Intentional Adulteration and Food Defense

Industry Preparedness Report

from

THE ACHESON GROUP

Food Protection and Defense Institute
A Homeland Security Center of Excellence

INTRODUCTION

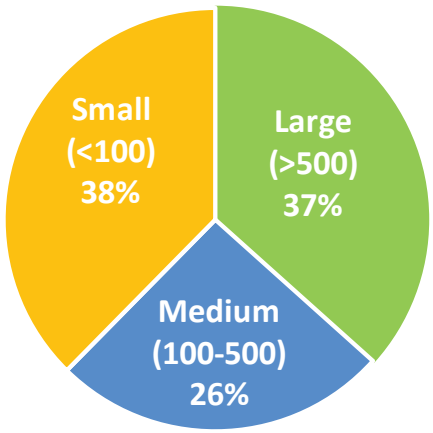
The Mitigation Strategies to Protect Food Against Intentional Adulteration Rule (IA Rule) of the Food Safety Modernization Act (FSMA) is the first regulation requiring food facilities to train employees in food defense and develop a Food Defense Plan (FDP). With the rule's first compliance date of July 26, 2019, quickly approaching, The Acheson Group (TAG) and the Food Protection and Defense Institute (FPDI) were interested in the extent of the food industry's knowledge about, and preparedness for, the IA Rule.

ABOUT THE SURVEY

In September 2018, The Acheson Group (TAG) and the Food Protection and Defense Institute (FPDI) collaborated on a survey of food industry representatives to assess the understanding of and preparedness for compliance with the Mitigation Strategies to Protect Food Against Intentional Adulteration Rule (IA Rule) of the Food Safety Modernization Act (FSMA). The survey — which asked specific questions concerning individual companies' food defense training needs, occurrence of intentional adulteration incidents, and knowledge and use of Food Defense Plans — was broadly accessible on the TAG website and was distributed through email and social media by TAG, FPDI, and media sponsor Food Safety Tech.

To determine this, a survey was conducted. (See *About the Survey*, above.) A total of 250 survey responses were gathered. Respondents indicated that they represented a diversity of food industry roles including growers; retailers; and processors, manufacturers, and distributors. This report reviews the 184 responses from self-identified food processors, manufacturers, and distributors—as this group includes those potentially impacted by the IA Rule — and makes recommendations based on the findings from this group.

Figure 1. Company Size by Number of Employees

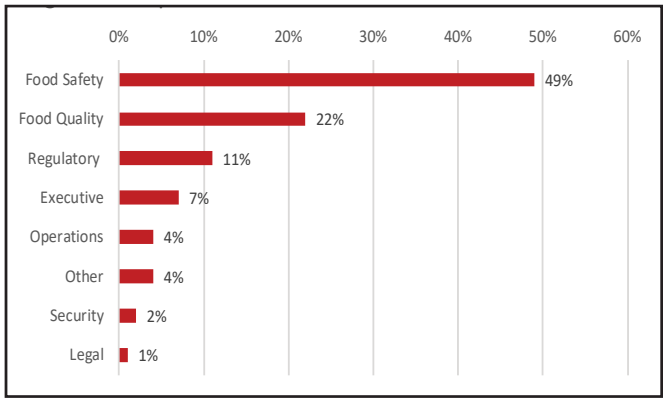


Number of respondents = 184

The food processor, manufacturer, and distributor respondents provided fairly equitable representation of food facility company sizes (Figure 1) and nearly 80% of respondents were located in North America (74% in the United States and 9% in Canada). Approximately, 17% of the food processor, manufacturer, and distributor respondents represented foreign facilities. However, it should be noted that these foreign facilities must also comply with the IA Rule if they produce food for sale within the United States.

Of the food processor, manufacturer, and distributor respondents, 71% held roles typically associated with responsibility for overseeing and implementing the food safety regulations, that is: food safety (49%) and food quality (22%) personnel (Figure 2). While the IA Rule and its Food Defense Plan are components of FSMA, food safety and/or quality experts are not inherently food defense experts, as food safety and food defense are not the same. (See Food Safety vs. Food Defense, page 3.)

Figure 2. Respondent Organizational Role



Number of respondents = 184

INDUSTRY AWARENESS

Being aware of the IA Rule and understanding if the rule applies to the respondent's company is an essential step towards compliance. The survey found that 76% of food processor, manufacturer, and distributor respondents indicated they were covered by the IA Rule.

An equal percentage said they are fully aware of the rule's requirements, with a significant majority, 92%, at least partially aware of the rule's requirements (Figures 3 and 4). Only two of the 139 companies reporting they were covered by the IA Rule indicated they were not aware of the IA Rule, whereas 50% of the 18 companies not covered by the IA Rule were fully aware of the IA Rule.

When evaluating the responses by company size, several trends were identified. Among the large and medium size companies, which are almost certainly required to comply with the

Figure 3. Companies Covered by the IA Rule

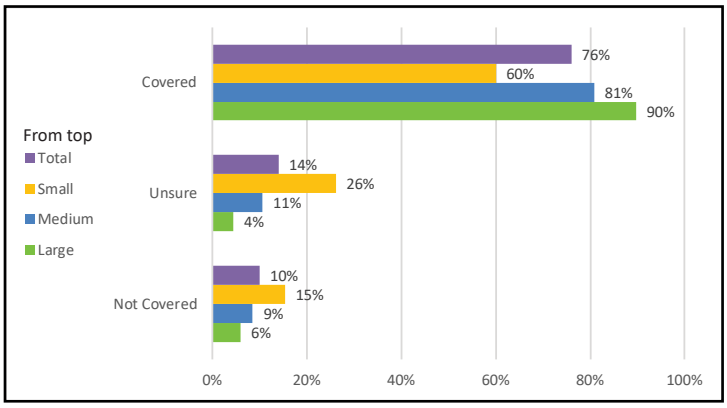
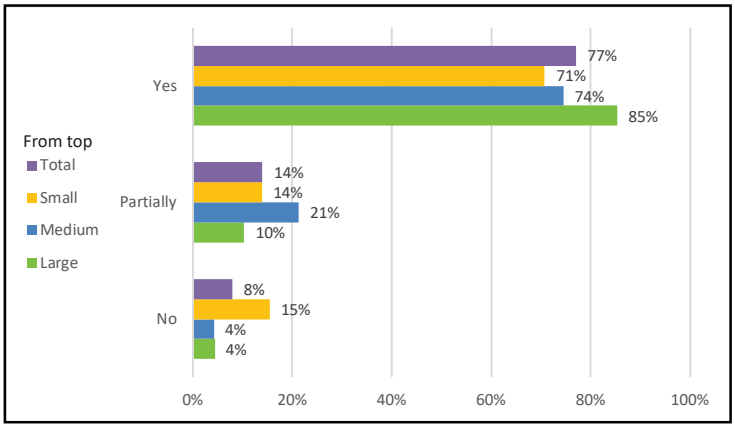


Figure 4. Awareness of IA Rule requirements



Number of respondents (Figures 3 and 4) = 184

FOOD SAFETY vs. FOOD DEFENSE

The difference between food safety and food defense is not always well understood. In brief:

- Food safety is the prevention of unintentional adulteration.
- Food defense is guarding against intentional adulteration.

Food safety incidents occur more frequently, so measures to protect against and respond to them have been standard in the food industry for decades. While intentional adulteration is as old as time, there was little focus on food defense in the United States until after 9/11, and its focus is still often secondary to food safety.

Intentional adulteration can take a variety of forms, including economically motivated adulteration; tampering with food with the intent to cause consumer or company harm; adulteration intended to cause wide-scale public health harm; and other malicious, criminal, or terrorist actions intended to cause damage or disruption to the system. It tends be covert, perpetrated by intelligent adversaries who strive to work around existing safety and security measures. Thus, additional protective strategies are needed to prevent it.

Prevention or mitigation of intentional adulteration is required under several regulations. Economically motivated adulteration is addressed in the FSMA Preventive Controls for Human Food Rule and is, thus, outside the scope of this survey. The IA Rule, the focus of this survey, aims to prevent intentional adulteration from acts intended to cause wide-scale public health harm, including acts of terrorism targeting the food supply.

Food safety and food defense incidents may initially present themselves in similar ways. That is, public health officials become aware of a foodborne illness when clinical cases are diagnosed and linked to a common source. However, distinguishing if the incident was caused by unintentional or intentional adulteration is often difficult. In both cases, food regulatory and public health agencies are typically involved in the response, but food defense incidents involve a criminal act so law enforcement is generally involved in the investigation.

IA Rule if they process or manufacture food for consumption in the United States, 10% of the large companies and almost 20% of the medium companies indicated they may not be covered by the IA Rule. Awareness of the IA Rule was also lower than expected for this group with only 85% of large companies and 74% of medium companies indicating full awareness of the rule less than a year prior to the first compliance dates.

Within the small companies, only 60% indicated they were covered by the IA Rule and 71% indicated full awareness of the IA Rule. The IA Rule contains exemptions for the smallest companies, but without awareness of these exemptions it is difficult for a company to evaluate if they are covered. This is exemplified in the survey responses by 58% of the small companies that indicated they were not covered or unsure if they were covered also indicating they were either unaware or partially aware of the IA Rule requirements.

When considering the responses across company sizes, if a company is unaware of the IA Rule, how can they make the judgement that they are not covered?

With compliance dates quickly approaching for the IA Rule, fully understanding the IA Rule requirements and including how your company is covered is essential. While FDA is likely to take a phased inspection approach, focusing on education around the Rule, ignorance of the law will not be an excuse if FDA shows up at the door and the facility is required to have a Food Defense Plan. (See *The IA Rule In Brief*, below.)

IA Rule Guidance

The FDA released IA Rule Draft Guidance for public comment in June 2018 with an update in March 2019. This guidance, the first and second of three parts FDA plans to publish, is intended to help facilities develop and implement a Food Defense Plan (FDP) in accordance with the IA Rule's requirements.

Guidance documents do not establish legally enforceable responsibilities; rather they describe FDA's current thinking and recommendations. Data from the survey indicates, however, that 22% of the respondents indicating their company is covered by the rule were not aware of the IA Rule Draft

THE IA RULE IN BRIEF

The Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Rule) was published May 27, 2016. It requires FDA-registered food facilities to identify specific vulnerabilities in their facilities that could allow the deliberate introduction of an adulterant into a food. From that assessment, the facility must develop a written Food Defense Plan specific to the facility to prevent or mitigate those vulnerabilities at each actionable process step, that is, where a significant vulnerability exists. The vulnerability assessment, identification of mitigation strategies, and development of the Food Defense Plan must be conducted by a qualified individual.

The IA Rule requires that employees who work at actionable process steps in food facilities have:

- Education, training, and experience to perform their responsibilities.
- Knowledge of the mitigation strategies at their actionable process step.
- Training in food defense awareness.

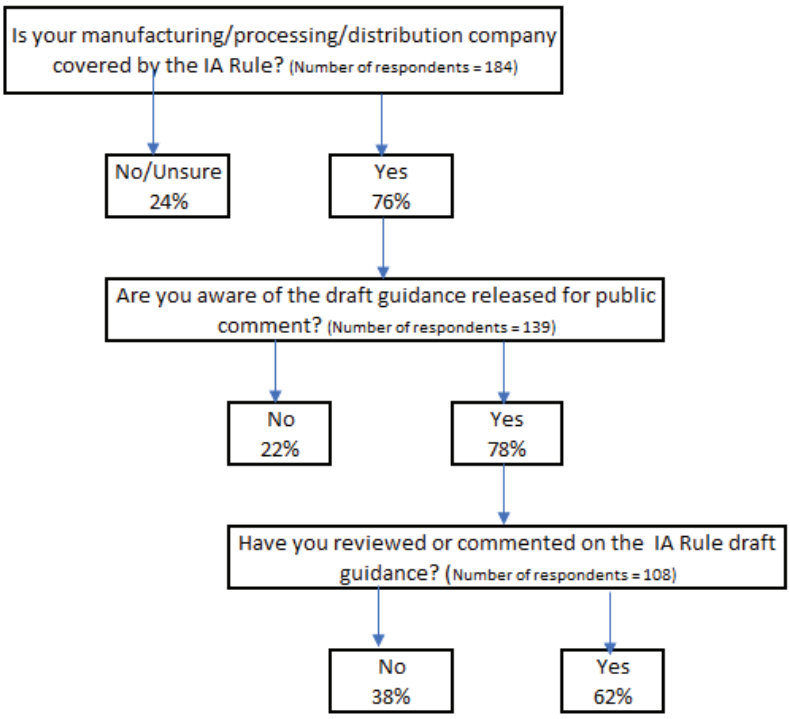
Compliance dates for the IA Rule vary by business size:

- July 26, 2019 - Business that average $10 million or more per year and have more than 500 full-time employees.
- July 27, 2020 - Small businesses which employ fewer than 500 full-time employees.
- July 26, 2021 - Very Small Businesses that average less than $10 million per year are exempt, except that they must, upon request, provide for official review documentation sufficient to show that the facility meets the exemption.

Guidance. And of those that were aware, only 62% have reviewed or commented on it.

Draft guidance documents are important to review. They offer valuable insights for the application of the IA Rule, and they offer opportunity for industry to comment on, and possibly shape, FDA thinking before it is finalized.

Figure 5. IA Rule guidance awareness and review



The first of the IA Rule Draft Guidance documents provides information concerning:

- Components of an FDP and the importance of each component.
- Conducting vulnerability assessments to identify significant vulnerabilities and actionable process steps.
- Identification and implementation of mitigation strategies for the actionable process steps associated with a facility's processes.
- Identification and application of mitigation strategy management components (e.g., food defense monitoring).

The second installment of the IA Rule Draft Guidance provides additions addressing:

- Conducting vulnerability assessments using the three fundamental elements or a hybrid of key activity type and fundamental elements.
- Education, training, and experience.

A third installment of the IA Rule Draft Guidance is expected to address:

- Identification and application of mitigation strategy management components (i.e., food defense corrective actions and food defense verification).
- Reanalysis requirements associated with the FDP.
- Recordkeeping requirements associated with the FDP and its implementation.

Companies that may be covered by the IA Rule should review the draft guidances for FDA's current thinking on rule compliance.

Additional Resources

For more information on the guidance documents:

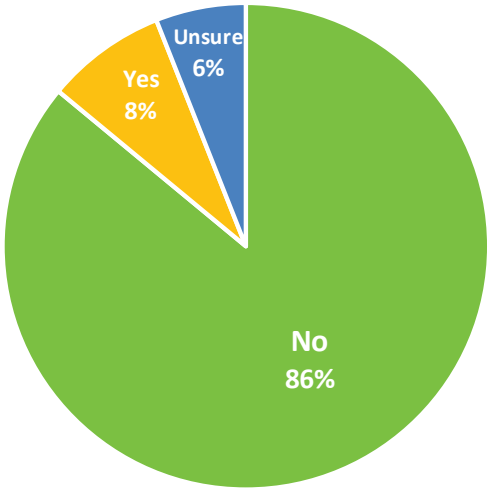
- Review the Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration, June 2018.
- Review the Revised Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration, March 2019.
- Read TAG's discussion of the guidance, Have You Written Your Food Defense Plan? FDA Provides Guidance to Help.
- Attend FPDI's Food Defense Training.
- Contact TAG or FPDI for more information and consultation.

INDUSTRY KNOWLEDGE

The survey also provided insights on the general knowledge of food processors, manufacturers, and distributors related to intentional adulteration incidents — and the actions facilities took when intentional adulteration was suspected.

First, survey participants were asked if they had experienced an intentional adulteration incident (Figure 6). The question focused broadly on intentional adulteration and included both EMA and IA intended to cause wide-scale public health harm. The examples that were given in the survey question focused on adulteration by needles in strawberries (IA potentially covered under the IA Rule) and melamine in infant formula (EMA covered under the Preventive Controls Rule). As a result, the response for this question includes experience with both EMA and potentially IA Rule covered incidents.

Figure 6. Respondents' Experience of an IA Incident

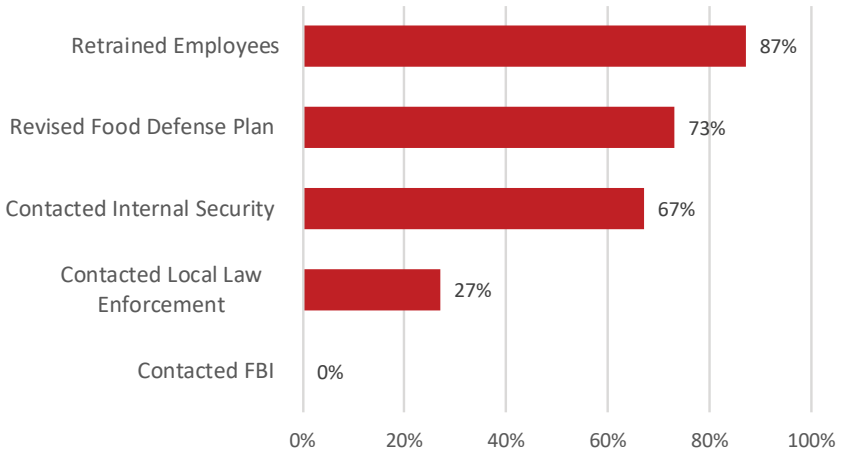


Number of respondents = 184

Even with the inclusion of EMA incidents that are not covered by the IA Rule, 86% of the respondents indicated they had not experienced any type of intentional adulteration incident. Only 8% of respondents indicated that they had or may have experienced an IA incident at their organization and 27% of these IA incidents adversely affected food safety. Of IA incidents experienced, large companies were as likely as the medium and small companies combined to have experienced an incident. This could indicate there is more internal awareness among the larger companies or that those facilities pose a greater risk profile.

When reviewing the actions taken by the 15 respondents indicating experience with intentional adulteration, it appears that many of these incidents may be similar to those covered by the IA Rule (Figure 7). This is due to the collaboration with internal security (67%), retraining employees (87%), and revision of the Food Defense Plan (73%). In significant IA incidents, local law enforcement and FBI would also likely be involved. However, only 27% reported contacting local law enforcement and none reported definitively contacting the FBI although 13% were "unsure" if FBI was contacted.

Figure 7. Actions taken when IA incident suspected.
(Total greater than 100% as respondents were to select all that apply.)



Number of respondents = 15

Having relationships with local law enforcement and FBI is integral to the food defense posture at your processing facility. Food processing facilities regularly prepare for emergency response with the local emergency response agencies (e.g., fire and police). Response to an intentional adulteration event will be an emergency. The time to connect with local law enforcement and FBI is before an intentional adulteration event occurs. It is easier to have a conversation over a cup of coffee about what to expect in the unlikely event of a food defense incident and investigation rather than having a conversation in the midst of a crisis.

The IA Rule's preamble discussion notes the importance of collaboration with external authorities and relevant industry stakeholders in the event of a credible food defense threat. It is important to remember that an IA incident, or a suspected IA incident, is considered a criminal event. According to the online FDA Food Defense "ALERT" training, when a food producer experiences an IA event, or a suspected IA event, the food producer is to:

1. Save any food leftover that may have been affected and place the remainder into quarantine.
2. Contact the FDA.
3. Contact the local law enforcement authorities and/or the FBI.

According to the FBI, there are two dedicated officers per region to investigate IA events. These FBI officers work within the Weapons of Mass Destruction Directorate and work closely with the FDA Office of Criminal Investigations (OCI). OCI conducts the criminal investigation and prosecution in an IA incident. Should an incident reach this level, you will need to cooperate with the FBI by providing them with any information your company may have.

If an IA incident occurs, post-incident training and FDP revision are paramount. In fact, the IA Rule requires reanalysis if there is a significant change within the facility that creates the potential for a new vulnerability or a significant increase in one previously identified, if new information is learned about potential vulnerabilities associated with a food operation or facility, or at least every three years.

Additional Resources

Further resources, consultation, and assistance on proactive mitigation, as well as preparedness plans for IA incidents, are available through:

- **FPDI**. Experts in food defense training programs and stakeholder engagement to address needs at all levels within an organization — entry level to C suite— and across a variety of sectors in food manufacturing, retail, and foodservice.
- **TAG**. Regulatory and food defense experts assist in the development of a robust and efficient food defense system and FDP, including a comprehensive food defense facility vulnerability testing.

INDUSTRY PREPAREDNESS

Survey participants were asked to indicate their top three concerns relative to food defense and intentional adulteration at their organization.

Food processor, manufacturer, and distributor respondents rated employees as their top concern (62%). This aligns with the IA Rule requiring insider attack as a key component of food defense vulnerability. As defined by the guidance, an inside attacker is anyone with legitimate access and can include anyone who is familiar with operations (such as contractors, drivers, equipment repair persons, etc.).

To help address the risk from inside attacks, food processors, manufacturers, and distributors should reflect on their employee concerns including those related to risks associated with the use of temporary or day labor, low employee morale, high employee turnover, or other workforce issues.

Figure 8. Top Food Defense Concerns

Number of respondents = 184

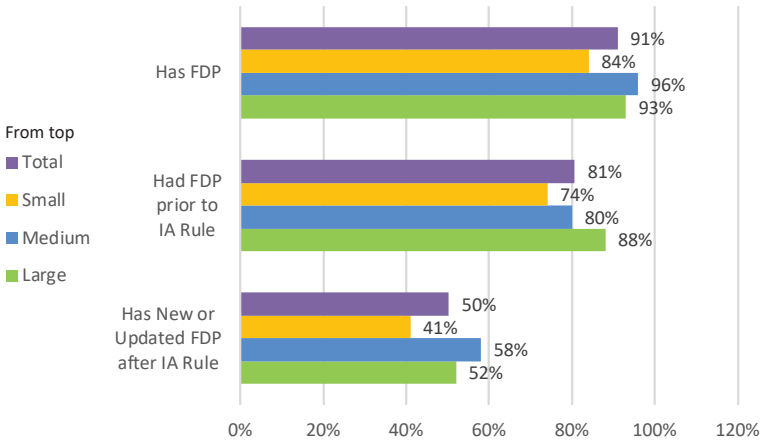
The second-highest (facilities, 45%) and third-highest (training, 39%) rated concerns align with IA Rule requirements for mitigation strategies within facilities and the training requirements for qualified individuals responsible for food defense plans and front-line workers at actionable process steps. Based on several years of FPDI IA Rule food defense training programs, training participants were most concerned about how to manage employees in the context of inside attacker considerations; modifications of facility equipment, flow, processes, and procedures; and how to adequately and efficiently train employees.

Funding for training and management, senior management buy-in, and visitor concerns rounded out the concerns with ratings near 30%. (Management buy-in and support is further discussed on page 11.)

The Food Defense Plan

The preparation of the Food Defense Plan is integral to preparedness and required by the IA Rule. Survey responses (Figure 9) indicate the vast majority of facilities have an FDP (91%) with small differences across the company size categories. Approximately 80% of the respondents with a Food Defense Plan indicated it was

Figure 9. Food Defense Plan Availability and Readiness
Of those covered by the IA Rule, the facility:



Number of respondents: Has FDP = 184; Had prior to rule/Has new or updated = 167

in place prior to the release of the IA Rule. However, many respondents (50%) indicated that their company either developed a new FDP or updated their previous FDP after the IA Rule issued. These FDPs are more likely to be compliant with the IA Rule. Unfortunately, this leaves approximately 50% of the respondents with an FDP that was developed prior to the IA Rule and has not yet been updated. These FDPs may not be compliant with the IA Rule requirements. Companies that developed Food Defense Plans prior to IA Rule finalization need to undergo a thorough review to update their FDP to meet the new requirements.

As noted in the guidance, Food Defense Plans must consider the possibility of an inside attacker and contain the following required components:

- Vulnerability assessment of each point, step, and procedure in a facility's process for each type of food produced.
- Mitigation strategies for each identified actionable process step.
- Food defense monitoring.
- Food defense corrective action procedures.
- Food defense verification procedures.

Current regulations require much more than perimeter fences, locks on gates, and visitor access controls.

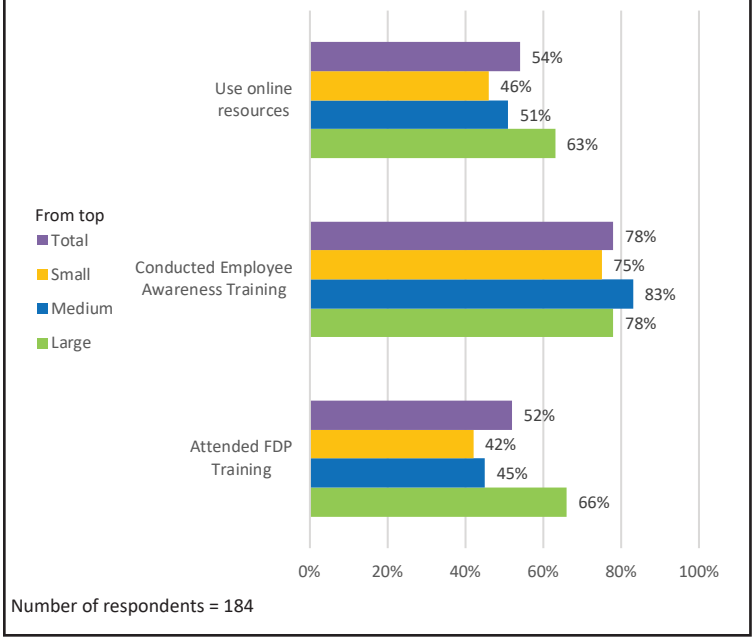
With food defense being a newly regulated requirement, particularly the need to have a written FDP, a number of those surveyed closely equated the FDP to the Preventive Controls-required Food Safety Plan (FSP). This is evidenced by the 63% who felt that implementing and managing the FDP will be as resource intensive as that of the food safety plan which is consistent with the concern about adequate funding for food defense training and management. However, the risk assessment and implementation of relevant mitigation strategies against identified vulnerabilities should not represent an economic burden to any food business and should be less resource-intensive when compared to the drafting and execution of a food safety plan under FSMA.

The IA Rule also requires that each facility must have its own Food Defense Plan. However, of the 75 companies (40%) indicating they have multiple facilities within or import into the U.S., 16% did not have separate FDPs for each facility.

INDUSTRY COMMITMENT

The final set of survey questions assessed overall commitment of food processors, manufacturers, and distributors to the mitigating of intentional adulteration incidents and improving food defense protocols, based on factors such as training, FDP testing, and executive team support.

Figure 10. Food Defense Training and Resource Use



Number of respondents = 184

The IA Rule requires, and guidance further explains, that there are different training needs for different roles in the facility. From awareness training for front-line workers to more comprehensive training for qualified individuals responsible for food defense plans, different team members need varying levels of training or awareness.

As shown in Figure 10, companies are more likely to conduct awareness training than to have personnel attend Food Defense Plan training. This is not really a surprise as in-house training is more economical and efficient, and the FDA Employees FIRST Training has been available for several years. However, the Employees FIRST Training does not contain the food defense awareness components covered by the IA Rule. It will be important for those companies that already have food defense awareness employee training programs in place to update those programs to align with the IA Rule.

Figure 11. Company Understanding and Commitment

OUR COMPANY	YES	NO	UNSURE
Understands the risks related to intentional adulteration and food defense (number of respondents = 182)	70%	12%	18%
Has tested the FDP (number of respondents = 184)	48%	39%	13%
Has calculated the potential risk of an intentional adulteration incident (number of respondents = 184)	21%	60%	19%
Executive team supports the efforts in preparing for and mitigating risk (number of respondents = 182)	77%	9%	14%

With only a little more than half (52%) of respondents having attended food defense training, there is a distinct opportunity for companies to improve their food defense strategy through expert training and consultation. (See Conclusions and Recommendations, page 12.)

Additionally, while it would have been expected for smaller companies to be more likely to use outside resources due to lesser availability within company, it was found that more large (63%) than small (46%) companies used FDA online tools, such as the mitigation strategies database or the FDA Food Defense Plan Builder software. With FDA actively updating these online tools to reflect the IA Rule, it will be essential for companies using these tools to monitor and adopt the versions aligned with the IA Rule.

Risks and Costs

While a majority of respondents indicated understanding food defense associated risks and support from their executive team (Figure 11), there are companies who do not understand or are unsure of food defense risks (30%) and companies that may not have executive support to mitigate food defense risks (23%). This is very concerning, particularly when combined with very few respondents indicating calculation of the potential risk of an incident (21%), and less than half of companies (48%) testing their FDP.

As with any successful initiative, and especially those related to the safety of food and employees, executive support is essential. Just as a company's food safety and worker safety cultures need to be supported and modeled from the top, so too, does its food defense culture. And without such culture, understanding, and commitment, a company leaves itself vulnerable to potential food defense incidents with risk to food safety, cost of recalls, and brand damage.

CONCLUSION AND RECOMMENDATIONS

Compliance dates for the IA Rule are approaching quickly with the first date occurring in July 2019. Companies affected by the IA rule should be working to initiate or update FDPs. Even small companies with later compliance dates are advised to begin working on their plans. The following is a seven-step process to get you started:

1. **Assess**: Consider information already available through past food defense planning efforts. Identify and document where action may be needed. Use the FDA IA Rule Draft Guidance as a roadmap for the next steps in the process.
2. **Plan**: If you have a Food Defense Plan, evaluate and update it for compliance with the requirements of the IA Rule. Include consideration of an inside attacker as required by the IA Rule. If you don't have an FPD, determine who in your company is qualified to develop the plan, and create a timeline for development and review.
3. **Conduct Vulnerability Assessments**: Evaluate and prioritize each point, step, or procedure of the food product to determine where it may be susceptible to intentional adulteration.
4. **Determine Actionable Process Steps**: From the vulnerability assessment, identify the processes during food production where mitigation strategies must be applied to significantly minimize or prevent the vulnerability.
5. **Identify Mitigation Strategies**: Identify mitigation strategies for each actionable process step based on the vulnerability assessment. FDA has a database of mitigation strategies and examples in the IA Rule Draft Guidance that may be helpful. Consider cost and ease of implementation of the mitigation strategies to identify those that will provide the most cost-effective and efficient implementation. Initiate a plan to implement selected strategies.
6. **Evaluate**: Establish how and when the food defense plan will be evaluated. Determine if and when the plan should be challenged or exercised.
7. **Educate and Train**: Different team members need varying levels of training or awareness. Identify who will have a role in food defense and align the appropriate training.

Whether or not you are specifically covered by the IA Rule, and no matter when your company must comply with the IA Rule, a Food Defense Plan will help protect your product against acts of intentional adulteration or outright terrorism — and protect your business and brand as well.

The Acheson Group (TAG) and the Food Protection Defense Institute (FPDI) have the knowledge, experience, and dedicated experts to assist in understanding rule requirements, developing a Food Defense Plan, and reviewing your food defense program. We are here to help.