NCR

NATIONAL COUNCIL OF CHAIN RESTAURANTS
of the 〉 National **Retail** Federation

(handwritten notes across top: 12/10 · Camille/Mary/Dort · Did we take their comments? · Fax · → 12/11 to Melissa Scarler)

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Reference Docket #03D-0092
Retail Food Stores and Food Service Establishments:
Food Security Preventive Measures

ATTN: Camille Brewer

Attached you will find comments (both italicized and in red line version) to your Guidance Draft document for Retail Food Stores and Food Service Establishments. These represent the comments of the National Council of Chain Restaurants. We would greatly appreciate the opportunity to sit down once again with representatives of your agency to discuss these comments in greater detail before you move to finalize this guidance document.

Please contact me at your earliest convenience to discuss this possibility. I would also appreciate a status report of the entire guideline process.

Thank you for your attention to this matter.

Sincerely,

Terrie M. Dort

Terrie M. Dort
President

03D-0092

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 21, 2003

Guidance for Industry Retail Food Stores and Food Service Establishments:
Food Security Preventive Measures Guidance Draft Guidance

This draft guidance represents the Agency's current thinking on the kinds of measures that retail food store and food service establishment operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Purpose and Scope:

This draft guidance is designed as an aid to operators of retail food stores and food service establishments (for example, bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for home-bound persons, mobile food carts, restaurants, and vending machine operators). This is a very diverse set of establishments, which includes both very large and very small entities.

This draft guidance identifies the kinds of preventive measures they may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. Operators of food retail food stores and food service establishments are encouraged to review their current procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements.

This draft guidance is designed to focus operator's attention sequentially on each segment of the food delivery system that is within their control, to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment. To be successful, implementing enhanced preventive measures requires the commitment of management and staff. Accordingly, FDA recommends that both management and staff participate in the development and review of

such measures.

<u>Limitations:</u>

Not all of the guidance contained in this document may be appropriate or practical for every retail food store or food service establishment, particularly smaller facilities. FDA recommends that operators review the guidance in each section that relates to a component of their operation, and assess which preventive measures are suitable. Example approaches are provided for many of the preventive measures listed in this document. These examples should not be regarded as minimum standards. Nor should the examples provided be considered an inclusive list of all potential approaches to achieving the goal of the preventive measure. 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.

<u>Structure:</u>

This draft guidance is divided into five sections that relate to individual components of a retail food store or food service establishment operation: management; human element -- staff; human element -- public; facility; and operations.

<u>Related Guidance:</u>

FDA has published two companion guidance documents on food security, entitled, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance" to cover the farm-to-table spectrum of food production. Both documents are available at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

<u>Additional Resources:</u>*

A process called Operational Risk Management (ORM) may help prioritize the preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against food. Information on ORM is available in the Federal Aviation Administration (FAA) System Safety Handbook, U.S. Department of Transportation, FAA, December 30, 2000, Chapter 15, Operational Risk Management. The handbook is available at: http://www.asy.faa.gov/Risk/SSHandbook/Chap15_1200.PDF

The U.S. Department of Transportation, Research and Special Programs Administration has published an advisory notice of voluntary measures to enhance the security of hazardous materials shipments. It is available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-3636-filed.pdf. The notice provides guidance to shippers and carriers on personnel, facility and en route security issues.

The U.S. Postal Service has prepared guidance for identifying and handling suspicious mail. It is available at: http://www.usps.com/news/2001/press/mailsecurity/postcard.htm.

The Federal Anti-Tampering Act (18 USC 1365) makes it a federal crime to tamper with or taint a consumer product, or to attempt, threaten or conspire to tamper with or taint a consumer

product, or make a false statement about having tampered with or tainted a consumer product. Conviction can lead to penalties of up to $100,000 in fines and up to life imprisonment. The Act is available at: http://www.fda.gov/opacom/laws/fedatact.htm.

The National Infrastructure Protection Center (NIPC) serves as the federal government's focal point for threat assessment, warning, investigation, and response for threats or attacks against U.S. critical infrastructure. The NIPC has identified the food system as one of the eight critical infrastructures, and has established a public-private partnership with the food industry, called the Food Industry Information and Analysis Center (Food Industry ISAC). The NIPC provides the Food Industry ISAC with access, information and analysis, enabling the food industry to report, identify, and reduce its vulnerabilities to malicious attacks, and to recover from such attacks as quickly as possible. In particular, the NIPC identifies credible threats and crafts specific warning messages to the food industry. Further information is available at http://www.nipc.gov/ and http://www.foodisac.org/.

Finally, FDA encourages trade associations to evaluate the preventive measures contained in this guidance document and adapt them to their specific products and operations and to supplement this guidance with additional preventive measures when appropriate. FDA welcomes dialogue on the content of sector specific guidance with appropriate trade associations.

Retail Food Store and Food Service Establishment Operations:

Management

FDA recommends that retail food store and food service establishment operators consider:

- <u>Preparing for the possibility of tampering or other malicious, criminal, or terrorist events</u>

  - assigning responsibility for security to knowledgeable individual(s)

  - conducting an initial assessment of food security procedures and operations, which we recommend be kept confidential

  - having a crisis management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected products

  - planning for emergency evacuation, including preventing security breaches during evacuation

  - becoming familiar with the emergency response system in the community

  - making management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/<u>homeland security agencies</u> *Comment: In restaurants, personnel are typically instructed to contact "911" for any emergencies.*

  - making staff aware of who in management they should alert about potential security problems (24-hour contacts)

- promoting food security awareness to encourage all staff to be alert to any signs of tampering or malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and to report any findings to identified management (for example, providing training, instituting a system of rewards, building security into job performance standards)

- having an internal communication system to inform and update staff about relevant security issues

· having a strategy for communicating with the public (for example, identifying a media spokesperson, preparing generic press statements and background information, and coordinating press statements with appropriate authorities)

· <u>Supervision</u>

- providing an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers [*Comment: The appropriate level of supervision for staff should be flexible and be based on the specific situation/setting. Many of the suggestions above are not practical or feasible for restaurants. We would recommend deleting these specific methods as definitive steps restaurants should take in all cases.*], data entry and computer support staff, and especially, new staff (for example, supervisor on duty, periodic unannounced visits by supervisor, daily visits by supervisor, two staff on duty at same time ~~not necessarily the case/feasable~~, monitored video cameras ~~leaves question as to where to be placed and how many?~~ , off line review of video tapes, one way and two way windows ~~not practical~~, customer feedback to supervisor of unusual or suspicious behavior by staff) ~~overall impractical clearly implies this to be the expectation~~.

· conducting routine *security checks [Comment: What exactly does a "security check" entail? There needs to be better guidance as to the scope of (what and how often) and who should be conducting these security checks.]* of the premises, including utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions, or areas that may be vulnerable to such actions

· <u>Investigation of suspicious activity</u>

- investigating threats or information about signs of tampering or other malicious, criminal, or terrorist actions

· alerting appropriate company, law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

· <u>Evaluation program</u> *[Comment: We recommend that the FDA provide more details about what the purposes/goals of such an evaluation program should be (e.g., specific factors to be measured, etc.). Then we will be in a better position to provide more specific comments and recommendations with respect to this entire section.]*

- evaluating the lessons learned from past tampering or other malicious, criminal,

or terrorist actions and threats *[Comment: For multi-unit restaurant operators or systems, there needs to be clarification as to whether the evaluation activities described below should be conducted at a macro-level/across the system and/or individual restaurant level, as appropriate.]*

- reviewing and verifying, at least annually, the effectiveness of the security management program *as a whole* (for example, using *appropriate* k̶n̶o̶w̶l̶e̶d̶g̶e̶a̶b̶l̶e̶ in-house or third party staff to conduct tampering or other malicious, criminal, or terrorist action exercises and to challenge computer security systems), revising accordingly (using third party or in-house security expert, where possible), revising the program accordingly, and keeping this information confidential

- performing random food security inspections of all appropriate areas of the facility (including receiving and storage areas, where applicable) using knowledgeable in-house or third party staff, and keeping this information confidential *[Comment: Inherent in managing a restaurant is the continuous observation and "inspection" of food prep and serving areas for potential issues. Therefore, we recommend that the FDA engage in further dialogue with the restaurant industry on what an appropriate food security inspection would entail.]*

- verifying that security contractors are doing an appropriate job, when applicable

Human element -- staff

Under Federal law, retail food store and food service establishment operators are required to verify the employment eligibility of all new hires, in accordance with the requirements of the Immigration and Nationality Act, by completing the INS Employment Eligibility Verification Form (INS Form I-9). Completion of Form I-9 for new hires is required by 8 USC 1324a and nondiscrimination provisions governing the verification process are set forth at 1324b.

FDA recommends that retail food store and food service establishment operators consider:

· <u>Screening (pre-hiring, at hiring, post-hiring)</u>

· examining the background of all staff (including seasonal, temporary, contract, and volunteer staff, whether hired directly or through a recruitment firm) as appropriate to their position *[Comment: We do not, as a general rule, employ seasonal, temp or contract labor in our restaurants.]*, considering candidates' access to sensitive areas of the facility and the degree to which they will be supervised and other relevant factors (for example, obtaining and verifying work references, addresses, and phone numbers, participating in one of the pilot programs managed by the Immigration and Naturalization Service and the Social Security Administration [These programs provide electronic confirmation of employment eligibility for newly hired employees. For more information call the INS SAVE Program toll free at 1-888-464-4218, fax a request for information to (202) 514-9981, or write to US/INS, SAVE Program, 425 I Street, NW, ULLICO-4th Floor, Washington, DC 20536. These pilot programs may not be available in all states], having a criminal background check performed by local law enforcement or by a contract service provider [Remember to first consult any state or local laws that may apply to the

performance of such checks])

- Note: screening procedures should be applied equally to all staff, regardless of race, national origin, religion, and citizenship or immigration status.

· Daily work assignments

- knowing who is and who should be on premises, and where they should be located, for each shift

· keeping information updated

· Identification

· establishing a system of positive identification and recognition (for example, issuing uniforms, name tags, or photo identification badges with individual control numbers, color coded by area of authorized access), when appropriate

- collecting the uniforms, name tag, or identification badge when a staff member is no longer associated with the establishment

· Restricted access

- identifying staff that require unlimited access to all areas of the facility

- reassessing levels of access for all staff periodically

- limiting staff access to non-public areas so staff enter only those areas necessary for their job functions and only during appropriate work hours (for example, using key cards or keyed or cipher locks for entry to sensitive areas *[Comment: Some of these measures are extreme and may not be practical in a typical restaurant environment.]*, color coded uniforms [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])

· as appropriate and necessary to maintain security standards, changing combinations and alarm codes, collecting issued keys rekeying locks and/or collecting the retired key card when a staff member who is in possession of these is no longer associated with the establishment

· Personal items

- Reasonable restrictions on restricting the type of personal items allowed in non-public areas of the establishment *[Comment: The term "personal items" could be interpreted very broadly. Certain "personal" items (purses, wallets, prescription medicines, books) may be permissible whereas other "personal" items (weapons or illegal drugs) should not be permitted on the restaurant premises at all.]*

- allowing in the non-public areas of the establishment only those personal use medicines that are necessary for the health of staff (other than those being stored or displayed for retail sale) and ensuring that these personal use medicines are

properly labeled and stored away from stored food and food preparation areas

☐preventing staff from bringing personal items (for example, lunch containers, purses) into nonpublic food preparation or storage areas *[Comment: The breadth of this guideline is not practical in most restaurant environments. Instead, we recommend restating this guideline to require operators to limit such items in non-public food preparation and/or food serving areas.]*

─• providing for regular inspection of contents of staff lockers (for example, providing metal mesh lockers, company issued locks), bags, packages, and vehicles when on company property (Remember to first consult any federal, state, or local laws that may relate to such inspections) *[Implementation of this guideline should be subject to applicable legal, privacy and other requirements/ restrictions. In many states, "cause" or reason to inspect must be shown.]*

- · <u>Training in food security procedures</u>

- incorporating food security awareness, including information on how to prevent, detect, and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including seasonal, temporary, contract, and volunteer staff <u>, as appropriate</u>

- providing periodic reminders of the importance of security procedures (for example, scheduling meetings, providing brochures, payroll stuffers)

- encouraging staff support (for example, involving staff in food security planning and the food security awareness program, demonstrating the importance of security procedures to the staff)

- ~~encouraging staff support (for example, involving staff in food security planning and the food security awareness program, demonstrating the importance of security procedures to the staff)~~ <u>[repeat of the above]</u>

· <u>Unusual behavior</u>

· watching for unusual or suspicious behavior by staff (for example, staff who, without an identifiable purpose, stay unusually late after the end of their shift, arrive unusually early, access files/information/areas of the facility outside of the areas of their responsibility; remove documents from the facility; ask questions on sensitive subjects; bring cameras to work)

· <u>Staff health</u>

- being alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal, or terrorist actions (for example, an unusual number of staff who work in the same part of the facility reporting similar symptoms within a short time frame), and reporting such conditions to <u>restaurant management personnel and, asappropriate,</u> local health authorities

Human element -- public

FDA recommends that retail food store and food service establishment operators consider:

· <u>Customers</u>

- preventing access to food preparation and storage and dishwashing areas in the non-public areas of the establishment, including loading docks

- monitoring public areas, including entrances to public restrooms (for example, using security guards, monitored video cameras, one-way and two-way windows, placement of employee workstations for optimum visibility) for unusual or suspicious activity (for example, a customer returning a product to the shelf that he/she brought into the store, spending an unusual amount of time in one area of the store) *[Comment: Many of the above measures are not practical and/or necessary in a restaurant setting (vs. a manufacturing facility or food distributor warehouse. Accordingly, we recommend restating this guideline as follows: "Implement security devices and processes, as appropriate and feasible based on the restaurant environment, to monitor for unusual or suspicious activity..."]*

· monitoring the serving or display of foods in self-service areas (for example, salad bars, condiments, open bulk containers, produce display areas, doughnut/bagel cases)

· <u>Other visitors (for example, contractors, sales representatives, delivery drivers, couriers, pest control representatives, third-party auditors, regulators, reporters, tours)</u>

- restricting entry to the non-public areas of the establishment (for example, <u>and as appropriate,</u> checking visitors in and out before entering the non-public areas, requiring proof of identity, issuing visitors badges that are collected upon departure *[Comment: The above measures are not always practical or necessary. For example, it is not practical to issue visitor badges to 3rd party personnel who may be delivering food or other supplies to the restaurant throughout the day. Rather than issuing visitor badges, we recommend implementing a policy whereby all visitors must be verified and identified as "authorized" (e.g., check identifiation such as driver's license or company badge) before they may enter the back of the house areas of the restaurant. In our system, only visitors who are "authorized" in this manner by restaurant staff may enter the non-public areas of the restaurant.]*

- ensuring that there is a valid reason for all visits to the non-public areas of the establishment before providing access to the facility - beware of unsolicited visitors

- verifying the identity of unknown visitors to the non-public areas of the establishment

- inspecting incoming and outgoing packages and briefcases in the non-public areas of the establishment for suspicious, inappropriate or unusual items, to the extent

practical

Facility

FDA recommends that retail food store and food service establishment operators consider:

- <u>Physical security</u>

    - protecting non-public perimeter access with fencing or other deterrent, when appropriate <u>and permitted under applicable laws, regulations and ordinances</u>

    - <u>as applicable and to the extent practical,</u> securing doors (including freight loading doors, when not in use and not being monitored, and emergency exits), windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, ice manufacturing and storage rooms, loft areas and trailer bodies, and bulk storage tanks for liquids, solids and compressed gases to the extent possible (for example, using locks, "jimmy plates," seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes]) *[Comment: Although some of the above-mentioned methods for securing doors is appropriate for restaurants, most are neither practical nor applicable to the restaurant environment. Many of the measures listed above appear to be more applicable to factory/manufacturing facilities.*

    - using metal or metal-clad exterior doors to the extent possible when the facility is not in operation, except where visibility from public thoroughfares is an intended deterrent (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)

    - minimizing the number of entrances to non-public areas (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)

    - accounting for all keys to establishment (for example, assigning responsibility for issuing, tracking, and retrieving keys) *[Comment: Would restate this guideline as "establishing and implementing a process for managing issuance and collection of keys and/or maintaining an alarm lock key system."]*

    - monitoring the security of the premises using appropriate methods (for example, using security patrols [uniformed and/or plain-clothed], monitored video surveillance) *[Comment: In many cases, monitored video surveillance and security patrols are not practical or necessary. However, there are appropriate processes for employees to monitor/check locks and alarm systems throughout the day, particularly when opening and closing the premises for business.]*

    - minimizing, to the extent practical, places in public areas that an intruder could remain unseen after work hours

    - minimizing, to the extent practical, places in non-public areas that can be used to

temporarily hide intentional contaminants (for example, minimizing nooks and crannies, false ceilings

- providing adequate interior and exterior lighting, including emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activity

- implementing a system of controlling vehicles authorized to park in the non-public parking areas (for example, using placards, decals, key cards, keyed or cipher locks, issuing passes for specific areas and times to visitors' vehicles) *[Comment: This guideline is not practical for the restaurant industry as a whole.]*

- · keeping customer, employee and visitor parking areas separated from entrances to non-public areas, where practical *[Comment: This guideline is not practical for the restaurant industry as a whole.*

Storage and use of poisonous and toxic chemicals (for example, cleaning and sanitizing agents, pesticides) in non-public areas

- limiting poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are being stored or displayed for retail sale

- storing poisonous and toxic chemicals as far away from food handling and food storage areas as practical

- limiting access to and securing storage areas for poisonous or toxic chemicals that are not being held for retail sale (for example, using keyed or cipher locks, key cards, seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire codes before making any changes]) *[Comment: The above requirements are not practical for restaurant operations; however, it would be appropriate to provide that poisonous or toxic chemicals, if any, be stored in a non-food preparation or storage areas.]*

- ensuring that poisonous and toxic chemicals are properly labeled

- using pesticides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (for example, maintaining rodent bait that is in use in covered, tamper-resistant bait stations) *[Comment: This requirement should be restated to apply to pest control suppliers/services engaged by restaurants. It is impractical to expect typical restaurant staff to be able to evaluate this compliance. Our recommendation would be for restaurants to have processes in place to ensure that suppliers who provide/use these kinds of pest control services to restaurants are reputable, licensed and approved vendors who are required to comply with the applicable laws and regulations in performing their services.]*

- knowing what poisonous and toxic chemicals should be on the premises and keeping track of them *[Comment: This guideline in generally acceptable, provided that, the FDA understands that (at least in our restaurant system), the concept of "knowing" involves (1) implementing guidelines as to what chemicals are allowed and prohibited in each restaurant, (2) providing each restaurant with technical specification sheets for any toxic chemicals that are allowed on the premises, and (3)include inspection for such chemicals in our restaurant audits.]*

- investigating missing stock or other irregularities outside a normal range of variation and alerting <u>management personnel,</u> local enforcement and public health agencies about unresolved problems, when appropriate

Operations

FDA recommends that retail food store and food service establishment operators consider:

- <u>Incoming products</u>

  - using only known and appropriately licensed or permitted (where applicable) sources for all incoming products

  - informing suppliers, distributors and transporters about FDA's food security guidance, "Food producers, processors, and transporters: Food security preventive measures guidance" and "Importers and filers: Food security preventive measures guidance," available at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

  - taking steps to ensure that delivery vehicles are appropriately secured

  - requesting that transporters have the capability to verify the location of the load at any time, when practical

  - establishing delivery schedules, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments

  - supervising off-loading of incoming materials, including off hour deliveries, directly conflicts with the practice of "off hour" deliveries at which time no staff are present. *[Comment: Off-hour deliveries are essential to most large scale restaurant operations, and by its very nature, would involve "supervision" in non-traditional ways (e.g., employees are no necessarily physically present for deliveries made after closing). In fact, in some areas, local ordinances/regulations provide that larger delivery vehicles can only be parked around the restaurant during certain times of the day, including after closing time. However, we employ alarm codes and key drops with each vendor that is pre-authorized to deliver products/supplies to our restaurants off-hour. Accordingly, we recommend that the FDA engage in further dialogue with the restaurant industry to provide clarity on this guideline in the context of restaurant operations (vs. factory/manufacturing facilities).]*

- reconciling the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents, taking into account any sampling performed prior to receipt

- investigating shipping documents with suspicious alterations

- inspecting incoming products and product returns for signs of tampering, contamination or damage (for example, abnormal powders, liquids, stains, or odors, evidence of resealing, compromised tamper-evident packaging) or "counterfeiting" (for example, inappropriate or mismatched product identity, labeling, product lot coding or specifications, absence of tamper-evident packaging when the label contains a tamper-evident notice), when appropriate

- rejecting suspect food

- alerting appropriate company, law enforcement and public health authorities about evidence of tampering, "counterfeiting," or other malicious, criminal, or terrorist action

- Storage

  - having a system for receiving, storing and handling distressed, damaged, and returned products, and products left at checkout counters, that minimizes their potential for being compromised (for example, obtaining the reason for return and requiring proof of identity of the individual returning the product, examining returned or abandoned items for signs of tampering, not reselling returned or abandoned products)

  - keeping track of incoming products, materials in use, salvage products, and returned products

  - investigating missing or extra stock or other irregularities outside a normal range of variability and reporting unresolved problems to appropriate law enforcement and public health authorities, when appropriate *[Comment: This guideline is generally acceptable, but it's important to recognize that some minimal level of missing/extra stock of in our restaurants may be par for the course and, therefore, would not necessarily trigger an investigation.]*

  - minimizing reuse of containers, shipping packages, cartons, etc., where practical

- Food service and retail display

  - displaying poisonous and toxic chemicals for retail sale in a location where they can be easily monitored (for example, visible by staff at their work stations, windows, video monitoring)

  - periodically checking products displayed for retail sale for evidence of tampering or other malicious, criminal, or terrorist action (for example, checking for off-condition appearance [for example, stained, leaking, damaged packages, missing or mismatched labels], proper stock rotation, evidence of resealing, condition of

tamper-evident packaging, where applicable, presence of empty food packaging or other debris on the shelving), to the extent practical

· monitoring self-service areas (for example, salad bars, condiments, open bulk containers, produce display areas, doughnut/bagel cases) for evidence of tampering or other malicious, criminal, or terrorist action

<u>Security of water and utilities</u>

- limiting to the extent practical access to controls for airflow, water, electricity, and refrigeration

- securing non-municipal water wells, hydrants, storage and handling facilities

- ensuring that water systems and trucks are equipped with backflow prevention

- chlorinating non-municipal water systems and monitoring chlorination equipment and chlorine levels

- testing non-municipal sources for potability regularly, as well as randomly, and being alert to changes in the profile of the results

[Comment: The above highlighted language/guidelines are not typically applicable and/or practical for restaurants to implement. If applicable, performance of these tasks would most likely be delegated to (e.g., service contract) a 3rd party vendor who specializes in these services.]

- staying attentive to the potential for media alerts about public water provider problems, when applicable

· identifying alternate sources of potable water for use during emergency situations where normal water systems have been compromised (for example, bottled water, trucking from an approved source, treating on-site or maintaining on-site storage)

· <u>Mail/packages</u>

· implementing procedures to <u>help detect significant irregularities and potential risks with</u> ~~ensure the security of~~ incoming mail and packages

· <u>Access to computer systems</u>

- restricting access to critical computer data systems to those with appropriate clearance (for example, using passwords, firewalls) *[Comment: The processes for ensuring compliance with this type of guideline could differ depending on whether the computer data systems in question are implemented at the restaurant or at the corporate headquarters/macro level.]*

- eliminating computer access when a staff member is no longer associated with the establishment

- establishing a system of traceability of computer transactions using commercially available tools *[Comment: We would like further clarification from the FDA as to what "traceability" in the above context means.]*

- reviewing the adequacy of virus protection systems and procedures for backing up critical computer based data systems

- validating the computer security system, as applicable

Emergency Point of Contact:

U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-443-1240

If a retail food store or food service establishment operator suspects that any of his/her products that are regulated by the FDA have been subject to tampering, "counterfeiting," or other malicious, criminal, or terrorist action, FDA recommends that he/she notify the FDA 24-hour emergency number at 301-443-1240 or call their local FDA District Office. FDA recommends that the operator also notify local law enforcement and public health authorities.

FDA District Office telephone numbers are listed at:
http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.

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*Reference to these documents is provided for informational purposes only. These documents are not incorporated by reference into this guidance and should not be considered to be FDA guidance.

Guidance Documents | Food Safety and Terrorism