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June 27, 2014

Department of Health and Human Services
Food and Drug Administration

RE: Comments from the Association of Food and Drug Officials
Docket No. FDA-2013-N-1425, "Focused Mitigation Strategies to Protect Food
Against Intentional Adulteration; Extension of Comment Period"

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The Association of Food and Drug Officials (AFDO) is pleased to provide comments to the U.S. Food and Drug Administration regarding its proposed rule "Focused Mitigation Strategies to Protect Food against Intentional Adulteration".

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AFDO is the preeminent organization of federal, state and local food regulatory officials in the United States. AFDO's membership also includes non-voting representatives from industry, academia, and consumer groups who actively participate in AFDO committees, workgroups, and other organization efforts. During its 117 year history, AFDO has promoted uniform, science-based food safety laws and regulations and is well-recognized for advocating a nationally integrated food safety system that would coordinate government resources at all levels in order to reduce duplication of efforts and allow government officials to meet food safety challenges in a more strategic fashion.

In recent years, AFDO has, also, been very active in addressing food defense challenges and believes these challenges should be handled in a similar integrated, coordinated fashion as advocated for food safety. AFDO notes that most state food safety agencies have been very involved in providing food defense guidance and awareness information to farms and food industries within their jurisdiction. Some states have provided guidance to businesses on how to assemble food defense plans. AFDO has captured many of these plans and guidance documents and placed them into the "Food Protection Information Portal" on the AFDO website www.afdo.org so they may be shared among all food protection officials and agencies. This information may become useful as the proposed rule process evolves.

AFDO's Food Protection & Defense Committee provides a forum to discuss food defense issues, coordinate member food defense activities, as well as identify proactive strategies for protecting the food and agricultural sector critical infrastructure. This Committee actively participated in the development of AFDO's official comments on this proposed rule. Committee members also collaborated with members of the National Association of State Departments of Agriculture (NASDA) to identify areas of shared perspective.

I. General Comments / Concerns

A. AFDO Supports Regulatory Controls To Better Protect Foods From Intentional Adulteration

AFDO agrees that regulatory provisions are needed to better protect our food supply from intentional adulteration. It is important that these controls be risk-based and cost-effective so that implementation of new regulations does not weaken food safety programs by diverting limited resources. The FDA needs to work closely with local, state, territorial and tribal (SLTT) agencies to develop both an appropriately flexible regulatory framework and a workable implementation strategy. The development and implementation of a practical implementation strategy will help achieve the goals under an integrated food safety system (IFSS) should strengthen inspection capacity of SLTT agencies, foster earlier incident detection through improved foodborne illness surveillance, accelerate and improve the effectiveness of multi-agency foodborne illness outbreak responses, improve the effectiveness of partnerships across governments to coordinate food safety and defense resources, and share information on a timely basis.

B. Second Comment Period on Intentional Adulteration Rule

AFDO believes that the final rule will be significantly different than the current proposed rule. AFDO proposes that FDA analyze the comments it receives during the comment period and re-write the intentional adulteration rule based on comments received from stakeholders. The revised rule should be posted as a proposed rule draft for a second comment period prior to promulgating a final rule. AFDO seeks reassurance from FDA that the agency will not promulgate an interim final rule as a means to satisfy FSMA deadlines; an interim final rule is enforceable and does not provide the same level of stakeholder input and comment as a proposed rule.

FDA is encouraged to coordinate the re-publication of the intentional adulteration rule for comment with the produce safety, human preventive control, animal preventive controls, foreign supplier verification, third party accreditation and sanitary transportation rules. All of these rules are designed to work in concert yet have all been issued at different times allowing for only limited opportunity to cross reference provisions among the

rules. For example, while reviewing the Preventive Controls for Human Food Proposed Rule, Economically Motivated Adulteration was expected to be included in the proposed rule for Intentional Adulteration. It was not included in this rule and will now be pushed back into the Preventive Controls Rule. Viewing the two and commenting on all the rules together will be very important. A revised set of rules that incorporates public comment from a second review period would help ensure the success of each individual rule and FSMA as a whole. AFDO maintains that successful FSMA implementation is too important to food safety and defense to hastily promulgate the final rule for one component of FSMA without giving all affected sectors of the food industry, state & local governments and consumers sufficient opportunity to participate in a comprehensive rulemaking process.

C. Truly National Food Protection and Defense Strategy Is Needed

National security strategies have emphasized the importance of comprehensive critical infrastructure risk management strategies that engage all levels of government, the private sector, and other stakeholders. The Food Safety Modernization Act [FSMA] Section 108 National Agriculture and Food Defense Strategy, currently in the Office of Management & Budget [OMB] clearance process, is reported to focus only on federal agency roles.

The expanded scope of regulation brought on by FSMA will take considerable thought, training, learning, education and communication by all parties, to assure successful implementation.

AFDO strongly recommends that the FDA should take the lead in developing a truly national, not just federal, food defense strategy that identifies how FSMA food defense requirements align with other national initiatives within an IFSS. This would include aligning FSMA requirements with those of the Department of Homeland Security. Such a strategy would better define how officials at all levels of government can partner with industry, academia, and other stakeholders. This strategy needs to:

- Address the fact that intentional adulteration can happen at any point along the supply chain by persons with varying motivations,
- Better define how both regulatory and voluntary control measures will be used with the Food and Agricultural Sector,
- Identify and assess the cost-effectiveness of various best practices potentially appropriate for broader application in various segments of the Food and Agricultural Sector,
- Identify how the informational, training, and educational needs of SLTT officials will be addressed relative to food defense,
- Identify how stakeholders can manage food defense risks that cannot be cost-effectively prevented, and
- Align FSMA requirements with other federal and international food defense strategies and initiatives to avoid redundancies and inconsistencies. For example, Economically Motivated Adulteration, regardless of whether it is ultimately addressed within the Preventive Controls or Intentional Adulteration final rules, is a truly international issue that must be addressed at both the national and international levels.

Clear national leadership is particularly needed in the area of food defense for a number of reasons. The FDA has identified the lack of open source information that is accessible to a wide range of public and private sector decision-makers as a potential barrier that must be overcome. Stakeholders have less first-hand experience with protecting the food supply against intentionally introduced contaminants and most public sector food defense specialists are employed by federal agencies. Public health and food regulatory agencies use a variety of information sharing networks that are not always well coordinated. FSMA implementation provides the FDA with the mandate and opportunity to provide national leadership in areas related to food safety and food defense.

It is possible that FDA may need to collaborate with SLTT food safety agencies in order to meet the mandates of this proposed rule yet the oversight for and responsibilities of these agencies is not well defined. SLTT food regulatory programs have extensive expertise working with a broad range of stakeholders to identify and address threats to the food supply. This expertise should be effectively leveraged in the area of food defense. Depending on the number and types of facilities that will fall under this proposed rule and depending on what FDA delegates to SLTT agencies, it is possible that SLTTs may not have the resources to carry out inspections required by this rule. Questions have been raised regarding the mechanisms FDA will use to delegate authority to the SLTTs, whether commissions or credentialing will be required of state personnel conducting the inspections, and how enforcement be handled. It is unclear whether FDA or the SLTTs will conduct compliance efforts and whether there will be graduated sanctions. AFDO recommends that FDA clarify its position on compliance efforts that may be necessary as a result of the proposed rule. FDA should be mindful that SLTTs traditionally include educational assistance in current compliance efforts for food manufacturing and retail establishments.

AFDO recently conducted for FDA a survey of state and local food safety agencies that can help FDA to identify capacity needs for these agencies. This survey was conducted under FSMA Section 205(c)2, which requires FDA to conduct a review of State and local capacities in order to develop and enhance the food safety and defense capacities of State and local agencies. The survey explored both the current capacities and needs of State and Local regulatory agencies in terms of: staffing and expertise to perform food safety and defense functions, laboratory capacity to support surveillance, outbreak response, inspection and enforcement; and information systems to support data management and exchange among regulatory agencies.

Results of this survey should be used to assist FDA in determining which agencies can better help them meet the demands of this proposed rule. The survey information is currently in review through FDA's Office of Partnership [FDA/OP]. AFDO requests the FDA to work with SLTT officials to use these and other data to identify gaps and set capacity development priorities for successfully implement FSMA requirements.

While the focus of FSMA and the proposed rule is on prevention and mitigation, early incident detection and rapid well-coordinated responses at all levels of government and the private sector are an essential component of national efforts to develop a safe, robust, and resilient food supply. This is especially important as the element of criminal intent associated with intentional adulteration requires involvement of law enforcement officials and adds multiple layers of complexity to response efforts. Planning and additional resources need to be dedicated to improving national detection capabilities through the FERN network, and planning, training, and exercising needs to be include law enforcement at all levels of government.

AFDO strongly suggests that FDA continue funding of emergency response capacity development efforts, such as the Rapid Response Team (RRT) Program. The RRT Program serves as a model for developing effective integrated multi-agency and multi-disciplinary responses. Federal and state regulators work together to identify and test new response strategies that align with national priorities. The FDA should consider how to expand use federal/state collaborative projects like the RRT Program as FSMA rules are finalized and implemented.

D. Communication with Non-Federal Partners

AFDO has strongly supported efforts to develop a better Integrated Food Safety System (IFSS). However, many state officials are concerned about the lack of information FDA has provided on the nature of the federal/state cooperation relative to implementation of this and other FSMA proposed rules. Further development and implementation of the Intentional Contamination Rule, and other FSMA rules, will require a coordinated effort from FDA and its SLTT partners. The differences and nuances in state structures and authorities will make

implementation at each a unique challenge. If SLTT and Federal agencies fail to effectively implement FSMA or if qualified establishments are unable to comply, the rules will fail.

Currently, only conceptual discussions between current SLTT and federal food safety personnel have occurred to clarify roles, responsibilities, and resource needs to effectively implement FSMA rules. AFDO understands that the dialogue between SLTT and federal officials will take place independent of the drafting of FSMA rules; however, the structure of these new institutional relationships should be established as soon as possible. We believe that standardized mechanisms of communication between FDA and SLTT governments be established before, during and after final rulemaking to ensure well-coordinated implementation. This information exchange should address both direct (regulatory) and indirect (market driven) impacts of FSMA rules. FDA should continue to participate in forums or question and answer panels at AFDO and AFDO affiliate meetings that are attended by state and local government program managers.

E. Resources and Funding

One of the many challenges that FDA and states will face in implementing FSMA is the availability of funding and utilization of resources. Local and state agency staff are currently challenged to meet existing regulatory food safety requirements. Creating additional Food Defense requirements without increased resources may hinder implementation of FDA's Food Defense rule, could divert resources from food safety activities, and reduce the sharing of information promoting voluntary adoption of Food Defense practices. AFDO challenges FDA to recognize that SLTT regulatory agencies and land grant universities will require additional funding to create and communicate accurate, consistent, and understandable information. Significant and long-term funding will be necessary to add these responsibilities to the existing workload of the states, as they are in a position to more efficiently implement some elements of FSMA. AFDO suggests that FDA consider successful programs, such as the FREE-B Workshops, as it evaluates how to use grant and cooperative agreements to support local and state FSMA-related activities. AFDO requests that FDA provide information regarding how the implementation of FSMA will be funded.

The intent of this regulation is not to require industry and agencies to spend thousands of dollars understanding their roles and responsibilities under the rule and implementing resource intensive food defense programs that drain limited resources from food safety programs. In addition to the mandatory requirements, encouraging industry to continue to implement voluntary programs is a very important part of building a national food defense strategy. State agencies will be in a position to help promote these voluntary programs. It is imperative that FDA provide funding and other resources for outreach, training, education, implementation and enforcement of both FSMA regulations and the voluntary programs that compliment it.

F. Education, Training & Enforcement

AFDO believes that outreach, education, and training will be a critical component for assuring the successful implementation of this and other proposed FSMA rules. Local and state agencies have working networks that overlap in some areas and are complementary in others. Both types of networks are likely needed to share food defense messages and resources spanning the farm-to-fork continuum within the Food and Agriculture Sector. Staff at all levels of government can potentially serve as effective information multipliers if they are provided with timely and practical information that can be shared with industry owners and employees in a variety of formats. Providing cost-effective training options and effective outreach materials for local and state regulatory officials will be important for consistent implementation of FSMA food defense requirements. This will require extensive support by FDA for regulatory staff at other levels of government. Training and education must occur at several levels and must be available to accommodate seasonal variability in operating cycles. Section 209 (21 USC 1012) of FSMA requires that FDA set the standards and administer training and education programs for the employees of state, local, territorial, and tribal food safety officials related to the regulatory responsibilities and policies established by FSMA. While there are legacy inspection and training programs that supported state and local capacity building in the past, the Intentional Adulteration rule introduces new concepts that will require a

new educational support to state and local regulators. Additionally, although these rules will not directly affect many very small food processors, they will have an indirect impact that will drive these requirements to facilities that are exempt from regulation. To minimize the risk of transferring risks to non-regulated firms, it is vital that the FDA vigorously support development and distribution of educational and training resources that support voluntary compliance among very small facilities that are exempt from the regulations. For example, non-federal food regulatory officials often provide extensive educational and outreach efforts and need simple, targeted and engaging educational resources to effectively reach firms under their jurisdiction. Expanding the options for free downloadable and easily modifiable materials to reach a broad range of cultural and language groups is needed.

For these reasons, we believe FDA must engage national public health and food regulatory associations such as AFDO, NACCHO, NASDA, AAFCO, and land grant universities in the development of outreach and education programs to provide the necessary training and preparation to meet the mandates of the proposed rule. Failure to do so will result in inconsistent implementation by industry and inconsistent compliance & enforcement by regulatory agencies, including FDA.

Alliances have been successfully used to support implementation of other national requirements including other FSMA proposed rules. AFDO recommends that the FDA consider formation of an Alliance structure for the area of food defense as well. FDA food defense training materials (example: Food Defense 101, FIRST), while valuable resources, should be revised and additional training materials developed with the goal of providing a range of resources that are simple, targeted, culturally and linguistically appropriate and customizable to a variety of food workforce audiences. Local public health professionals can play an important role in information sharing and outreach. AFDO suggests that FDA consider use of education and outreach models used during implementation of previous regulatory changes such as the seafood HACCP and juice HACCP programs. Any training that is developed should be uniform and easy to access. These are areas that a formalized Alliance could also be helpful in.

II. Specific Comments / Concerns

A. Focused Mitigation Strategy

AFDO agrees with the general direction of the proposed rule to target focused mitigation strategies at high vulnerability processes instead of setting requirements for broad mitigation strategies for food defense. Requiring broad mitigation strategies would be far reaching and require significantly more capital investment from industry, while not directly protecting the most vulnerable processes. AFDO recognizes that limited resources are a factor when considering the impact of the proposed rule. While broad mitigation strategies are best practices among industry, when mandated by regulation they may pull essential resources from other programs that pose a higher risk to public health. For example, facilities may choose to spend resources on general security, like putting up fences around the building, instead of focusing on the processes with the highest vulnerabilities, like liquid storage tanks. Therefore, AFDO agrees, in general, that the focused mitigation strategy will allow industry to prioritize food defense efforts on the processes with the highest vulnerabilities.

However, throughout the industry there are cases where broad mitigation strategies have already been implemented to minimize the risk of key activity types. If facilities can justify that the nature of their process combined with broad mitigation strategies effectively minimize the risk of an attack, the broad mitigation strategies should be considered acceptable. Facilities should not be required to add focused mitigation strategies if risks have been minimized to an acceptable level by broad mitigation steps. This type of situation could be addressed through 121.130(b) vulnerability assessment. A vulnerability assessment conducted by a facility may be able to justify that certain processes do not represent actionable process steps due to the risk level of the product combined with broad mitigation strategies, even if some of the key activity types identified in 121.130(a) are present.

AFDO agrees with the need for continued encouragement of the implementation of broad mitigations strategies on a voluntary basis. FDA should continue to create and promote resources for industry to implement broad strategies that will continue to incrementally expand food defense plans at facilities that supply food into the US.

B. Key Activity Types

In the Proposed Rule, FDA has identified four key activity types that would require focused mitigation strategies and requested comment on these strategies. These activities present significant vulnerability of intentional adulteration caused by acts of terrorism and include: Bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, mixing and similar activities. AFDO agrees with the inclusion of these four activity types in the rule to cover section 420 of FSMA. AFDO also requests that FDA continue to develop and promote guidance that will encourage industry to expand mitigation strategies beyond the four key activity types.

C. HACCP Type Regulatory Approach

A primary question we have is whether the HACCP type, prescriptive approach outlined by FDA in this proposed rule is the appropriate approach for a wide range of facilities. As FDA points out, HACCP systems are most appropriate for standardized and relatively controlled processes for which data is available to assess both the probability of various hazards and the impact of process changes on those probabilities. While HACCP is universally accepted for food safety in many food processing industries, AFDO is not convinced that this systematic approach will cost-effectively address food defense concerns. Safeguards for intentional contamination may involve placing physical barriers in place to prevent an attacker from intentionally introducing a harmful agent into a food or feed. It also includes awareness and education of employees to respond to any suspicious activity they may observe. Food defense plans would require documentation of who is responsible for the plan; facility/location access information for employees/ visitors/ contractor; methods to protect sensitive processing points and secure raw material storage. We believe this is much different from food safety where critical control points are identified and a specific and prescriptive approach to controlling hazards is taken. The proposed rule provided relatively limited information on verification. AFDO is specifically interested in to what degree FDA intends to rely on documentation to assess adequacy of control under non-standardized, multi-purpose production and processing environments. AFDO questions if HACCP type documentation systems that would be required to support verification by regulators and auditors will tangible or cost-effective public health benefit. We request FDA clarify what type of enforcement strategies and triggers the FDA intends to use for noncompliance with various documentation issues in a wide range of food facilities.

D. Vulnerability Assessments and Food Defense Plans

The proposed rule requires facilities to develop a written food defense plan. This is not a new concept as both federal agencies (examples: FDA, USDA Food Safety Inspection Service, Department of Homeland Security), and third parties (examples: Global Food Safety Initiative, World Health Organization) have provided guidance in this area. However, the plan detailed in the proposed rules has some inconsistencies with other programs including the FDA's own Food Defense Plan Builder tool (example: certain requirements for monitoring corrective actions, and verification activities). Food Defense Plans required under this rule should be consistent with existing programs unless the new requirements can offer an addition level of public health protection. AFDO requests that FDA clarify how the rule's requirements will build on and align with other food defense initiatives and resources.

Qualified firms that do not choose to use the four key activity types to identify actionable process steps can conduct their own facility-specific vulnerability assessment as proposed in §121.130(b). It is unclear; however, what would be considered a "scientifically sound" vulnerability assessment and who would make this determination. Also, if a qualified firm determines there is no vulnerability, what type of justification would be

required to verify this opinion? The proposed rule also states that vulnerability assessments should be performed by a person qualified by experience and/or training but this term is very subjective and unclear. AFDO would recommend clarification of what a qualified individual would be.

E. Section 418 and Section 420

Intentional adulteration is included in three sections of the statute, 418, 419 and 420. The FDA determined that activities under section 419 (Produce Safety) would not be covered by the rule. Therefore, the proposed rule contains a combination of provisions under sections 418 (Preventive Controls) and 420 (Intentional Adulteration). This combination has created complexity with the proposed rule that could be eliminated by disconnecting acts intended to cause massive public health harm from section 418 and covering them solely under section 420. Although section 418 does contain the language “including acts of terrorism” within the hazard analysis, AFDO does not believe Congress intended to add this level of complexity to the rule and create new work that is inconsistent with materials previously created to address food defense. Therefore, facilities that have pro-actively followed FDA’s guidance and voluntarily implemented these programs will not meet the requirements of this rule. If these new requirements represented a clear reduction in risk compared to the previously released guidance, then that would be acceptable. However, it appears these new requirements were included in the rule as a consequence of the language written into the statute.

AFDO requests that FDA disconnect acts of intentional adulteration with the intent to cause massive public health harm from section 418 and strictly cover them under section 420. AFDO believes it would be within the charge of the statute to make this change. One key difference between sections 418 and 420 is that section 418 requires the facility to identify hazards related to intentional adulteration while section 420 requires the FDA to identify vulnerabilities that could result in serious adverse health consequences. Due to the confidentiality of information that serves as the basis for the FDA assessments, it would be more appropriate for the FDA to perform the assessment for acts that could cause massive public health harm and for the facility to perform an assessment for other types of intentional adulteration that may be specific to a facility and are outside of the FDA’s assessment. This would avoid some of the confusion related to dual definitions for terms like very small business and modified requirements and would not mandate provisions that are inconsistent with current guidance, like monitoring, corrective actions and verification .

FDA could use the same logic as the food safety rules under section 418. In the proposed Preventive Controls Rule for Human Food, only hazards that are “reasonably likely to occur” fall under the preventive controls requirements. If the same criteria applied to intentional adulteration, then acts intended to cause massive public health harm would not be considered “reasonably likely to occur”, as they are expected to be very rare. Therefore, these acts would not fall under section 418, but they would be covered by section 420. Any other types of intentional adulteration that would be considered “reasonably likely to occur” would then fall under the provisions of 418 covered by the Preventive Controls Rule. AFDO believes the FDA could create a program that addresses the same risk as the proposed rules strictly under section 420, but avoid undue complexity and requirements.

F. Records – Retention and Access

FDA should provide sufficient flexibility for records retention schedules to accommodate current and future technologies used as part of food defense plans (examples: CCTV, card key readers).

FDA should also work with industry, SLTT , and other partners to develop guidance to ensure that the content of food defense plans and associated records will be protected from disclosure at the local, state, federal, and industry levels. We have very strong concern with this matter.

G. Scope and Coverage of the Rule

The Intentional Adulteration Rule addresses acts intended to cause massive public health harm. AFDO recognizes that FSMA charges FDA with implementing risk-based controls to protect against intentional adulteration and that different approaches are needed to address the various types of intentional adulteration. AFDO is concerned that focusing regulatory controls solely on acts of terrorism intended to cause massive public health harm, without also strengthening technical and educational support for voluntary implementation of controls for other sources of intentionally introduced adulteration, will leave our food supply at significant risk. For example, one of the intentional food contamination episodes mentioned in this proposal is the poisoning of 751 people in 1984 by cult members in The Dalles, Oregon, who aimed to influence local elections by contaminating salad bars with Salmonella. Forty-five individuals were hospitalized in that case, but none died. The rule's implementation however would not have impacted this event as restaurants are not covered. If regulatory requirements do not include the retail level, As the retail level is not immune to acts of terrorism, AFDO requests that the FDA clarify how it intends to work with stakeholders to strengthen educational, training and outreach resources to assist both regulators and industry with voluntary implementing of appropriate risk reduction measures.

AFDO, encourages FDA to work with stakeholders to better define strategies to reduce intentional contamination risks due to acts by disgruntled employees, competitors, or consumers that are not being covered under the final Preventative Controls or Intentional Adulteration rules. In our view, FDA's exclusion of disgruntled employees, consumers, or competitors is not a true exclusion. The rule reads "Action taken to mitigate the potential for a terrorist attack against the food supply are likely to have collateral benefits in reducing the potential for an attack by a disgruntled employee, consumer or competitor." If FDA does not want to label a disgruntled employee a "terrorist", they should revisit Section 103 of FSMA which directs "...facilities to consider hazards that may be intentionally introduced, including by acts of terrorism." FSMA does not explicitly link intentional adulteration to terrorism alone.

H. Exemptions

AFDO does not typically support exemptions because they are difficult to enforce. With this proposed rule, FDA has determined that larger companies are at higher risk for intentional contamination, and in keeping with FSMA's risk-based approach, the proposed rule would only apply to facilities with more than \$10M in annual food sales. How would this monetary amount be determined and who would verify it for FDA?

Carriers

The FDA requested comments on the tentative conclusion that the measures implemented by shippers and receivers of bulk liquids would sufficiently protect from intentional adulteration and that no further actions by a carrier would be needed. AFDO requests that the FDA clarify the expectation for situations where only one of the entities involved is covered by the Intentional Adulteration Rule. For example, the shipper is covered, but the receiver is exempt due to size or vice versa. How would the rule apply to the three entities (shipper, carrier and receiver) in that situation? The Sanitary Transportation Rule exempts carriers under \$500,000 in total annual sales. AFDO believes a closer look into exemptions of carriers may be needed by FDA.

Also, AFDO does have concerns about the vulnerability of product during transit. This is one of the most vulnerable stages in a process, as product is not protected by a secure facility. Product may often be parked at a truck stop or other unsecure locations for extended periods of time. This provides the opportunity for an outside attacker to gain access to product without gaining access to a secure facility. AFDO understands that covering carriers under this rule may not be the best approach to addressing these concerns, but AFDO believes FDA should continue to develop materials and promote voluntary standards for carriers during transit.

I. Definitions

General

Within the proposed rule, several definitions contain language that will have a wide range of interpretations. For example, the definition of actionable process step contains the words “Significant Vulnerability” and is “Acceptable Level”. Although there is a definition for significant vulnerability, it requires assessment from a “prudent person knowledgeable about food defense”. Therefore, the term has a wide range of possible interpretations. The definition of focused mitigation strategies contains “reasonably appropriate measures” and “person knowledgeable about food defense”. Significantly minimize includes the term “acceptable level”, which is not defined. AFDO requests that FDA further define these terms and provide additional guidance that can be used by both SLTT staff and the private sector to ensure consistent implementation. FDA guidance will need to consider the entire breadth of food defense. The Intentional Adulteration Rule is new territory for many regulators and industry. Terms such as “significant”, “acceptable”, “prudent” and “knowledgeable” will mean very different things to different people based on their level of experience related to food defense.

Qualified facility

The definition of a qualified facility is very confusing in the proposed rule. AFDO understands the definition was pulled directly from Section 418 of the statute, but part (2)(i) and (ii) do not seem to have any purpose within the proposed rule. In part (1), a very small business is a qualified facility, which is defined as a business with less than \$10,000,000 in annual sales in this proposed rule. Or, under part (2), the business has less than \$500,000 in annual sales with over 50% sales to a qualified end user. Since the sales volume for a very small business is greater than the criteria described under part 2(i) and (ii), under what condition would the criteria of part (2)(i) and (ii) apply? AFDO requests that the FDA clarify whether there are any conditions where a facility that meets the criteria for a very small business must also comply with part (2)(i) and (ii).

Very Small Business

Throughout the proposed rules FDA has released for public comment, the definitions of very small business has been inconsistent from one rule to the next. AFDO understands that this is due to the language within the statute. However, it will be very challenging for businesses to understand that they are a very small business under one rule, but not the others. Many businesses will fall under at least three of the rules and in some cases, five of the rules may apply. It will be challenging for all parties involved to maintain a clear understanding of which very small business definition applies in any given situation. AFDO suggests using one consistent system for defining business size across the seven rules, but applying various size categories to different rules. For example, FDA could define business Tier 1 – 8 using the values below.

Tier 1 = less than \$25,000

Tier 2 = \$25,000 - \$250,000

Tier 3 = \$250,001 - \$500,000

Tier 4 = \$500,001 - \$1,000,000

Tier 5 = \$1,000,001 - \$2,500,000

Tier 6 = \$2,500,001 - \$10,000,000

Tier 7 = >\$10,000,000 but less than 500 employees

Tier 8 = Greater than 500 employees

Facilities and regulators could then categorize each company under one consistent system and map out how the rules impact that tier. See the chart below as an example:

Tier	Produce Safety Rule	PC Human Food	PC Animal Food	Intentional Adulteration	Sanitary Transportation	FSVP
1	Exempt	Modified Requirements 3 year compliance date	Modified Requirements 3 year compliance date	Exempt	Exempt	Exempt
2	Modified Requirements 4 year compliance date	Modified Requirements 3 year compliance date	Modified Requirements 3 year compliance date	Exempt	Exempt	Exempt
3	Covered 3 year compliance date	TBD once <u>very small business</u> is defined.	Modified Requirements 3 year compliance date	Exempt	Exempt	Exempt
4	Covered 2 year compliance date	TBD once <u>very small business</u> is defined.	TBD once <u>very small business</u> is defined.	Exempt	Covered 2 year compliance date	Covered 6 months after PC or Produce Safety Rule
5	Covered 2 year compliance date	Covered 2 year compliance date	TBD once <u>very small business</u> is defined.	Exempt	Covered 2 year compliance date	Covered 6 months after PC or Produce Safety Rule
6	Covered 2 year compliance date	Covered 2 year compliance date	Covered 2 year compliance date	Exempt	Covered 2 year compliance date	Covered 6 months after PC or Produce Safety Rule
7	Covered 2 year compliance date	Covered 2 year compliance date	Covered 2 year compliance date	Covered 2 year compliance date	Covered 2 year compliance date	Covered 6 months after PC or Produce Safety Rule
8	Covered 2 year compliance date	Covered 1 year compliance date	Covered 1 year compliance date	Covered 1 year compliance date	Covered 1 year compliance date	Covered 6 months after PC or Produce Safety Rule

Secondary Ingredient Handling

In the preamble, the FDA has requested comments on ways the proposed regulation can be further focused on foods that present a high risk of intentional adulteration caused by acts of terrorism. One area of the proposed rule that may expand the number of foods covered by the rule is the definition of the key activity type, secondary ingredient handling. The activity is defined as “staging, preparation, addition, or rework step where a contaminant can be intentionally introduced into a relatively small amount of ingredient or rework and, if it is, it is likely that the contaminant will be distributed into a larger volume of food”. This definition contains some vague terms and could be interpreted to include many different processes that do not present a high risk for intentional adulteration.

Small Amount of Ingredient and Larger Volume of Food

The terms “small amount of ingredient” and “larger volume of food” can have a wide variety of interpretations. A company with \$10,000,000 in annual sales will view “small” and “large” very differently than a company with \$500,000,000 in annual sales. The two terms can also have a variety of interpretations regarding the ratio of ingredients for what constitutes “small” into “larger”. It may be interpreted by some that if the ingredient makes up less than 50% of the product, it is a relatively small amount that will contaminate a larger volume of food. Others may decide the ingredient must be less than 1% of the total formula to meet this definition. AFDO requests that the FDA better define these terms to narrow the range of interpretation and further focus the rules on foods that present a high risk of intentional adulteration caused by acts of terrorism.

Additionally, many different types of food could fall under this category. For example, steps within the process of making protein/diet bars would fall under this activity type. These products have a long shelf life, typically low serving size and targeted intended consumer. These factors may make them a lower risk for intentional adulteration. AFDO requests that FDA consider and include other factors under this key activity type to further focus the rules on foods that present a high risk of intentional adulteration caused by acts of terrorism.

Low-risk on-farm activities

Since the FDA performed a separate risk assessment under the Preventive Controls Rule for on-farm activities, there are now two categories of “low-risk” on-farm activities. There is low-risk from a food safety perspective which will impact coverage of the PC rule and low-risk from a food defense perspective which will impact coverage of this rule. Both these terms will apply to the same facilities and it will be challenging to get farmers to understand that a specific activity is “low-risk” for section 420, but not “low-risk” for section 418. AFDO requests that FDA use “low-vulnerability” or other terminology to define low-risk from a food defense perspective.

J. Economically Motivated Adulteration (EMA)

It is AFDO’s view that FDA must cover EMA within the FSMA rulemaking process. The proposed rules that include EMA must be released for public comment prior to being included in any of the final regulations. Although the intent of EMA is not to cause public harm, human illness and death can result due to unintended consequences. AFDO, in general, supports FDA’s proposed approach for dealing with economically motivated adulteration within the preventive control framework as it is fundamentally different than intentionally introduced contamination that is intended to make produce great public health harm. However, AFDO is opposed to exempting Seafood and Juice facilities from any EMA regulations. AFDO suggests FDA update 21 CFR parts 120 and 123 to include EMA requirements in order to address these industries that are exempt from the rule. Education, training and outreach activities related to EMA should be developed to support implementation and could be included within an Alliance structures. For example: some universities are already offering massive open online courses (MOOC).

K. Dairy Farms

Dairy farms are not covered in the proposed rule. However, the preamble discusses potentially covering dairy farms in the final rule and requests comments on mitigation strategies. AFDO recognizes the risk posed by intentional adulteration on dairy farms. However, addressing that risk through the FSMA rulemaking process is not the most effective way to reduce risk and effect change in the industry.

It is the view of AFDO that FDA should consider any new standards for dairy farms go through the NCIMS process and be implemented through the Pasteurized Milk Ordinance [PMO].

If FDA intends to cover dairy farms in the final rule, there must be a comment period for that provision. Dairy farms are exempt from the proposed rule, which means many stakeholders in that industry may not be analyzing this rule as carefully as they would if it directly impacted them. FDA has released a very large quantity of rules and information in the recent past and many stakeholders struggle to stay up to speed on all the information. Therefore, it's expected that many people filter this information and focus on the rules that will directly apply to their industry. Since dairy farms are exempt from the proposed rules, many stakeholders may not have read the fine print to realize that they could in fact be added to the final rule. Adding a whole new industry into the final rule should be considered a significant change to the rule and an additional comment period should be allowed in order to get the rules right. AFDO also suggests that any new dairy industry requirements for EMA go through the NCIMS process and be implemented through the PMO.

L. Imports and Ensuring Regulatory & Food Safety Equality

AFDO requests that FDA clarify what steps it will take to ensure consistent food defense regulation of both domestic and foreign facilities.

AFDO recognizes that imported foods present a distinct challenge to the FDA; enforcement can be impacted by limitations in FDA authority overseas. The intentional adulteration rule poses unique challenges due to the confidentiality of information in Food Defense Plans. If this information is not properly protected, it could result in an increased risk to public health. As a result, AFDO recognizes that parity and equal enforcement of the regulations may require the FDA to adopt different enforcement mechanisms to ensure that all manufacturers, regardless of location, are subject to the same requirements and enforcement provisions. Regardless, the FDA must assure that the regulation of imported foods is consistent with the regulation of domestic food. FDA must ensure that the intentional adulteration rule is applied equally to both domestic and foreign producers with parity and consistency in enforcement. Domestic facilities should not be placed at an unfair disadvantage when competing against products, ingredients or raw materials sourced from foreign suppliers.

AFDO is concerned that food produced abroad and imported into the United States will not be subject to the same food defense requirements as domestic facilities. As a result, domestic industry will be placed at an unfair disadvantage when competing against firms importing food from other countries. Import rules and inspection and compliance programs must ensure parity and consistency between domestic and foreign facilities. It is equally important that FDA continue to coordinate FSMA rules closely with requirements of and initiatives of the Department of Homeland Security. Examples include: Customs-Trade Partnership Against Terrorism (C-TPAT) and the Chemical Facility Anti-Terrorism Standards (CFATS)

M. Low-Risk On-Farm Activities

The preamble to the proposed rule contains a request for comment on whether the FDA should exempt on-farm manufacturing, processing, packing, or holding of the foods identified as having low-risk production practices when conducted by a small or very small business if such activities are the only activities conducted by the business that are subject to section 418 of the FD&C Act. AFDO believes activities that have been identified by FDA as low-risk for small and very small businesses should be exempt from the rule. Several of the activities would fall under the definition of “farm” activities if they were conducted on Raw Agricultural Commodities (RAC’s) grown on a farm of the same ownership. As “farm” activities, they are exempt from this rule due to the fact that the statute states that section 420 (Intentional Adulteration) does not apply to farms and the fact that FDA has chosen to exempt activities that fall under section 419 (Produce Safety Rule). Performing the same activities on RAC’s that were grown on a farm of a different ownership does not appear to significantly increase the vulnerability of the process. This is supported by the fact that FDA has classified them as “Low-Risk” within their risk assessment. Therefore, if these activities were covered by the rule, it would not be because they pose a high risk of intentional adulteration. It would be due to a technicality in the way the term “farm” is defined. Due to these factors, AFDO requests that FDA exempt on-farm manufacturing, processing, packing, or holding of the foods identified as having low-risk production practices.

In addition to the comments above, AFDO requests that FDA exempt the same activities when they take place at a location that is off the farm. Unless FDA has reason to believe that moving from an on-farm location to an off-farm location will significantly increase the vulnerability of these activities, AFDO does not believe they should be covered by the rule. AFDO recommends that the FDA consider previous collaborative assessments made in collaboration with industry and state agencies, such as the Strategic Partnership Program Agroterrorism (SPPA) Initiative, when making these assessments. As stated earlier in this document, AFDO agrees with FDA’s approach for focused mitigation strategies at high vulnerability processes. Since the processes in question have been identified as low-risk, AFDO believes covering them would be inconsistent with the FDA’s approach to this rule and may require duplicative tasks and/or documentation requirements without additional public health benefit.

N. Confidentiality

AFDO has several concerns regarding the confidentiality of information related to food defense. The obvious concern is with food defense plans becoming public record once in FDA’s possession. This concern must be addressed by the FDA and measures must be taken to prevent food defense plans from becoming documents that can be accessed by the public. There are also other concerns that may be harder to address. When enforcing this regulation, how will inspectors document non-compliances? Typically, non-compliances are recorded on inspection reports and those inspection reports become public documents. If food defense related non-compliances are noted by an FDA inspector and become public record, it could increase the risk to public health by providing valuable information to a would-be attacker on the deficiencies of a facilities food defense plan. Any written information from inspectors on food defense must be kept separate from food safety items and must not become public record. FDA must also develop a national strategy to address this concern among states. It is expected that states may eventually adopt these standards into state law. Therefore, the concern expressed above would also hold true for state inspection systems. If a state were to adopt this rule into state law without first protecting the food defense information from becoming public record, it could increase the risk to public health.

In addition, The FDA should develop guidance and training for industry on how to protect food defense related documents. If FDA requires the creation of very sensitive documents and then have staff reviewing and evaluating them, FDA must ensure that these records are not disclosed. However, there are also concerns about information outside the FDA’s control. This rule will require industry to develop documents that could pose a significant risk to public health if in the wrong hands. Therefore, FDA should also take measures that will help

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industry protect the documents required by this rule. Even though this information is outside the FDA's control, it's being developed to meet an FDA requirement and has the potential to increase risk to public health. Therefore, FDA must take measures to help industry protect this information.

AFDO appreciates the opportunity to share these comments with FDA.

Respectfully submitted,

A handwritten signature in black ink that reads "David Read". The signature is written in a cursive style with a large, prominent initial "D".

David Read
AFDO President