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IDFA
INTERNATIONAL DAIRY FOODS ASSOCIATION SM

Via electronic submission

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-1425 (RIN 0910-AG63); Focused Mitigation Strategies to Protect Food Against Intentional Adulteration; Proposed Rule; 78 Fed. Reg. 78014 (Dec. 24, 2013)

Dear Sir or Madam:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a $125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's nearly 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

IDFA and NMPF support FDA's efforts to address intentional adulteration of our food supply (also referred to herein as "food defense"). FDA's proposed rule is the first its kind, as intentional adulteration of food has never previously been the subject of regulation in the United States. The food industry's focus on food defense issues is relatively new, having only developed out of necessity following the terrorist attacks of September 11, 2001. As there is no existing precedent to follow for regulating food defense activities, the most effective food defense strategies are continuously evolving while the government and industry learn more about potential threat sources and mitigation techniques.

At the outset, we want to emphasize the success that voluntary efforts in this area have achieved in the absence of a regulatory mandate. What our industry has been doing voluntarily to prevent intentional adulteration has been working. To the best of our knowledge, since September 11, 2001, there has not been a credible threat against, nor has there been an incident of massive public health harm involving the US food supply. Accordingly, the agency should proceed with caution and address regulation in this area one step at a time. Our experience has taught us that there are many different ways to effectively manage food defense programs, which is why we are concerned by the prescriptive nature of the proposed rule that focuses only on a narrow scope of activities and mitigation strategies.

Our comments include the following points:

- The context of the current circumstances surrounding intentional adulteration, the state of the intelligence and how FDA can communicate it to the dairy industry, and the dairy industry's use of mitigation strategies.
- Our general concerns with the proposed rule, and why we believe it is important for FDA to fundamentally reconsider its proposed approach.
- The approach that we think FDA should take instead. We support a requirement that every registered facility (unless exempt) conduct a vulnerability assessment and then implement mitigation strategies for any significant vulnerabilities that were identified, applying practical and tailored management oversight as needed. It should be acceptable for the vulnerability assessment to be conducted prior to publication of the final rule, and FDA should deem a facility to be in compliance if that facility participated in a government-led vulnerability assessment process.
- The dairy industry already has robust mitigation strategies in place.
- Recordkeeping matters need to be reconsidered, including the need to prohibit copying of food defense documents by FDA investigators.
- We have several other issues of concern, including our request that FDA re-propose this regulation to allow stakeholders an opportunity to comment on any modifications the agency plans to make in response to comments.

I. The Context of Intentional Adulteration in Today's World

In the preamble to the proposed rule, FDA identifies a number of "Incidents of Intentional Adulteration" that have occurred—ranging from The Dalles, Oregon salad bar contamination, to contaminated pastries in a medical facility, to salsa contamination at a restaurant, to an incident of economically motivated adulteration (namely the addition of melamine to Chinese milk). It is important to note that each and every one of the cited incidents is outside the scope of the proposed rule. In addition, virtually every other incident that IDFA and NMPF are aware of would also be outside the scope of the rule. Indeed, IDFA and NMPF cannot think of a single food incident in the US that was intended to cause massive public health harm. We do, however, acknowledge the potential for such harm to occur, which is why IDFA and NMPF have worked very closely with FDA on intentional contamination issues for the past 12 years.

IDFA and NMPF have also reviewed some of the documents that indicate terrorist organizations have discussed contamination of the food supply and, while disturbing, they are rather crude and unfocused. Further, these documents are now more than a decade old, and no attacks on the food supply have occurred, nor have there been any new discoveries that would indicate a

continued or meaningful interest by terrorist organizations in pursuing intentional adulteration as a means to inflict massive harm. IDFA has also reviewed The Global Terrorism Database, which is described below.

> The Global Terrorism Database (GTD) is an open-source database including information on terrorist events around the world from 1970 through 2012 (with additional annual updates planned for the future). Unlike many other event databases, the GTD includes systematic data on domestic as well as transnational and international terrorist incidents that have occurred during this time period and now includes more than 113,000 cases. For each GTD incident, information is available on the date and location of the incident, the weapons used and nature of the target, the number of casualties, and--when identifiable--the group or individual responsible.
>
> Statistical information contained in the GTD is based on reports from a variety of open media sources. Information is not added to the GTD unless and until we have determined the sources are credible. Users should not infer any additional actions or results beyond what is presented in a GTD entry and specifically, users should not infer an individual associated with a particular incident was tried and convicted of terrorism or any other criminal offense. If new documentation about an event becomes available, an entry may be modified, as necessary and appropriate.
>
> The National Consortium for the Study of Terrorism and Responses to Terrorism (START) makes the GTD available via this online interface in an effort to increase understanding of terrorist violence so that it can be more readily studied and defeated.
>
> Characteristics of the GTD
> - Contains information on over 113,000 terrorist attacks
> - Currently the most comprehensive unclassified database on terrorist events in the world
> - Includes information on more than 52,000 bombings, 14,400 assassinations, and 5,600 kidnappings since 1970
> - Includes information on at least 45 variables for each case, with more recent incidents including information on more than 120 variables
> - Supervised by an advisory panel of 12 terrorism research experts.[1]

IDFA notes that of the 113,000 terrorism incidents in the database, only 13 involved the use of biological, chemical or radiological agents targeting food or water supply facilities. The one incident in the US involved the New York City water supply and a radiologic agent, which resulted in no property damage, no casualties, and no fatalities. Further, this incident occurred in 1985.[2] The GTD characterized that incident as unsuccessful. Similarly, 11 of the 12 remaining incidents did not result in any casualties or fatalities. In 1978, the Arab Revolutionary Army did manage to injure 5 people at a food facility in the Netherlands using mercury, though the details are scarce.

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1 Overview of the GTD, *available at* http://www.start.umd.edu/gtd/about/.

2 GTD ID: 198504150003

If we expand the target list beyond food and water facilities, we do see considerably more incidents; in fact there are 265 incidents in the database involving attacks that included biological, chemical or radiological agents, some of which involve contamination of food or water at non-food manufacturing facilities. The Dalles incident, an attack on restaurant salad bars, is in the database and, as FDA has indicated, did result in a large number of casualties. The same is true for several gas attacks on transportation facilities in Japan. The Taliban in Afghanistan frequently attack educational institutions, especially those that teach young girls, as well as police stations with food and water used on occasion as the vector at those institutions. Overall the tendency appears to not result in a great deal of fatalities or casualties, though it is not clear if that is due to lack of intent or failure in execution.

Inasmuch as FDA has not defined what massive public health harm is, it is not clear, in IDFA's opinion, whether The Dalles incident rises to the level of being a massive public health harm event. While 751 people were sickened, only 45 were hospitalized. On the other hand, at least one of the gas attacks in Japan appears to have cleared the hurdle with approximately 5,000 people being injured. We want to reiterate that both of these awful events would not have been altered had the proposed rule been in place—because neither occurred at a registered food facility—which begs the question "What is it that we are trying to accomplish?"

Based on the information above, it is clear that massive public health harm is a novel threat that the US and foreign food suppliers have not had to deal with previously. It is also clear that, to date, the fear of terrorists using the food supply as a vector to cause massive public health harm has not come to fruition despite some documentation discovered more than a decade ago. Clearly, the bad actors do in fact embrace the use of bombs and other traditional and improvised weapons. Whether they ever will shift their focus to intentional adulteration of the food supply is a great unknown. That said, we share FDA's concern and also recognize the Congressional mandate before us. IDFA and NMPF would like to point out though, that we must not hand the terrorists a victory by crippling the food industry with overly complicated and expensive regulatory requirements.[3]

II. What Does the Intelligence Say and How Can FDA Communicate That to Stakeholders?

IDFA and NMPF recognize that we are not under the same pressure when the US was looking for weapons of mass destruction (i.e., botulism toxin) in Iraq in 2002, nor are we focused on where all the scientific expertise on weaponized anthrax from the Soviet germ warfare programs ultimately wound up. Twelve years ago we were forced by circumstances to take action without all the facts, but as time has gone by we have learned a lot. Intentional adulteration could result in a devastating event, but the likelihood is extremely remote. That said, we are certainly not advocating that the industry stand down and not take proactive measures. We just urge FDA to take the current context into consideration in fashioning the regulatory requirements.

Specifically, FDA needs to monitor the degree of risk to the food supply and temper the mitigation requirements to be in sync with that risk. Risk involves not just food facilities' vulnerabilities, but also the terrorists' intentions and capabilities. A vulnerability in and of itself is nothing more than that, so it is imperative to make sure when we talk of risk we note the potential vulnerability, the adversaries' intentions, and their ability to act. We are confident the

[3] FDA also needs to recognize that adding regulatory costs, if not fully justified, can have the unintended effect of hindering access to affordable food in this country, a valid concern considering one in six Americans lack adequate food.

intelligence community is aware of what to look for to ascertain whether there is risk. We are confident that FDA has the appropriate connections to the intelligence community via its connection with the National Counterterrorism Center (NCTC) to stay abreast of and assess the evolving vulnerabilities. Most importantly, FSMA states that "regulations promulgated under subsection (b) shall apply only to food for which there is a high risk of intentional contamination as determined by the Secretary...", which we believe further indicates that FDA needs to consider all factors, not just the presence of a vulnerability.

As discussed in these comments, IDFA and NMPF propose that FDA only require basic food defense plans that contain cost-effective mitigation strategies and identify reserved focused mitigation strategies that can be utilized in periods of heightened concern should they materialize in the future. Reserved strategies may include steps like changes to processes such as pasteurization temperature or the hiring of additional personnel to be part of a heightened observation process. When and if credible threats or intelligence of terrorist intentions and capabilities surface, FDA needs to communicate that information to its stakeholders so that we can take appropriate action to safeguard our products and the general public. We believe FDA can do that as we describe below.

In 2002, Congress passed the Bioterrorism Act. Among many provisions in the Act, FDA was required to create a food facility registration system, which FDA has done. The registration system was tweaked by FSMA to provide a mechanism by which the information contained therein would be kept up-to-date through biennial registration renewal. The database as it stands today can be enormously useful. For example, food facilities are required to identify the categories of foods that they manufacture, process, pack, or hold at their facility. In addition, they are required to identify a responsible person and are required to have 24 hour a day contact capabilities. For foreign facilities, there is a requirement to have a US-based registered agent who can be contacted 24 hours a day. Congress envisioned that FDA could use the database to identify and contact individuals at food facilities rapidly if a situation arose involving a particular food or a group of foods.

IDFA and NMPF envision that if intelligence picked up credible information that a particular food (for example, milk), was planned to be targeted for intentional adulteration, FDA would query the FDA registration database to identify all facilities and their contact information that identified themselves as manufacturing, processing or holding a food in category #26 (Milk, Butter or Dried Milk Products) and contact them. FDA should also reach out to any trade association that represents that industry, in this case IDFA and NMPF, and as it has done many times before on traditional food safety issues, reach out to the 50 states to engage them on the issue. In addition, FDA should make use of the Food and Agriculture Sector Coordinating Councils and the infrastructure and communication capabilities that reside with the Department of Homeland Security.

While IDFA and NMPF believe the components and concepts are all present, FDA needs to formalize its capability to communicate credible threat information to owners and operators of foreign and domestic food facilities and their trade associations, as well as other key stakeholders such as state government departments of agriculture and public health as well as state homeland security personnel. IDFA and NMPF believe that FDA should hone its skill in reaching out to targeted entities and optimize this process to do so rapidly and efficiently. IDFA and NMPF would be pleased to work with FDA in conducting a test of an emergency contact system and volunteer the dairy industry to be part of such an exercise, involving all aspects of the industry – from milk collection through manufacturing and distribution.

In addition to FDA developing its communication system so they can reach stakeholders in the event credible threat information surfaces, FDA should convene, on at least an annual basis, a panel of food industry stakeholders to review the status of food industry threat intelligence. Such an activity can be accomplished with the existing mechanisms and cleared personnel in the Food and Agriculture Sector. It should be done at the classified "Secret" level. In addition, food industry professionals should, on a periodic basis, meet with intelligence analysts in the respective intelligence community and exchange information about concerns to ensure that analysts and private sector personnel understand the scenarios that are of most concern and that analysts are cognizant of the signs that should cause alarm or additional scrutiny. This, too, can be accomplished as a Food and Agriculture Sector activity, and in fact, the Office of the Director of National Intelligence has already expressed support for this activity.

III. The Dairy Industry Already Has Robust Mitigation Strategies in Place

As FDA is well aware, the US dairy industry has partnered with FDA for the last 12 years and we have taken an active approach to food defense in dairy operations. No other food industry sector can come close to what we have achieved. IDFA recently polled its membership on their broad and focused mitigation strategies and the results were extremely clear: the dairy industry is doing a lot and we have been doing so for years on a voluntary basis. If there is one takeaway from those polls, it should be clear that many strategies are in use and there is enormous variability among the plants and the companies that responded. This does not mean some plants and companies are doing better than others. Rather, it means each plant and company is unique and what makes sense at one plant may not make sense at another. Further, the implementation of one or more mitigation strategies may obviate the use of another. This is a very important point that we believe is critical to convey to the FDA and state inspectors – one size does not fit all.

In addition to the polls, further evidence that the industry is willing and able to act was gathered in the not too distant past. Following September 11, the prior Administration expressed some concern about a potential vulnerability and a specific mitigation strategy that IDFA recommended to the industry in light of the potential for harm. At FDA's direction, field investigators were sent out to dairy facilities to characterize and quantify what was being done. Ultimately, the facts supported everything that IDFA had communicated to FDA – industry had taken decisive proactive action. In the end, the Administration was satisfied with the voluntary approach the industry had taken concomitant with FDA's help and knowledge. At a time when concern about intentional adulteration of the food supply was at its pinnacle, our approach and collaboration was deemed to be fully responsive, as we believe it is now.

IV. The Proposed Rule Needs to Be Significantly Revised

Upon reviewing FDA's proposed rule, we understand why the agency would have preferred to start with an Advance Notice of Proposed Rulemaking (ANPR), as the agency did in the Sanitary Food Transportation rulemaking. We agree with the scope of FDA's proposed rule in a broad sense, but believe that the agency's specific approach needs to be revisited. Regarding the general scope, we support FDA's approach of targeting those who would seek to cause massive public harm and not focusing on preventing economically motivated adulteration or actions by disgruntled employees. When considering the specific approach in the proposal, however, the regulation needs to be reconsidered in order to achieve the fundamental goal of mitigating the risk of intentional adulteration.

A. Food Defense and Food Safety Should Be Regulated in Different Ways

As FDA itself has recognized, food defense is different from food safety, both from scientific and risk-analysis perspectives, and therefore the two issues should be approached differently in FDA's regulations. As FDA explains in its Food Defense Plan Builder:

> Food Defense is the effort to protect the food supply against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means. Potential contaminants include biological, chemical and radiological hazards that are generally not found in foods or their production environment. Food defense differs from food safety, which is the effort to prevent unintentional contamination of food products by agents reasonably likely to occur in the food supply (e.g., *E. coli*, *Salmonella*, *Listeria*).[4]

Food safety is grounded in scientific knowledge in the natural science areas such as microbiology, toxicology and chemistry. In contrast, food defense is based more on social sciences, such as criminology (the study of crime and behavior), and is not readily quantifiable because of the inexact nature of the subject matter. Thus, food defense is more art than science.

Another area of divergence is the approach to analyzing risk. Food safety is focused on analyzing whether a risk is "known or reasonably foreseeable" or "reasonably likely to occur." In contrast, food defense deals with threats that are not known, reasonably unforeseeable, or not reasonably likely to occur. While a food safety risk can be prevented or reduced to an acceptable level (e.g., through a 5-log pathogen reduction treatment), food defense threats can never be completely prevented—they only can be mitigated. Moreover, the food defense mitigation level cannot be quantified or proven.

Accordingly, the new food defense regulation needs to take a different approach than FDA's food safety-oriented regulations. In particular, the new regulation should:

- Use distinct terminology that differentiates food defense from FDA's food safety regulations;
- Follow a foundational approach that captures what companies are doing today under their food defense plans; and
- Be adequately broad so companies can build on their plans over time, based on emerging threats, new understandings about criminal behavior and new mitigation technologies.

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[4] FDA's Food Defense Plan Builder Frequently Asked Questions, *available at* http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm (emphasis added); *see also* U.S. Department of Agriculture Food Safety and Inspection Service (FSIS), *Developing a Food Defense Plan for Meat and Poultry Slaughter Processing Plants* (June 2008), *available at* http://www.fsis.usda.gov/shared/PDF/Food_Defense_Plan.pdf ("Food defense is *not* the same as food safety. Food defense focuses on protecting the food supply from intentional contamination, with a variety of chemicals, biological agents or other harmful substances by people who want to do us harm. . . . Food safety addresses the accidental contamination of food products during processing or storage by biological, chemical or physical hazards.").

B. The Regulation Should Encourage Thoughtful Analysis of Threats

Our second major concern with the proposed rule is that it does not encourage facilities to engage in a thoughtful, tailored analysis of the specific threats that could affect the food they process. FDA proposes that facilities can either (i) identify actionable process steps associated with any key activity types (KATs) in the facility or (ii) conduct their own vulnerability assessment to identify vulnerable processes and actionable process steps. Although facilities are given the option of conducting their own vulnerability assessment, the regulation applies a strong presumption that mitigation strategies are needed for any KATs. That is, even if a facility does its own vulnerability assessment that does not determine a need for mitigation strategies at any KATs, there is concern that an FDA (or state) investigator may consider the facility out of compliance because this conclusion is contrary to the presumption in the regulation that all KATs need to be addressed. Furthermore, the proposed rule ties the vulnerability assessment to determination of actionable process steps—but this skips an important step in the process: facilities first need to determine if they have any significant vulnerabilities before identifying actionable process steps.

Rather than establishing a regime that applies predetermined outcomes across the industry, FDA's food defense regulation simply should direct each facility to determine what mitigation strategies are appropriate based on their own vulnerability assessment. We are concerned that the proposed rule, with its focus on KATs, applies a "one size fits all" approach that does not encourage facilities to engage in this thoughtful, tailored analysis. The vulnerabilities affecting a given facility, and the food industry as a whole, evolve over time. By focusing on prescribed KATs, FDA suggests that the vulnerabilities are static and discourages continuing consideration of how they may shift. Further, experience shows that there is no one "right" way to address intentional adulteration. Each facility is unique and what makes sense at one facility may not make sense at another.

C. FDA Should Not Distinguish Between Broad and Focused Mitigation Strategies

Our final macro concern about the proposed rule is the proposed approach of distinguishing between broad and focused mitigation strategies. Under the proposed rule, only focused mitigation strategies are required. However, in the preamble FDA recognizes the importance of broad mitigation strategies and suggests it is "prudent" for facilities to implement such strategies. This approach is akin to requiring facilities to develop hazard analysis and critical control point (HACCP) plans, which focus on critical control points that are essential for food safety, without first requiring implementation of good manufacturing practices (GMPs), which lay the foundation necessary for a HACCP plan to be effective. For example, it does not make sense to control access to the bulk liquid receiving and loading area (a focused mitigation strategy), without first establishing physical security for the facility itself (a broad mitigation strategy).

Further, the impact of broad mitigation strategies needs to be considered when determining whether focused mitigation strategies are necessary. This is analogous to considering the benefits provided by GMPs when conducting a hazard analysis under a food safety plan – specific elements of the program cannot be assessed in the abstract. For example, when considering whether to implement a system to control employee access to a given area, the facility should be able to take into account systems it already has in place that restrict employee movement, such as identification passcard access systems and color-coded attire required for GMP/zoning reasons.

The line that FDA draws between focused and broad mitigation strategies also detracts attention from the more important issue of whether the facility is taking appropriate steps to mitigate significant vulnerabilities—regardless of whether they are focused or broad. It is not always clear whether a given approach would fall into the "focused" or "broad" category, nor should it matter as the difference really is just a matter of semantics. The proposed approach that zeroes in on focused mitigation strategies sets up the potential for unnecessary future disputes with FDA investigators about whether a strategy truly is focused or actually is broad (and therefore does not "count" under the regulation). Instead, FDA should write a regulation that ensures facilities have the appropriate mitigation strategies in place to effectively address the identified vulnerabilities—regardless of whether they are broad or focused.

D. FDA Has the Legal Authority to Take a Different Approach

Before explaining our specific recommendations to revise the regulatory framework, we want to emphasize that FDA is not legally bound to regulate intentional adulteration in the manner proposed. The statute does not mandate FDA to zero in on KATs, to differentiate between broad and focused mitigation strategies, or to regulate management elements in the same manner as under a food safety plan. First, the law directs FDA to focus the regulation on foods at a "high risk" of intentional adulteration, but the KATs are defined so broadly that FDA essentially brings the entire food manufacturing industry within this scope. Requiring each facility to conduct its own vulnerability assessment would be a more tailored way to achieve the statutory goal of focusing on only these high risk foods, as each facility is in the best position to determine its degree of risk/vulnerability. Second, FSMA only requires "mitigation strategies," and does not distinguish between strategies that are broad or focused, so FDA clearly has the legal authority to move away from its sole emphasis on focused mitigation strategies. Finally, while FSMA requires monitoring, verification, and corrective actions, it is quite open-ended with respect to the nature of these procedures. By no means does the law require a traditional HACCP approach. For example, FSMA simply directs facilities to "monitor the performance" and "the effectiveness" of their preventive controls—and this can be achieved in a much more flexible manner than the agency has proposed. Our comments that follow discuss our recommendations to revise the proposed rule, which are all in line with the scope of the agency's legal authority.

V. Recommendations to Revise the Regulatory Framework

We support a regulation that sets a broad requirement for every facility to analyze threats, identify vulnerabilities, and implement mitigation strategies in a tailored manner that best fits its own circumstances. The regulation should encourage facilities to be proactive, such that they take action when needed, but also to consider food defense in the broader context of the operations. More specifically, we offer the following recommendations:

A. Registered Facilities Should be Required to Conduct Vulnerability Assessments

The foundation of a food defense plan is a thoughtful, facility-specific vulnerability assessment, which should be required of every registered facility unless exempt or the facility has been part of a thorough assessment in the past. For example, most fluid milk plants have extensive knowledge of their vulnerabilities and historically have worked diligently to counter these vulnerabilities. The goal of the vulnerability assessment should be to identify significant vulnerabilities—not actionable process steps as FDA has proposed. Where that goal has been

met by past activity, whether through a formal vulnerability assessment or otherwise, there should not be a requirement to do so again for the sake of checking a box.

For example, the fluid milk industry has been through at least three multi-day vulnerability assessments, one led by FDA in 2002, prior to the SPPA program, and two under the SPPA program. The yogurt industry was one of the first SPPA vulnerability assessments. The ice cream industry participated with Battelle Memorial Institute and FDA in a vulnerability assessment after the SPPA program had been completed. In each of these cases, the goal of assessing vulnerabilities has been met. IDFA staff participated in even more such programs and could easily host a workshop that could serve as a refresher course or training for preparation of a first time vulnerability assessment for those who have not previously engaged in a vulnerability assessment process. We believe this could be especially effective if done in conjunction with use of FDA's Food Defense Plan Builder tool, which does in fact focus on facility specific parameters.

The vulnerability assessment should consider the facility as a whole and each processing line, but there is not necessarily a need to conduct separate analysis for each type of food manufactured in the facility. Vulnerability assessments also should consider the contribution of existing practices, procedures and programs that already may function to mitigate threats. Relatedly, the assessment should consider factors influencing the potential risk of harm, such as downstream processing steps, the volume of product, its shelf life, marketplace turnover, and distribution and consumption patterns.

IDFA and NMPF are somewhat surprised that FDA has abandoned one of its earlier criteria in the food defense arena: namely, shelf life and speed of product moving to consumption. The past concept was that fast-moving foods with short shelf lives were better targets for intentional adulteration because they would be rapidly consumed by large numbers of people before the adulteration was detected and intervention could occur. Slow-moving foods with long shelf lives do not make good targets because detection would likely occur long before very much of a particular batch or run of a product was consumed. For dairy, we note that ice cream can be kept for up to two years in a deep freezer, and some milk and whey powders can be stored for even longer. As such we do not believe ice cream or dry milk-based powders would be good targets and FDA should allow facilities to consider how to account for this important factor as part of their vulnerability assessments.

A benefit of conducting a vulnerability assessment, as opposed to relying on pre-identified KATs, is that it encourages facilities to think critically about threats and results in a tailored assessment. It also allows companies to take more factors into account than an industry-wide regulation can, for example considering how various factors interrelate and counterbalance. It also provides greater protection for the food supply as a whole, as a regulation that focuses just on KATs could provide a roadmap for a potential wrongdoer to circumvent a facility's mitigation strategies. Further, it recognizes that vulnerabilities evolve over time, rather than taking a "one size fits all" approach that simply considers the existence of KATs.

B. FDA Should Develop Guidance About How to Conduct a Vulnerability Assessment

We believe that a large segment of the food industry already has adequate knowledge to conduct a vulnerability assessment and develop a food defense plan. In particular, existing food defense plans should be adequate under the FSMA regulation so long as they were

thoughtfully developed. There are several existing tools already in place that can assist the remainder of the industry. For example, companies may use FDA's Food Defense Plan Builder, consider guidance from FSIS, or take consideration of programs established under the Customs-Trade Partnership Against Terrorism (C-TPAT). Ideally FDA should enhance the Food Defense Plan Builder tool's capability so that it, by itself, can be used to conduct a vulnerability assessment.

C. Mitigation Strategies Should Be Determined Based on the Vulnerability Assessment

After conducting the vulnerability assessment, facilities should implement mitigation strategies for any significant vulnerabilities that were identified. FDA's regulation should not differentiate between mitigation strategies based on whether they are broad or focused. There may well be situations where broad mitigation strategies are sufficient to mitigate risk, and it is that sufficiency that matters and not whether the mitigation strategies are broad or focused. In addition, broad and focused strategies often work in tandem to mitigate significant vulnerabilities. Consistent with the statute, FDA also should not dictate what mitigation strategies are needed, but rather should leave this decision up to each facility to determine independently.

The approach of allowing both broad and focused mitigation strategies also is more cost-effective than simply mandating focused mitigation strategies as proposed. Some of the approaches that FDA suggests simply may not be necessary if a broad strategy is in place. For example, this could be the case for peer monitoring, adequate lighting, use of enclosed equipment, and reduced staging time.

Further, some broad mitigation strategies can be used to address insider threats and already are in place at most facilities. These include:

1. Limiting access to the facility;
2. Conducting background checks for employees and contractors;
3. Controlling movement and access within the facility (e.g., through zoning and GMP programs); and
4. Conducting employee training to increase awareness of intentional adulteration threats (e.g., adding a "see something, say something" training module to an existing training program).

Notably, not only are these approaches functionally effective, but they also are cost-effective.

D. Mitigation Strategies Should Be Overseen by Facilities Differently than Preventive Controls

Given that food defense and food safety are distinct disciplines, we disagree with FDA's proposed approach of applying the same management oversight elements for mitigation strategies as for preventive controls (i.e., monitoring, corrective actions, and verification with the same rigor as applied under a food safety plan). FSMA does not require this type of approach for food defense. Rather, the statute reflects the need to take a proactive approach but does not restrict the method or terminology that is used. Accordingly, FDA should revise the regulation to establish distinctions between the management oversight required by the food

defense and food safety regulations. To help reinforce and clarify this distinction, we recommend using different language in the regulation to refer to the general concepts of monitoring, verification, and corrective actions. For example, monitoring could be called "checking," verification could be called "evaluation," and reanalysis could be referred to as "reassessment."

Fundamentally, the regulation should keep the oversight requirements flexible and simple. The level of oversight that may be appropriate for a critical control point in the food safety context may not be applicable for a food defense mitigation strategy. A monitoring procedure may be very simple and built into the mitigation strategy itself. A corrective action procedure may be as basic as "report to supervisor and correct as needed." For example, a security guard may confirm that a tanker truck making a delivery is on the list of visitors expected that day. A supervisor may periodically conduct a walk-through to confirm that the mitigation strategies in the food defense plan are being implemented appropriately. An employee may "see something" is out of place and "say something" to their supervisor, but the issue does not necessarily need to be documented. This approach is different than traditional oversight under a food safety plan because food defense is fundamentally different from food safety.

VI. Mitigation Strategies Need Careful Consideration

Special attention needs to be given by FDA to the appropriate mitigation strategies to address significant vulnerabilities. We offer the following comments.

- **History of Mitigation Strategies**

Most of the focused mitigation strategies in FDA's Mitigation Strategies database were developed by FDA in conjunction with trade association and industry personnel during the Strategic Partnership Program on Agroterrorism (SPPA) vulnerability assessments that were conducted years ago. The strategies were developed when it was feared that an attack of the food supply was imminent. As a result, some of the strategies are very detailed and costly to put or keep in place: for example, peer monitoring and monitored video surveillance. Many of these strategies do not make sense when there is no known threat to the food supply. Other mitigation strategies are less costly and have benefits in non-heightened periods of concern for other reasons, for example theft prevention.

- **Reason For Concern: Examples of Past Governmental Recommendations for Farm Security**

IDFA's and NMPF's experience has been that the best envisioned solutions by well-intentioned government personnel do not always pass muster when it comes to practicality of implementation. We call your attention to a number of food defense strategies that were recommended to the dairy industry in 2004. IDFA and NMPF have good reason to be concerned about well-intentioned, but impractical, recommendations to secure a facility or farm. Among the several hundred recommendations, several from the farm section alone clearly show the best of intentions do not always result in sound, efficient and practical solutions. We offer the following for FDA's consideration and urge FDA to consider the feasibility and effectiveness of what we were encouraged to do in the past. The challenges presented by some of these strategies speak for themselves.

1. Contact any local utility company that has an easement allowing it access to equipment situated on farm property and request, for security purposes, the utility company notify the farm prior to these visits.

2. Install “No Trespassing” signs for deterrent effect.

3. Install safety/security lighting to illuminate the main barn and areas where milk tankers are parked on farm property. This activity will deter unauthorized individuals from accessing these areas. The addition of infrared lights and closed circuit television (CCTV) cameras on or near barns, milk houses, milk tanks, bulkheaded tanks, loading areas, hose ports, feed storage areas, etc., will further protect the farm’s assets.

4. Consider installing a sensor and alarm system at farms with Automated Milking Installations (AMIs.) Because AMIs require a substantial capital investment, the addition of a sensor and alarms system will help protect the investment and the raw milk. Due to the nature of the milking parlor environment (moving cows, temperature fluctuations, blowing dust, etc.) sensor choices that will provide security while allowing AMIs to perform as designed are limited. The proper selection of sensors and an annunciation system will minimize the potential of false and nuisance alarms while providing protection to the cows, machines, raw milk and other farm assets.

5. Arrange for the local police department to perform periodic patrols and sporadic security checks of farm property. The activity will deter unauthorized individuals from accessing the farms, and may alter a potential perpetrator’s intent at a particular farm.

6. Provide security awareness and technology training to farm personnel. Such programs may be supported by local industry contacts such as IDFA, NMPF, etc. who should then consider levying a security tax system to ensure compliance after training is completed.

7. Consider utilizing federal unmanned aerial vehicle (UAV) program for surveillance of remote tracts of land. To minimize the cost impacts associated with this program, such usage could be done on a random basis for select locations and when intelligence reports identify a high level threat.

8. Institute a rapid toxin detection and reporting system for agricultural areas.[5]

Although these were all valid ideas in the abstract sense, they were not practical or feasible to implement. We urge FDA to learn from this experience.

- **Video Surveillance & Peer Monitoring are Very Expensive**

We cite two of FDA’s mitigation strategy recommendations as being of particular concern: video surveillance and peer monitoring.

[5]Security of Milk Transport in the United States (U.S.) Project, U.S. Department of Transportation, May 2004

Video surveillance equipment is installed in many dairy processing facilities, typically in the receiving bays where raw milk is offloaded and also in production areas. Usually these cameras are not monitored but instead are used for after-the-fact investigations. When dealing with intentional contamination situations, unmonitored surveillance is not helpful in significantly minimizing the risks. Monitoring is the only way video makes sense, but it is extremely costly and as such should be reserved for times when it is warranted as described above, based on a current and credible threat. To quantify the cost of this strategy, note that most fluid dairy operations operate 24 hours a day with two production shifts and then a clean-up shift. Additionally, other dairy operations, like cheese, butter, and powder manufacturers, which produce much longer shelf-life products, tend to operate 24 hours a day, 7 days a week, 365 days a year. We envision that that FDA's proposal would require at least 4 additional employees, but possibly 5 or 6, to monitor operations.

The average cost per worker is approximately $50,000 for wages and benefits. Therefore, this one focused mitigation strategy would cost a typical dairy plant $200,000 to $300,000 per year. We strongly urge FDA to avoid the imposition of this focused mitigation strategy unless it has credible information about a current threat to the facility or that industry sector. In addition, hiring peer monitors to cover the same situations as monitored video surveillance will require an equivalent number of additional employees with an equivalent cost. Accordingly, we do not believe this is a viable focused mitigation strategy under non-emergency circumstances.

IDFA and NMPF believe that most of our 600 member-owned dairy processing facilities will be subject to the food defense requirements. Applying the aforementioned costs estimates, this will cost our industry between $120,000,000 to $180,000,000 per year for this activity alone just in our industry. Clearly, FDA would not have envisioned this cost. Unnecessarily imposing those kinds of costs on the dairy industry is unwarranted and, absent intelligence to the contrary, excessive.

- **Safe Quality Food (SQF) and the Global Food Safety Initiative (GFSI)**

In addition to the voluntary actions most IDFA and NMPF members have taken, many of our members are certified under a GFSI-recognized scheme (e.g., SQF), which includes robust food defense requirements. We believe the SQF and GFSI Food Defense requirements should be deemed to satisfy any regulatory requirements for the Intentional Adulteration rule. FDA should recognize and support what has been accomplished under that program. We suspect there may be other robust strategies that deserve similar treatment and are optimistic that this will be discovered through this notice and comment rulemaking process.

- **Focus on Drivers at Food Facilities**

We find it curious that in the discussion of mitigation strategies there is a great deal of attention being focused on the truck driver while he/she is unloading at the plant. During the vulnerability assessments, we quickly realized scrutinizing a driver at the plant was unsound as that same driver had just been in possession and control of that vehicle, alone and outside of any scrutiny whatsoever. Why would that driver attempt to contaminate the truckload at the plant where it could be observed when ample opportunity to go unobserved was previously at hand? Despite seals, locks and other technology, we all understand a corrupt driver could intentionally adulterate a load. The key is not to monitor every move of the driver, but rather to know the

driver or know that the driver's company is familiar with the driver and has an acceptable degree of confidence that the driver is trustworthy. The driver is merely one example – a corrupted plant manager or other plant personnel could easily evade whatever mitigation strategies are implemented in a food facility as well. This illustrates the point that no food defense strategy is foolproof, and FDA regulations should not seek to achieve such an unattainable standard.

VII. Recordkeeping and Records Access Requirements Should Be Tailored for Food Defense

We recommend modifications to three aspects of FDA's proposal with respect to recordkeeping, primarily because the proposed rule does not consider the unique nature of food defense records. First, FDA proposes that all records required by the regulation must be maintained for 2 years. Compliance with this requirement is neither feasible nor cost-effective for some food defense records. In particular, if a facility uses a video monitoring system, there are capacity limitations on the amount of recorded content that can be stored. In some cases it simply is not possible to store 2 years' worth of video content and in other cases it would cost a significant amount (and require a significant amount of storage space) to do so. The agency should establish flexibility in the regulation with respect to this aspect of the recordkeeping requirements (e.g., allow video tapes to be reused upon completion).

Second, FDA proposes that required records must be made available to FDA upon oral or written request. We believe this should be strictly limited to reviewing documents on-site and not extend to copying of records and bringing them to FDA. Indeed, FDA should prohibit agency investigators (or state investigators working on their behalf) from copying food defense plan records. These documents are highly sensitive. If they get into the wrong hands, they could provide a roadmap to circumventing a facility's mitigation strategies. Furthermore, given the large number of major data breaches that have occurred in recent years from various private and public institutions, we do not think it would be prudent for FDA to store this information on its own computer systems. The more straightforward and judicious approach to protecting this information is for records access to be limited to the facility that manages implementation of the plan and for agency investigators only to review the information on-site.

Third, FDA proposes that electronic records must be kept in accordance with 21 CFR Part 11. As we advocated in our comments regarding the other FSMA proposed rules, FDA should exempt records from compliance with Part 11. Instead, FDA should require a simplified, practical set of requirements to ensure authenticity of electronic records. As FDA itself noted in implementing the Bioterrorism Act of 2002, it would be extremely burdensome for the food industry to have to comply with Part 11. The burden would be even greater here given the larger volume of records. FDA should take a practical approach that focuses on ensuring authenticity of the records using controls that work with existing systems.

VIII. Additional Areas for Further Consideration

We also offer the following comments on other aspects of the proposed rule:

- **Qualified Individuals**

The vulnerability assessment should be required to be conducted by a qualified individual. This person should be able to be qualified based on either training or experience. Moreover, given the relatively new expertise for food defense in general, the agency should be careful not to be

overly restrictive in specifying who could operate as a qualified individual; however, at the same time, FDA needs to describe the qualifications in some detail so that we can ensure that "unqualified" consultants are not misleading the regulated community as to their expertise and competency. We also recommend using different terminology to identify "qualified individuals" under each of the different FSMA regulations (preventive controls, foreign supplier verification, intentional adulteration) so as to prevent confusion within the industry.

Finally on this point, we note that IDFA personnel have been involved in numerous vulnerability assessments and countless tabletop and other exercises with a variety of private sector and government entities. We believe our staff lead is qualified and know in fact that he could rapidly identify vulnerabilities given his extensive work in this area.

- **Research and Development (R&D)/ Pilot Plants**

Both R&D and pilot plants should be exempt from the regulation. Intentional adulteration is quite unlikely at these facilities given the narrow scope of consuming individuals—and regulation of such facilities is inconsistent with the agency's stated goal of focusing on the potential for causing massive public harm. As a vulnerability assessment likely would conclude that there are no significant threats to these facilities due to their low volume of product and the fact that their food is not for sale, it should not be necessary to conduct such an assessment.

- **Economically Motivated Adulteration**

We agree with FDA's approach of not addressing economically motivated adulteration in this regulation, but we also believe this subject should not be addressed in the preventive controls final rule, either. Instead, we urge the agency to refrain from regulating economically motivated adulteration until after the FSMA regulations have taken effect, as their implementation may mitigate the need to specifically regulate in this area.

- **Inspections**

Food defense should be inspected as part of routine food facility inspections; however, FDA's investigators need to be trained about how to evaluate the adequacy of a food defense plan. Inspections should have a "big picture" focus that thoughtfully evaluates whether a facility has properly conducted a vulnerability assessment and implemented designated mitigation strategies. A food defense plan should not be considered deficient simply because it does not employ a particular mitigation strategy that another facility in our same industry or even within the same company may decide to use. As stated above, plants are not all the same, there are many variations in a host of variables. Ensuring calibration between or consistency among investigators and inspectors would be challenging and critical in evaluating food defense plans. The agency also should defer citing food defense-related items on 483's until both facilities and inspectors learn about compliance with these new regulatory requirements, which would reasonably take additional time beyond the effective date for preventive controls.

- **The Small Business Exemption and Other Exemptions**

IDFA and NMPF have mixed feelings on exemptions. If FDA creates an overly complex and burdensome rule, which we feel the proposed rule may be, we would advocate for more exemptions such as raising the $10 million sales amount to $25 million. In addition we would

urge FDA to at least exclude facilities that manufacture long shelf-life foods (such as ice cream, aged cheeses, and dry milk-based powders) for the reasons stated above. On the other hand, if FDA were to streamline the proposed rule and focus on basic food defense plans with cost effective mitigation strategies, we would advocate for fewer exemptions so that the vast majority of processed dairy products would come from a covered facility.

- **Pasteurized Milk Ordinance (PMO)-Regulated Facilities**

IDFA and NMPF believe that Grade "A" facilities regulated under the PMO should not be regulated under this rule. FDA should consider working though the National Conference on Interstate Milk Shipments process and amend the PMO to address any needed requirements through that cooperative program. That said, based on years of experience with those facilities and the aforementioned actions fluid milk plants have taken, we find it hard to believe that any changes are warranted – those facilities were hardened years ago and remain so.

- **Foreign Facilities**

FDA has proposed that food facilities that have less than $10 million in total annual sales are exempt. With respect to foreign facilities, we believe that $10 million figure (or whatever number is contained in the final rule) should be based on US sales, not overall sales. For example, we envision there are many food facilities that may sell only small quantities of food to the US and it would be disproportionate to subject them to this rule when a US facility selling $9,999,999 would not be subject to the rule. Similarly, a domestic facility that exports a significant volume of their product overseas, such that their domestic sales are less than the proposed level for exemption, should also be exempt from these regulations in their entirety. For example, it would not make sense for a facility dedicated to supplying dairy ingredients to the international marketplace to have to comply with food defense regulations, which have the objective of preventing a threat to the US food supply.

- **Dairy Farms**

IDFA and NMPF both acknowledge that Congress has provided FDA with the authority to regulate dairy farms under this rule if there is a high risk of intentional contamination at those farms. We do not believe there is a high risk, and therefore urge FDA to address the lower risk in guidance. Please see NMPF's separately filed comments on this issue for further details.

- **Re-proposal**

In light of the significant revisions that we are recommending for the regulation, FDA should publish a re-proposal that allows an opportunity for stakeholders to comment on any modifications the agency plans to make in response to comments. This approach not only would be equitable, but also would be consistent with the agency's plans for other significant FSMA regulations. The fact that Intentional Adulteration is the last FSMA regulation to be published under the agreed-upon deadlines under the court order[6] means FDA has ample time to go through this additional step. In essence, the first proposed rule could serve the same purpose as the ANPR that FDA had originally hoped to publish.

[6] *Center for Food Safety v. Hamburg* (No. 12-4529, N.D. Cal.).

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Based on IDFA's and NMPF's years of experience with vulnerability assessments and close work with the government, we would be remiss in not mentioning this critical point: We can never make any food 100% safe. At times during various vulnerability assessments it became clear that no matter what a facility did there would always be vulnerabilities. We can and should do our best to mitigate whatever vulnerabilities we can, but we should not be foolish enough to think we will ever eradicate all threats. Again we are not using this as an excuse to do nothing. We believe that our industry has proven time and time again that we will do what we can to mitigate significant vulnerabilities, but the actions must be reasonable. We request that FDA proceed cautiously and incrementally in the development of this rule.

Respectfully submitted,

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