or extensive reviews of the foreign facilities' food safety programs to ensure the risks are being controlled. This rule is likely to have a major impact on foreign firms who export food into the United States as well as on the importers who cause that food to be imported. A key point to remember with FSVP is that it is about the FDA requiring importers to oversee that their suppliers are compliant with the Food Drug and Cosmetic (FD&C) Act. What this means is that they will have to be compliant with all the new components of FSMA, and that is where there will be some clear challenges.

5 Third-Party Auditor Rules

As part of FSMA, the FDA has authority to require certificates prior to importation for certain types of food that they deem are high risk. The FDA has not fully established that list nor have they issued any requirements yet. But when they do, one of the questions is: Who will be authorized to issue the certificates for high-risk food? The answer is a third party if accredited by an FDA-appointed accreditation body. This will be a three-tiered process. Tier one is that FDA sets the standards – which are the FSMA requirements we have been talking about (preventive controls, produce rules, etc.); second, FDA will appoint accreditation bodies whose job will be to oversee those actually doing the audits to ensure they are doing them to the FDA standard. There are many controls for potential conflict of interest in this proposed rule, but it will leverage private third-party audit firms for the first time. We expect that this will somehow align with the Global Food Safety Initiative (GFSI) – although it is not exactly clear how just yet.

6 Food Defense Rule

The Food Defense rule is focused on preventing our food supply from being attacked by terrorists. This rule does not apply to tampering events or economically motivated adulteration. The focus is on larger companies (greater than $10m in annual revenue) that manipulate food in such ways that a terrorist could add an agent at one point and, as a result, contaminate many servings of food. Examples are bulk holding tanks or mixing operations. As with many of the other rules, firms will have to develop a written plan for this rule.

7 Sanitary Transportation Rule

The Sanitary Transport rule is the only rule in FSMA that applies to both FDA and USDA regulated facilities. The rule will apply to food that is in intrastate commerce as well as interstate commerce. It is focused on ensuring that food that is transported remains safe. So the focus is on time/temperature control for foods that support the growth of microbes. It is on ensuring there is no cross contamination (e.g., for allergens) during transport and on ensuring that trucks are clean and in good repair. Of note: this rule will apply to both trucks and railcars.
The rule will impact shippers of food in that they will have to set clear written standards for the movement of their food and ensure that the carriers are aware of those standards and that the vehicle moving the food is appropriate (temperature, cleanliness etc.). The rule will apply to carriers of food to ensure they are following all the requirements to keep the food safe and recording it. The rule will also have some impact on the recipients of food – for example recipients of food will need to have handwashing facilities available for those carrying the food.

FSMA represents the greatest change to US food regulation since 1938. It will impact many companies all over the world as those growing, processing, holding, distributing, and transporting food come to terms with what they will have to do. Many of the rules revolve around prevention and assessing where risks may be, and capturing all of that in a plan around how those risks will be controlled. But the key to compliance with FSMA is to be able to demonstrate that you really are controlling the risks you have identified. It is also important to note that FDA expects food companies to stay current and to update their plans when things change, either in their facility or when new risks are identified.

Finally, as we look at all this complexity, there is not all that much time to get the job done. FDA has recently announced specific dates by which the rules will be final and they start to become final in August 2015. Additionally, all but two rules (sanitary transport and food defense) are due out in final form by the end of October 2015. These latter two are due out by May 2016. So what this means is that by fall of 2016, these rules will be enforceable. To some, over two years away seems like a long time, but remember these rules are very comprehensive and very complicated, and it is highly likely that if you make food you will be hit by many of them at the same time – so don't wait, get moving now on understanding what you will have to do and which sets of rules will impact you, and start to plan how to implement changes.

Mitigate Your Recall Risk – Response XL

With the vastness of the food supply chain, the possibility of malicious or economic adulteration and unintentional contamination due to simple human fallibility, incidents leading to recalls are a risk that every food and beverage business must face at some point in time. So much so that this risk of recall is deemed a risk that is potentially, or even reasonably, likely to occur (RLTO) under FSMA's proposed rule for Preventive Controls for Human Food. And with FSMA's ratification (see FSMA Adds New Recall Requirement) and today's "Court of Public Opinion" (see Hot Topics), if, or when, a recall must be implemented at your facility, the damage to your brand, reputation and bottom line can be irreparable.

But with preparation and intervention, the risk can be mitigated and your business and brand protected. The best part is – you don't have to do it alone! The services of Response XL will help you assess your situation and build sound prevention strategies, with the aim of reducing your recall losses or avoiding a recall altogether – and it's all a part of your insurance plan. XL Group contributes a portion of the policy premium for pre-incident consulting projects in addition to covering all immediate crisis response costs to protect consumer health and safety, your company and brand.

The **360° Approach**. Mitigating recall risk involves pre-incident preparation for prevention and incident management. Get 360° coverage through focused "AIMing" of the 4 P's: prediction, prevention, preparation and protection.

1. **Predicting** problems that are likely to occur includes assessing your operational risk, reputational risk and regulatory risk. To attain this, your current system is evaluated to identify gaps before they arise, establish early warning and identification systems, and set supply chain controls.
2. **Prevent** recalls, or reduce the impact of crises, through the AIM system of assessment, identification and management (see diagram).

3. **Prepare** for the worst. Despite your best efforts, recalls can happen, and it is critical that you are prepared before they occur. This includes assessing the work flow and food safety systems of your business, developing recall and crisis plans, and conducting full crisis simulations.
4. **Protect** your brand and manage risk by implementing the right solution. Whether you face a potential or actual product contamination due to an accidental contamination, malicious tampering, or economic adulteration, policyholders have 24/7/365 priority access to Live Crisis Response Hotline actively managed by food safety experts at The Acheson Group.

Response XL. In crisis or in calm, XL Group's Product Contamination insurance provides you with financial protection but Response XL provides even more. Response XL helps you drive down your contamination and recall risk through its network of specialist consultants and organizations including public relations firms, quality assurance experts, laboratory services, food safety experts, malicious tamper and security consultants, regulatory and legal advisors, and product retrieval services. Customized to your needs, Response XL provides a pre-incident and crisis expert sounding board, health hazard evaluations, decision-making facilitation, communications expertise, media management, regulatory interaction consumer helplines and post-mortem assessments.

FSMA Adds New Recall Requirements

FSMA includes new requirements and FDA authorities for recalls, some of which went into effect upon the January 2011 signing of the Act, and some that are included in the proposed rules.

Mandatory Recall
Probably the most critical is the new authority FSMA gives FDA, by which the Agency can, for the first time, mandate that a facility recall a food should it not voluntarily do so following an FDA recommendation.

A Written Plan
Additionally, the proposed Preventive Controls rule requires that each food facility have and implement a written food safety plan — including a written recall plan for food for which there is a hazard that is reasonably likely to occur. As FDA notes in the rule, "Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall … and helps ensure critical actions are not overlooked."

As detailed in proposed §117.137(b), the recall plan would need to include procedures that describe the steps to be taken, and assign responsibility for each, including:

- Notify the direct consignees of the product and how to return or dispose of it.
- Notify the public about any hazard as needed to protect public health.
- Conduct effectiveness checks to verify that the food is recalled.
- Appropriately dispose of recalled food.

It is important to note that the above is not an exhaustive table of contents—effective recall plans contain much more than these topics. However these are the "must haves" per FSMA.

HOT TOPICS

@ Foodborne Illness: How do the U.S. and the E.U. compare?
It is said that pathogens don't carry passports, and this is confirmed by the outbreaks and recalls on both sides of the ocean. So which is better (if either)?

@ Proposed Sanitary Transportation Rule Packs a Heavy Load
The last of the seven FSMA rules to be proposed, this one packs an arguably big punch to an otherwise historically under-regulated industry sector — that includes about 83,600 businesses.

@ The Court of Public Opinion
When a product is associated with a recall or linked to an illness or injury, the legal rights and wrongs often matter little to bloggers, tweeters, and the general media who will drag a brand through the muck in their own court of public opinion.

Visit **achesongroup.com/blog/** to read more about these hot topics

GRAS: The Gray Zone between Safety and Secrecy

GRAS – Generally Recognized as Safe – was first defined by the FDA in 1958. But today, more than 50 years later, the term and all its intricacies and pending regulations are still being debated, with increased focus and challenge coming from both government and consumer action groups. What are the issues? And, more importantly, what impact are they having on the food industry?

A Brief History. The 1958 enactment of the FD&C Food Additives Amendment established all food ingredients as categorized into one of three classifications:

- **Prior Sanction –** The specific use and level of a substance in a specific product explicitly approved by FDA or USDA prior to the passing of the Food Additives Amendment.

- **Food Additive –** All substances not exempted by section 201(s) of the FD&C Act that are a component of food or otherwise affect the characteristics of food. Requires a petition process and rulemaking where the regulation will include all applicable uses and limitations

- **GRAS –** Indirectly defined in the United States Code (USC) by excluding them from the formal FD&C Act definition of Food Additives. The substance must be generally recognized by applicable scientific experts and through scientific procedure as safe under the conditions of its intended use. It is important to note, however that the ingredients are considered GRAS for an intended use, at a specific level, in a specific product. That is, caffeine may be GRAS for cola at one level, but that doesn't mean it is GRAS in an energy drink at a higher level.

In the 1960s, new scientific information raised questions about the safety of cyclamate salts which were considered GRAS. As a result, FDA was directed to re-examine the safety of GRAS substances. In addition to doing so, FDA established procedures by which individuals could petition FDA to review the GRAS status of substances not covered in the FDA's 1958 GRAS review. Then, in 1997, FDA determined that it did not have the resources to continue to devote to this petition process, and issued a proposed rule for a GRAS notification process to replace the petition process. That rule is still pending.

In 2010, the Government Accountability Office (GAO) conducted a review and issued a 74-page report, with a listing of areas needing attention and the general finding that "FDA's oversight process does not help ensure the safety of all new GRAS determinations." In 2011, FDA reopened the comment period for the proposed rule. But having made no further progress on finalization since then, the Agency was sued earlier this year by the Center for Food Safety for indefinitely operating under a proposed rule. Despite this, given FDA's lack of resources and budget constraints, it is unlikely that a final rule will be issued in the near future, as other activities are taking priority for FDA – such as the Food Safety Modernization Act (FSMA).

Current Status

Where does this leave the industry? Facing numerous challenges, with the subject of transparency as one key issue of debate. Consumers are seeking full disclosure of all components of a food, while industry attempts to protect proprietary formulations. This balance between food company investment and consumer right to know is proving to be a challenge. If a company withholds proprietary formulas as trade secrets and/or does not disclose chemicals and their safety determinations, there is no way to designate the

ingredients as being GRAS – or not.
In early April, the Natural Resources Defense Council (NRDC) issued a memorandum with a callout of this very challenge, stating, "'Generally Recognized as SECRET' rather than 'Generally Recognized as SAFE' is a better name for the GRAS loophole that has allowed manufacturers to sanction the use of hundreds of chemicals in food that Americans eat every day." As the NRDC paper concluded, "A chemical additive cannot be 'generally recognized as safe' if its identity, chemical composition, and safety determination are not publicly disclosed."
Another issue is the ever-increasing global aspect of the food supply chain, with ingredients and additives sourced from a vast array of foreign suppliers, which may or may not be completely known or disclosed.

Into Tomorrow

Given all this, what should the food industry do today? While we don't know exactly where GRAS is headed, it is safe to say that change is coming. The best way to prepare is to get a handle now on your GRAS vulnerability:

- How many GRAS substances are you using?
- When and how were they determined GRAS?
- Do you have the scientific validation to back up the use, level, and product?
- Do you have any GRAS substances that may now have new science linked to them to indicate new risk profiles, etc.?

If the proposed rule based on notification becomes final, it will provide certain benefits to the industry and consumers as it is less resource intensive for FDA; does not require a formal rulemaking process; would benefit consumers through application of current science, use of biotechnology, and availability of functional foods; and could increase industry profitability through innovations with new and novel ingredients.

On the other hand, with the food industry going by the 1997 proposed rule, it is anybody's guess how many GRAS ingredients are being used in food. This is because the rule, as with the previous petition process, allows companies to determine that a substance is GRAS without submitting a GRAS notice. So we have to wonder — Does this really allow for GRAS safety in today's environment? And are some actually abusing this process? It is this latter concern that is raising shouts among consumer, advocacy groups – and Congress.

It remains to be seen exactly the form that the GRAS process and regulation will take in the future, but we should anticipate that there will be changes and be ready to take on those changes and ensure they are sound public health decisions and are economically viable. Even more importantly, however, we'd advise that you not wait to see what happens, but start planning now for changes to GRAS.

Contact us

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About Us

The Acheson Group, LLC (TAG), led by Dr. David Acheson, is a strategic consulting firm for food and beverage companies and those providing technical support to the food industry. With a focus on strategic risk management, TAG provides the latest food safety consulting insights in a global environment in providing Operational Risk management, Reputational Risk management, and Regulatory Risk services—all with the goal of achieving brand protection. TAG works with all supply chain segments, from farms to manufacturers, retail and food services providers – domestic and foreign – all focused on providing first-rate services in a cost-conscious environment.

Operational Risk

- Supply chain risk evaluation
  - Assess risk of incoming products and suppliers and develop management strategies
  - Raw material specification criteria review
  - Raw material facility management review (storage and handling, etc.)
- Internal operation
  - Design and help implement comprehensive food safety systems
  - Documentation review, desk audits and/or onsite evaluation
  - Sanitation and environmental monitoring testing plan development and data analysis
  - Finished product testing plan development
  - Food safety system review
    - GFSI-related documents
    - HACCP document review and training
    - FDA and USDA requirements
  - Traceability assessments, system design, and training/simulations
- Customer complaint handling
- Food defense vulnerability assessments and food defense plans
- Crisis and recall preparedness
  - Recall plan assessment/gap analysis and plan development
  - Recall training and simulations (end-to-end interactive recall plan test)

Reputational Risk

- Track social media trends for your brand/company
- Learn what consumers are saying about you
- Assist you in staying better informed of the changing food safety & social media risks
- Develop key messages and programs to inform your customers
- Add credibility to your food safety systems
- Identify avenues to create good relations with regulators

Regulatory Risk

- Navigate FDA and USDA food regulations and compliance
- Provide deep expertise on FSMA
- Respond to regulatory issues (e.g., NR, 483, Import alert)
- Assist in responding to a crisis and recalls
  - 24/7 Hotline for immediate help
  - Health Hazard Evaluations of a given situation
  - Assistance with interactions with Local, State or Federal regulators
  - Assistance in composing appropriate messages to customers, the public and the media
  - Develop issue talking points and FAQs
  - Work with the designated spokesperson and/or serve as the spokesperson

Out Reach

The TAG team is also available to conduct training, provide webinars, author white papers, and give keynote and other presentations.

TAG Customers

TAG works with highly successful food and beverage industry leaders – some of the largest in the United States and the world. We have a wide range of clients from recognizable, full-service dining brands to multinational manufactures and processors regulated by FDA, USDA, CFIA and other international agencies. Our clients span farm to fork and include technology companies and service providers looking to assist all sectors of the food industry.