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Docket Clerk
FSIS Docket Room
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 102, Cotton Annex
Washington, DC 20250-3700

03-015N
03-015N-2
David French

Re: Comments on FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products; Docket No. 03-015N

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products. 68 Fed. Reg. 45,789 (August 4, 2003) (hereinafter, "safety and security guidelines" or "guidelines"). IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 135 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than \$64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

IFDA and its members strongly support the purpose of the safety and security guidelines—that all foods should be transported and distributed as safely and securely as possible in order to ensure the health of the American public. The guidelines are, however, flawed. IFDA is deeply concerned that the guidelines will become *de facto* regulations. In addition, the food security measures are outside of the statutory purview of the Department under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA).

Even to the extent that the agency is positioned to offer guidance, some of the recommendations contained in the document are simply inapplicable to all distributors. Still other recommendations within the guidelines will place unnecessary time and

economic burdens on distributors without any commensurate enhancement of food safety. FSIS should carefully consider the comments received, withdraw the food security section, and revise the guidelines accordingly.

Moreover, IFDA is deeply concerned that FSIS is setting a standard beyond its statutory authority that could be improperly used against regulated entities. Regardless of whether material in the guidelines in fact enhances food safety or whether opining on security is within FSIS authority, insurance carriers and others will look to the guidelines as a standard of care that regulated entities *should* comply with.

IFDA therefore submits the following comments and urges FSIS to substantially revise of the guidelines to conform to the agency's mission.

FSIS SHOULD CLEARLY ARTICULATE THE NON-BINDING NATURE OF THE GUIDELINES

FSIS should adopt a regulatory process for the promulgation of guidelines similar to that used by the U.S. Food and Drug Administration (FDA). Pursuant to 21 C.F.R. § 10.115, FDA uses guidance documents to describe the agency's interpretation of or policy on a regulatory issue. "Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA . . . [Regulated entities] may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations." 21 C.F.R. § 10.115(d)(1) - (d)(2). FDA guidance documents contain statements tracking this regulatory disclaimer.

Such an approach would be wholly appropriate as to the food safety portion of the guidelines. For example, FSIS should add language to its guidelines that is similar to that found in the CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, FOOD PRODUCERS, PROCESSORS, AND TRANSPORTERS: FOOD SECURITY PREVENTIVE MEASURES GUIDANCE (March 21, 2003). That language reads, in pertinent part:

Not all of the [information] contained in this document may be appropriate or practical for every food establishment, particularly small facilities and distributors. FDA recommends that operators review the [information] in each section that relates to a component of their operation, and assess which preventive measures are suitable . . . FDA recommends that operators consider the goal of the preventive measure, assess whether the goal is relevant to their operation, and if it is, design an approach that is both efficient and effective to accomplish the goal under their conditions of operation.

FOOD SECURITY MEASURES FALL OUTSIDE SCOPE OF FSIS AUTHORITY

FSIS contends that the food security measures within the guidelines are provided to prevent intentional contamination as part of criminal or terrorist acts. 68 Fed. Reg. 45,790. While it certainly is the province of FSIS to oversee the production and distribution of safe and wholesome products under the FMIA, PPIA, and EPIA, FSIS is not a criminal investigation or law enforcement agency. In the event of intentional contamination of food as a terrorist incident, it will be the federal anti-tampering statute, 18 U.S.C. § 1365, not violation of the adulteration provisions of the FMIA, PPIA, or EPIA that will be charged. Indeed, should cases of intentional food tampering arise, it will be FBI agents with proper warrants, not FSIS Compliance Officers, who will conduct investigations.

The food security portions of the guidelines also contain either redundancies of or inconsistent requirements regarding matters that are otherwise already regulated by the Occupational Safety and Health Administration (OSHA), the Environmental Protection Administration (EPA), as well as state and local governments. Furthermore, the lead federal agencies for transportation security and safety are the Transportation Security Administration (TSA) within the Department of Homeland Security and the Department of Transportation (DOT). FSIS should defer to these agencies, which have already promulgated and are developing transportation security regulations that impact upon food distributors.

Specifically, TSA is responsible for “security in all modes of transportation” which includes assessing threats to transportation; developing policies, strategies, and plans for dealing with threats to transportation; and ensuring the adequacy of security measures for the transportation of cargo. 49 U.S.C. § 114. TSA recently promulgated an interim final rule, effective May 5, 2003, which provides that, as of September 2, 2003, no individual may hold a commercial drivers license (CDL) with a hazardous materials endorsement if the individual does not meet citizenship requirements or has a disqualifying criminal offense, mental defect as specified under regulations, or poses a security threat. 68 Fed. Reg. 23869 (May 5, 2003). No later than November 3, 2003, no state may issue, renew, or transfer a hazardous materials endorsement for a CDL unless the State receives a Notification of No Security Threat from TSA. 68 Fed. Reg. 23870. To the extent that persons subject to these interim regulations are also responsible for the transportation and distribution of meat, poultry, and egg products, a framework has been developed by an agency with the proper expertise to respond to any possible threats posed by such persons.

The U.S. Coast Guard has also published interim regulations aimed at helping to protect ports, ships and maritime facilities from possible terrorist threats. 68 Fed. Reg. 39240 (July 1, 2003). The interim rule requires owners or operators of vessels calling on U.S. ports, as well as owners or operators of facilities in U.S. ports to designate security officers, develop security plans based on security assessments, and implement security measures specific to the vessel or facility operation. On or before December 29, 2003,

each vessel or facility owner or operator must submit to the Coast Guard its security plan that incorporates detailed preparedness, prevention and response activities. 68 Fed. Reg. 39,303 and 39,323. Security systems and equipment must be in good working order and inspected, tested, calibrated and maintained; security plans must be provided for restricted areas and address the handling cargo; and facility personnel must be trained and drilled regarding relevant provisions of the plan. 68 Fed. Reg. 39,307-39,309, and 39,325-39,329.

Furthermore, DOT is currently establishing a Transportation Worker Identification Credential (TWIC) system. See: <http://www.tsa.dot.gov/public/display?theme=68>. The functional objective of the TWIC is to provide one standardized, common credential (supported by a single integrated and secure network of databases) to manage transportation worker access into secure transportation areas and operations. DOT envisions that TWIC will minimize redundant credentials and background investigations, provide capability to quickly disseminate threat alerts throughout the system and to revoke security access system-wide for specific individuals, and allow the TSA to focus resources on unknown individuals who present a greater threat risk. See: <http://www.tsa.dot.gov/public/display?theme=86&content=516>.

Moreover, existing DOT regulations provide that motor carriers must systematically inspect, repair, and maintain all motor vehicles (49 CFR Part 396), such that no commercial motor vehicle is permitted to be driven unless the driver ensures that emergency equipment is in place and ready for use (49 CFR 392.8); that brakes, steering, lights, tires, horn, coupling devices, wind shield wipers, and mirrors are in good working order (49 CFR 392.7); and that cargo is properly distributed and adequately secured as specified in regulations; that equipment used in its operations and means of fastening the cargo are secured (49 CFR 392.9). Furthermore, under 49 CFR 393.100, each cargo-carrying motor vehicle must be equipped with devices providing protection against shifting or falling cargo as required and specified in Part 393. In addition, DOT, Federal Motor Carrier Safety Administration (FMCSA) personnel are authorized to perform inspections of all vehicles in operation and declare any vehicle "out of service" if its mechanical condition or loading would likely cause an accident or breakdown. 49 C.F.R. § 396.9.

This highly organized and specific transportation regulatory scheme underscores the fact that FSIS security guidelines are well intentioned but at best redundant of other regulatory requirements, if not potentially conflicting. Given these issues, IFDA respectfully requests that FSIS withdraw the entire food security section from the guidelines. To the extent that the agency does not withdraw the food security section of the guidelines and considers proper rulemaking procedures, IFDA respectfully requests that FSIS closely coordinate its food security measures with the similar requirements of other government agencies that impact upon the food industry, and IFDA also submits the following comments regarding the food security measures.

Product Identification

IFDA assumes that the agency intended to give distributors considerable latitude in determining what is an appropriate identifier for a particular shipment of food when the agency recommends keeping detailed production records which include packaging lot or code numbers. Guidelines at 30. As the agency is aware, FDA is currently engaged in a rulemaking on establishment, maintenance, and availability of records under section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). 68 Fed. Reg. 25,188 (May 9, 2003). IFDA has provided comments to FDA in that rulemaking. Under FDA's proposed rule, a nontransporter is required to retain records sufficient to identify both the immediate nontransporter source of food and the transporter that transported the food to it. For example, if a distributor receives food from nontransporter A via transporter X, the distributor must keep detailed records about both nontransporter A and transporter X. In the preamble to the proposed rule, FDA acknowledges that "requiring nontransporters to keep records on both previous and subsequent transporters and nontransporters is potentially burdensome" and that "there could be other interpretations" of section 306 of the Bioterrorism Act. 68 Fed. Reg. at 25,195. The agency said it is open to "alternative record keeping arrangements that would allow for the complete and efficient investigation of food-related emergencies." *Id.*

The regulation that will result from this rulemaking will contain detailed requirements for recordkeeping of documents that will necessarily entail product identification. Again, this FDA rulemaking underscores one of the significant problems of the FSIS guidelines: that much of the material is either redundant or contradictory to other regulatory requirements. At a minimum, FSIS should revise the guidelines to direct regulated entities to conform their product identification schemes to applicable law and regulation.

FSIS should also be aware the food industry is moving rapidly to adopt a new technology that would make it possible to trace food throughout the chain of distribution. Radio frequency identification technology (RFID) involves tagging pallets or cartons of food with a chip containing an electronic product code (EPC) that can be read by a scanner. Analysts are predicting the technology will be widespread in a few years. Given the fact that tracing of foods electronically is likely to be common practice in a few years' time, it does not make sense for the agency to recommend or implement a regulation in which an elaborate system of paper record keeping that will only be necessary for a short period of time.

Because a given shipment or pallet may contain food from multiple lots, most distributors track food by purchase order number—a far simpler and more efficient method. All foods have a purchase order and purchase order number. If a manufacturer recalls a product, it is an easy matter to translate lot numbers into a purchase order number and remove the recalled product. Such systems should be acceptable under FDA's regulatory scheme; FSIS should not be issuing guidelines that contradict regulatory requirements of the other food safety agency.

Seals

In addition, while the agency recommends the use of tamper-proof product seals (Guidelines at 24), such seals may be problematic when verifying product identification numbers or undergoing inspection activities that may require the breaking of seals. Furthermore, the removal of seals is inconsistent with agency recommendations regarding the maintenance of product temperature since activities requiring the removal of product seals will most likely compromise maintenance of the cold chain, as recommended in the food safety section of the guidelines, and which we comment on below.

Truck Security, Unscheduled Deliveries, Assessment of Vulnerabilities

FSIS recommends securing trucks, trailers and containers (Guidelines at 25). We respectfully submit that all prudent distributors already secure their facilities and vehicles if for no more mundane reason than to minimize theft of product. The agency recommendation to hold unscheduled deliveries outside premises pending verification of shipment and cargo (Guidelines at 27) also is problematic because trucks waiting outside the premises could conceivably pose a security risk, *i.e.*, become at risk of theft or tampering. Late deliveries are a fact of life and do not ordinarily pose any food safety concerns if equipment is functioning properly.

The guidelines recommend use of a recognized threat/risk/vulnerability model such as the Operation Risk Management and Systematic Assessment of Facility Risk to develop a comprehensive transportation security plan and assess vulnerabilities. Guidelines at 18. IFDA requests that the agency note the specific hazards that the industry should be concerned with instead of having the industry go through the time and expense of identifying hazards with which the agency will disagree. The agency should specify what constitutes a recognized threat/risk/vulnerability model. Again, the industry does not want to go through the time and expense of identifying hazards, only to have the agency reject the model that was used.

FOOD SAFETY ISSUES

FSIS states that the food safety measures within the guidelines are designed to help prevent contamination of food products during transportation and storage. While hazards may be present at any point during transportation and distribution, the agency asserts that they are most likely to occur at changes between transportation modes and during loading and unloading; therefore, FSIS contends that the guidelines help to improve food safety at every step in the process. 68 Fed. Reg. 45,789-45,790.

Most of the recommendations within the food safety section of the guidelines would most likely be covered under a distributor's Sanitation Standard Operating Procedures (SSOPs) as required by 9 C.F.R. § 416, or under current Good Manufacturing Practices (cGMP) obligations under 21 C.F.R. § 110.93. While FSIS recommends that

the industry not accept products known to be, or suspected of being adulterated, Guidelines at 15, acceptance of adulterated products is already a violation of the FMIA, PPIA, EPIA, and the Federal Food, Drug and Cosmetics Act (FFDCA). While FSIS may wish to reduce foodborne illness to the maximum extent possible by broadly approaching its food safety mission, creating redundancy is not the way to do it.

The FMIA, PPIA, and EPIA prohibit interstate transportation of adulterated or misbranded meat, poultry, or egg products intended for use as human food. *See* 21 U.S.C. §§ 610(c), 661(c), 454(c), 458(a)(2), 1037. Also, certain regulations (9 C.F.R Part 325 and Part 381, subpart S) require that transported meat and poultry products be “wrapped, packaged, or otherwise enclosed” so as to prevent their adulteration by air contaminants, unless the means of conveyance in which the product is transported is completely enclosed with tight-fitting doors or other covers for all openings. The means of conveyance onto which meat or poultry products are loaded, being loaded, or intended to be loaded also are subject to inspection at an official establishment.

Furthermore, because many distributors carry products regulated by the FDA, the FDA routinely examines food products transported in interstate commerce. FDA’s requirements for the conditions under which food is to be transported and stored are contained in the agency’s cGMP regulations (21 C.F.R. Part 110). For example, the regulations require all persons working in direct contact with food, food contact surfaces, and food-packaging materials to engage in proper hygienic practices. Also, all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food must ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Furthermore, the Department of Transportation (DOT) has promulgated regulations affecting the conditions under which edible products can be transported in commerce. For example, a carrier cannot transport certain hazardous materials in the same motor vehicle with food, feed, or any edible material intended for consumption by humans or animals unless packaged in specifically prescribed packages. 49 C.F.R. §§ 173.25(c), 177.841(e). It is standard industry practice in food service distribution for the manufacturer of the hazardous material to assure compliance with these requirements.

Moreover, many of the food safety measures within the guidelines are standard industry practice and FSIS provides no acknowledgement of industry use of quality assurance systems—it is just good business practice to maintain cleanliness for the transportation and storage of food. These existing laws, regulations, and practices provide the proper assurances that food distribution and storage activities do not jeopardize the public health. As such, the corresponding food safety measures within the FSIS guidelines create needless redundancy.

Notably, IFDA also is deeply concerned about the agency recommendation to “continuously maintain” the cold chain. Ambient temperature excursions are a reality within the food product transportation and distribution industry every time the loading door opens. Proper palletization and blanketing are key to ensuring product integrity.

Also, while it is feasible to pre-cool trailers and trucks for at least one-hour (Guideline at 10), the guideline should be revised to account for “real world conditions.” Specifically, the agency should recommend time and temperature not as specific targets, but rather as goals of ensuring that trailers and trucks are at appropriate temperatures at loading. The reason for setting a performance standard rather than an “one-hour precool” rule is the simple fact that pre-cooling during the summer months in Texas will be different from pre-cooling during the winter months in Chicago.

The guideline that transportation vehicles be dedicated “for food use only” (Guideline at 9) is another example of a guideline that does not take into account prudent industry practice, existing regulatory requirements, or whether such a guideline would, in fact, enhance food safety. For foodservice distributors in particular, use of dedicated transportation vehicles would be untenable. The foodservice distribution industry achieves its efficiencies --*and achieves its efficiencies while preserving food safety*-- precisely because it can deliver to hotels, restaurants, and institutional foodservice outlets a combination of food and non-food products for use in a foodservice setting. Imposing a requirement that linens, food utensils, paper products, and even properly packaged cleaning materials cannot be transported in the same truck as food products (with due regard for GMP compliance) does not enhance food safety and unnecessarily increases costs. Recommendations within the guidelines regarding mixed or partial loads does not take into account “full-line” distribution that is typical within the food service distribution industry. IFDA companies carry everything—table linens, glass, paper, frozen foods, etc. As such, HACCP plans and/or SSOPs require some attention to non-commingled goods. IFDA would be pleased to invite USDA staff to observe typical activities within the food service distribution industry so that the agency may have a better idea as to what constitutes industry practice and that agency guidelines better reflect industry practice.

FSIS recommends that regulated entities design and construct vehicles to protect product, to ensure that interior surfaces are suitable for direct food contact. Guidelines at 8. Such a recommendation is far beyond existing GMP requirements and arguably outside of FSIS authority.

FSIS also appears to be following FDA’s Seafood HACCP “Four-Hour Rule” under which refrigerated seafood products must have continuous temperature monitoring if they are under transport for more than four hours. *See* FDA, FISH & FISHERIES PRODUCTS HAZARDS & CONTROLS GUIDANCE; *THIRD EDITION* at 6. In the absence of an FSIS clarification regarding the non-binding nature of the guidelines, this “guideline” will inexorably transform into regulatory fiat without benefit of notice-and-comment rulemaking. The agency, if it wishes to impose specific requirements such as these, cannot do so by guideline. FSIS should revise the guideline to reflect that appropriate temperatures must be maintained and not specify the manner in which that temperature maintenance is to be accomplished.

The guidelines contain several provisions regarding imposition of recordkeeping on transportation. As noted above, FDA’s current rulemaking to implement section 306

of the bioterrorism legislation will impose its own regulatory requirements, and the guidelines should be revised to reflect that regulated entities should conform their recordkeeping to FDA requirements.

Lastly, FSIS acknowledges that it lacks data on whether adequate food safety controls are being employed during food transportation and distribution. 61 Fed. Reg. 59,376 (November 22, 1996). The agency also acknowledges that this lack of information does not by itself indicate the existence of a problem warranting regulatory intervention. *Id.* As such, IFDA requests that FSIS first identify whether a problem exists regarding food safety during transportation and distribution before offering any guidelines or regulations for industry. It is only when such food safety issues are properly identified that they may be properly addressed. Otherwise, agency behavior becomes arbitrary and capricious.

CONCLUSION

We appreciate the opportunity to comment on FSIS's Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products. While there has been considerable progress in the maintenance of food safety, we must remain vigilant and proactive in our efforts to ensure consumer confidence in both food safety and food security. However, vigilance is not served when the agency fails to follow proper administrative procedures, provides for measures that fall outside its scope of authority, and issues unnecessarily redundant requirements. IFDA urges the agency to revisit these guidelines and thanks the agency for its time and consideration of these comments.

Respectfully submitted,



David French
Senior Vice President, Government Relations
International Foodservice Distributors Association