

FDA Inspection Manual

A PRACTICAL GUIDE

by **Richard E. Gutting, Jr.**

Sponsored by
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This manual is an educational guide for owners, managers and quality control directors of seafood facilities processing ready-to-eat products when their facility is inspected by the U.S. Food and Drug Administration and they must respond to alleged violations. It does not constitute legal advice. Recommended actions are not intended to cover every situation and may not apply to your situation. Readers should consult with their legal and technical advisers to ensure that their procedures meet relevant requirements.

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Contents

Introduction	4
A. FDA Inspection Authority	4
1. What is Reasonable	5
2. Advanced Notice and Warrants.....	7
3. NOAA “Approved Establishments”	8
4. Credentials and Notice of Inspection.....	8
5. Inspection of Records	9
6. FDA Samples	12
7. Photographs.....	14
8. Affidavits	15
B. Preparing for Inspection	16
1. Appoint a Representative	16
2. Prepare an Inspection Manual	16
3. Conduct Training.....	20
4. Conduct Exercises	20
C. During the Inspection	22
1. Arrival of Inspector	22
2. Initial Meeting	22
3. Escorting the Inspector	25
4. Taking Samples	26
5. Preparing a Record of the Inspection.....	28
6. Correcting Deficiencies Noted by the Inspector	28
7. “Notice of Inspectional Observations” (Form FDA 483).....	28
8. Exit Meeting	29
D. Post Inspection.....	31
1. Responding to Inspectional Observations.....	31
2. Obtain Copies of the Establishment Inspection Report.....	32
3. Monitor FDA’s Classification of the Inspection	33
4. Warning Letters.....	34
E. Possible FDA Enforcement Actions	37
1. Administrative Detention	37
2. Seizures and Injunctions	37
3. Registration Suspensions	38
4. Re-Inspections	38
5. Criminal Prosecution.....	39
6. Private Enforcement.....	40
7. FDA Ombudsman	40
References.....	41

Introduction

In 2011 the Food Safety Modernization Act (FSMA)¹ directed the U.S. Food and Drug Administration (FDA) to increase its inspections of foreign and domestic food facilities and to base these inspections upon risk.² FDA also gained new authority to detain and recall products, suspend a facility's registration and collect fees for "re-inspections" when its inspectors found violations.

As a result, processors of "high risk potential" seafood --- particularly those cooking or smoking ready-to-eat products, or packing refrigerated products in Reduced Oxygen Packaging --- became the most likely seafood processors to be inspected and have the "observations" of FDA inspectors escalate into Warning Letters and FDA enforcement.³

This Manual explains how FDA inspections have changed under FSMA, and suggests how "high risk potential" seafood processors can manage and respond to FDA inspections to avoid costly disruptions.

A. FDA Inspection Authority

FDA's Office of Regulatory Affairs, which is traditionally called "FDA's inspectorate" or "the field", has 4,300 officials organized into 20 district offices and five regions, with over 225 offices/resident posts or home domiciles. It also operates from 12 FDA foreign offices, 5 of which include resident investigators.

The authority of these FDA investigators and compliance officers to inspect seafood facilities is set forth in Section 704⁴ of the Federal Food, Drug and Cosmetic Act (FDCA),⁵ and covers any establishment in which seafood is manufactured, processed, packed or held for introduction into interstate commerce or after such introduction, and any vehicle used to transport seafood in interstate commerce. The key wording is:

*“ . . . officers or employees . . . upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized
 (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food . . . are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food . . . and
 (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein . . . Each such inspection shall be commenced and completed with*

¹ Public Law 111-353

² "Selection and prioritization of processors and products for inspection will be risk based." Seafood Processor Inspection Program – Domestic and Foreign Facilities (CP 7303.842)

³ FDA listed "High-Risk Potential Products" in its Import Seafood Products Compliance Program in this descending order of priority: Refrigerated seafood products packed in oxygen limiting packaging or reduced oxygen packaged; Raw (fresh and fresh frozen) molluscan shellfish from uncertified shippers; Ready-to-eat fish or fishery products; Seafood mixes; Scombrototoxin-forming (histamine-forming) species; Aquacultured seafood; Ready-to-eat fish or fishery products that have not undergone a heat treatment; Salt-cured, and/or air-dried, un-eviscerated fish; and Acidified and low acid canned foods.

⁴ 21 USC 374

⁵ 21 USC 301 et seq

reasonable promptness . . . Upon completion of any such inspection . . . and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food . . . in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . . If the [inspector] obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained . . . and an analysis is made of such sample . . . a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.”

FDA inspectors, therefore, may inspect seafood facilities but are constrained by statutory requirements to:

- 1) Be “reasonable”;
- 2) Show appropriate credentials;
- 3) Issue a Notice of Inspection to the “owner, operator or agent in charge”;
- 4) Issue a receipt for any samples collected; and
- 5) Issue inspectional observations if violations are found.

1. What is Reasonable

FDCA Section 704 requires FDA inspections to be conducted “*at reasonable times, within reasonable limits, and in a reasonable manner*” and they must be “*completed with reasonable promptness*”.⁶

This wording was not changed by FSMA. No FDA rule, however, defines these reasonableness standards and their meaning has been litigated only a few times. When they have been challenged, courts have determined reasonableness based on whether FDA met the procedural requirements of Section 704 and have said that reasonableness depends on the facts of each situation, such as the enforcement needs of the agency and whether an unnecessary burden is placed on a firm.

a) Timing of Inspections

The calendar and clock do not establish what time is “reasonable” for a FDA inspection. Instead, what is happening in your facility determines what is reasonable.

FDA’s past practices and its “Compliance Program” documents, which instruct FDA personnel on how they should conduct different types of FDA inspections, have defined when it is “reasonable” to conduct an inspection of a facility under FDCA Section 704. FDA’s “Seafood Processor Inspection Program - Domestic and Foreign Facilities” (CP 7303.842), for example, says:

“HACCP inspections should be planned for times when the firm is known to be in production. For firms producing both high and low risk potential products, the

⁶ 21 USC 374(a)(1)

inspection should be conducted when high risk product(s) are produced. Product selections should be risk-based and target a particular higher risk product/process. . . .

For logistical reasons, it is recognized that it will be impractical to inspect most processing vessels when they are in operation. Inspections of these vessels will normally be performed when the vessel is in port and not in operation. . . .

In the event an investigator arrives at a firm prepared to do a HACCP inspection and the firm is not in operation, the inspection should be rescheduled if possible.”

Likewise, FDA’s Compliance Program for “Domestic Acidified and Low-Acid Canned Foods (7303.803a)” states:

“Inspections should occur when the firm is operating (which may require some advance planning) and should include observations of retort processing lines while in operation, to look for possible malfunctions. (This may involve the inspection team being at the firm for early or late shifts and overtime.)”

No FDA rule or guidance suggests that a facility must start production or otherwise change its operations when a FDA inspector arrives at the facility wanting to inspect its operations.

b) Limits and Manner of Inspection

FDCA Section 704 also requires FDA inspections to be conducted within “reasonable limits” and in a “reasonable manner”⁷ Exactly what these limits are is unclear.

FDA’s Investigations Operations Manual⁸ (IOM) instructs FDA inspectors as follows:

“Your authority to enter and inspect establishments is predicated upon specific obligations to the firm as described below. It is your responsibility to conduct all inspections at reasonable times and within reasonable limits and in a reasonable manner. Proceed with diplomacy, tact and persuasiveness. . . .”⁹

If you are being repeatedly used for FDA training sessions and these "inspections" are disruptive, express your concerns with the Director of the local FDA District Office.

Many other situations also raise the question of whether a FDA inspection is “reasonable”. For example:

- May you limit FDA inspections to times when the facility manager is present? No. If the facility is operating without the manager being present, this is probably not a reasonable limit.
- May you require a FDA inspector to follow safety and current good manufacturing practice standards? Yes. One of the “reasonable” limits is that FDA inspectors

⁷ 21 USC 374(a)(1)

⁸ The *Investigations Operations Manual* is the primary source regarding FDA policy and procedures for its field investigators and inspectors and is available on the FDA website. <http://www.fda.gov/iceci/inspections/iom/default.htm>

⁹ IOM, Sections 5.1.1.1 - 3

must comply with the safety and good manufacturing practices procedures (e.g. protective clothing, aseptic standards) of the facility.

- May you insist that an FDA inspector be accompanied by facility personnel? Yes. FDA guidance encourages this.
- Can you refuse FDA access to the living quarters of workers? Yes. Any such access can be gained only with a warrant.¹⁰
- Must you change your operations if asked? No. FDA inspectors cannot interfere with normal production process, or require that operations be conducted.

2. Advanced Notice and Warrants

In addition to the general requirements to be “reasonable”, FDCA Section 704 imposes several specific procedural requirements on FDA inspections.

FDCA Section 704, however, does not require prior notice of an inspection. As a result, FDA rarely provides advanced notice of inspections to domestic seafood facilities. FDA’s Field Management Directives Manual explains:

“It has been, and continues to be, the tradition and policy of the Food and Drug Administration, with very few exceptions, to initiate inspections and special investigations . . . without prior notification to the specific facility or its management of our intent to inspect.

The objective in not providing prior notification is to be able to inspect the establishment under conditions that represent normal day-to-day activities. This in theory, gives a true picture of a firm’s level of compliance. It can also be assumed, with due justification, that there are some firms operated by less than honest individuals where prior notification would permit the operator time to achieve some degree of temporary correction. In the case of a clandestine or truly illegal operation, the possibility of the facility not being in operation when the investigator arrives also exists.”¹¹

Foreign facilities, however, are given advance notice, although there is no regulatory requirement for an advanced notice. The FSMA, however, added a provision in FDCA Section 807(b) that requires foreign facilities to allow entry and inspection by FDA inspectors within 24 hours of a request, or have their products refused entry.¹²

FDCA Section 704 also does not say whether an inspection warrant is required and the court rulings on whether a warrant must be obtained are unsettled. It is unclear, therefore, whether FDA may conduct a warrantless inspection of a seafood facility. However, as a practical matter, virtually all FDA inspections are conducted with the consent of the company, making a warrant unnecessary. Refusal to allow a warrantless search is generally inadvisable anyway, because FDA will have no difficulty obtaining a warrant.

FDA, therefore, does not routinely request warrants in advance to inspect domestic seafood facilities. However, it may seek a preemptive warrant if it believes a company will refuse an inspection or refuse access to information and that this information will then be destroyed before an inspection warrant can be obtained.

¹⁰ IOM, Section 5.1.1.9

¹¹ Prior Notification to FDA Regulated Industries of Impending Inspections (17)

¹² 21 USC 384c

A refusal to permit entry or inspection is a Prohibited Act and FDA could seek an injunction or criminal penalties.¹³ More likely, FDA will obtain an inspection warrant from a U.S. Judge or Magistrate.¹⁴

3. NOAA “Approved Establishments”

If a processing facility or vessel is an “Approved Establishment” that has voluntarily contracted with the NOAA Seafood Inspection Program for inspection services and has been certified as being capable of producing safe, wholesome products, the FDA inspector is directed to invite the NOAA Seafood Inspection Program inspector to participate in the FDA inspection and to provide the NOAA inspector with a copy of the Inspectional Observations (Form FDA 483), if one is issued.

4. Credentials and Notice of Inspection

While neither a warrant nor an advanced notice is required for entry and inspection, before beginning an inspection, FDCA Section 704 requires a FDA inspector to present “*appropriate credentials and a written notice to the owner, operator, or agent in charge*” of a facility.¹⁵ In response, FDA’s Investigations Operations Manual instructs FDA inspectors to:

“Display your credentials to the top management official be it the owner, operator, or agent in charge. . . .

NOTE: Although management may examine your credentials and record the number and your name, do not permit your credentials to be photocopied. Federal Law (Title 18, 701) prohibits photographing, counterfeiting, or misuse of official credentials.

After showing the firm's representative your credentials, issue the original, properly executed, and signed FDA 482, Notice of Inspection, to the top management official.”¹⁶

This “Notice of Inspection” is a printed form (Form FDA 482) with spaces to be filled in, showing the date, the name and title of the responsible member of the firm to whom the notice is being issued, the firm name, and location of the plant. The Notice of Inspection also quotes wording from the FDCA which grants FDA its inspection authority. It should be signed by the inspector and should bear the name and address of the District Office from which he or she operates.

The Notice of Inspection does not provide a written explanation of why the inspection is being conducted, whether it is routine or a for-cause inspection, or what type of information is being sought.

FDA inspectors are directed to provide you with an original signed copy of the Notice of Inspection. You are not required to sign it. Instead it should be accepted and filed as evidence of the inspection.

¹³ 21 USC 331(f) and 333

¹⁴ 21 USC 331(f)

¹⁵ 21 USC 374(a)(1)

¹⁶ IOM, Sections 5.1.1.1 - 3

5. Inspection of Records

During an inspection, the FDA inspector typically asks to review a variety of records and documents. Whether you must provide access to these records and documents depends upon the requirements of several laws.

a) Basic Authority

A FDA inspector's basic legal authority to inspect and copy records is in FDCA Section 704(a),¹⁷ which provides

“ . . . shall extend to all records and other information described in section 350c of this title, when the standard for records inspection under paragraph (1) or (2) of section 350c(a) of this title applies, subject to the limitations established in section 350c(d) of this title . . . No inspection . . . shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data . . . ”

Section 350c, which is referenced in Section 704, gives FDA access to “*all records relating to*” a product when there is a belief it is adulterated. It also includes exceptions for “*recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales.*”

FDA draft guidance¹⁸ states that “*because the circumstances of each particular event vary, the scope of an FDA request for records may vary in each situation*”, but that examples of records that FDA can access and copy under FDCA Section 704 include:

- *“Manufacturing records*
- *Raw materials (ingredients and packaging) receipt records*
- *Product distribution records*
- *Product inventory records*
- *Test records*
- *Recall records*
- *Reportable food records*
- *Customer distribution lists*
- *Complaint and adverse event records.”*

Under FDCA Sections 704(a) and FDA rules, however, the FDA inspector does not have legal access to, or right to copy:

- *financial data,*
- *sales data other than shipment data,*
- *pricing data,*
- *personnel data*
- *research data, and*
- *recipes for food.*¹⁹

¹⁷ 21 USC 374(a)

¹⁸ Draft Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act

FDA rules define a “recipe” as the “*formula, including ingredients, quantities, and instructions necessary to manufacture a food. Because a recipe must have all three elements, a list of the ingredients used to manufacture a food, without quantity information and manufacturing instructions, is not a recipe.*”²⁰

A refusal to permit access to or copying of records is a prohibited act under FDCA Section 301(e).²¹

b) Seafood Believed to be Adulterated and Posing a Threat

FDCA Section 414(a)²² provides a FDA inspector with authority to inspect records that is similar to that in FDCA Section 704 when food may be adulterated, except that it imposes a 24-hour deadline. Under this section, a FDA inspector may access and copy records from the person responsible for a seafood facility that manufactures, processes, packs, transports, distributes, receives, holds, or imports food if:

- (1) FDA has a “*reasonable belief*” that the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner,
- a) is adulterated, and
 - b) presents a threat of serious adverse health consequences or death to humans or animals.
- OR

(2) FDA believes that there is a reasonable probability that use of or exposure to the food, and any other food that the FDA reasonably believes is likely to be affected in a similar manner will cause serious adverse health consequences or death to humans or animals.

If the circumstances in (1) are met, FDA may access and copy the records that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. If the circumstances in (2) are met, FDA may access and copy the records that are needed to assist FDA in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to human or animals.

FDA explains that “*decisions regarding whether FDA “reasonably believes” a food is affected in a similar manner to cause serious adverse health consequences or death to humans or animals would be made on a case-by-case basis because such decisions are fact-specific.*”²³

Because the scope of records available under FDCA Section 414 is similar to that under Section 704, FDA does not invoke this authority during routine inspections. However, if there is a determination that a food presents a threat of serious adverse health consequences or death to humans or animals and concurrence by the District, a written demand for these records will be issued in a “Notice of Inspection-Request for Records” (Form FDA 482c).

¹⁹ 21 CFR 1.362

²⁰ 21 CFR 1.328

²¹ 21 USC 331(e)

²² 21 USC 350c(a)

²³ 77 FR 2012 (February 23, 2012)

FDA rules provide that upon proper demand such records “*must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.*”²⁴

In contrast to this 24-hour deadline, there is no specific deadline for providing records and documents under FDCA Section 704, other than the general standard of “reasonableness”.

c) Reportable Food

Facilities that have held “*reportable food*” must maintain and provide FDA with access to “*records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section for 2 years.*”²⁵

These “reportable foods” are those where there is a reasonable probability that the use of, or exposure to, food will cause serious adverse health consequences or death to humans or animals. Typically, they are foods that would meet the definition of a Class I recall situation,²⁶ such as “smoked salmon contaminated with *Listeria monocytogenes* (Lm).”²⁷ Facilities that manufacture, process, pack, or hold these foods must report them to FDA within 24 hours under FDCA Section 415(a).²⁸

d) HACCP Plans and Records

All records and HACCP plans required by FDA’s HACCP rule “*shall be available for official review and copying at reasonable times.*”²⁹ These records, which include sanitation control records, must be retained at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.³⁰ These record access regulations were not amended by FSMA. However, proposed rules (Part 117) should be reviewed to ensure they provide for practical storage of records for seasonal and remote operations, as presently provided in 21 CFR 123.

e) Low Acid Canned Food Records

Processors of low-acid canned³¹ seafood products must maintain complete records of processing, production and initial distribution and permit the inspection and copying of these records³² and they must provide FDA with any information concerning processes and

²⁴ 21 CFR 1.361

²⁵ 21 USC 417f(j)

²⁶ 21 CFR 7.3(m)(1)

²⁷ Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)

²⁸ 21 USC 350d

²⁹ 21 CFR 123.9(c)

³⁰ 21 CFR 123.9(b)

³¹ Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as “cans,” the term “low-acid canned foods” has been used for decades as a shorthand description for “thermally processed low-acid foods packaged in hermetically sealed containers.”

³² 21 CFR 108.35(h)

procedures necessary for FDA to determine the adequacy of the process.³³ These records must be retained at the processing plant for one year, and at the processing plant or other reasonably accessible location for an additional two years. These record access regulations were not amended by FSMA. Specifically, current requirements of 21 CFR 113.100(g) state: “If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.” Also, 21 CFR 113.100 allows for maintaining records electronically, provided they are in compliance with 21 CFR 11.

The demand for these records must be in writing on a “Written Demand for Records” (Form FDA 482a), signed by the FDA inspector, and identify the records demanded.³⁴ Requests for information must be made using a “Request for Information” (Form FDA 482b).³⁵

FDA’s Emergency Permit Control rule³⁶ and the rule for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers³⁷ require processors to register and file with FDA information that includes the name of the establishment, principal place of business, location of each establishment in which that processing is carried on, the processing method, and a list of foods so processed in each establishment.³⁸ They also require processors to provide FDA with information on the scheduled process for each seafood product in each container size.

FDA rules define a scheduled process as the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility.³⁹ “Commercial sterility” of thermally processed food means the condition achieved either by 1) the application of heat which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution and free of viable microorganisms (including spores) of public health significance, or by 2) the control of water activity and the application of heat which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.⁴⁰ It is the responsibility of the processor to determine the adequacy of any process before it is used.

6. FDA Samples

FDA inspectors may take samples of seafood products or of the plant environment when they inspect a domestic facility, but they typically are collected “for cause” or because of a special assignment. The “Seafood Processor Inspection Program – Domestic and Foreign Facilities” (CP 7303.842) explains:

“Samples of seafood products should not be collected to support seafood HACCP charges. Samples may be collected if an investigator is unsure if critical limits are adequate based on the Seafood HACCP Guidance or consultation with CFSAN, but not when controls are clearly inadequate. Samples can be collected in response to illness outbreaks or as follow-up on consumer or industry

³³ 21 CFR 108.35(c)(3)(ii)

³⁴ 21 CFR 108.35(h) and 108.25(g)

³⁵ 21 CFR 108.25(c)(3)(ii) and 108.35(c)(3)(ii)

³⁶ 21 CFR 108

³⁷ 21 CFR 113

³⁸ 21 CFR 108.35(c)(1)

³⁹ 21 CFR 113.3(r)

⁴⁰ 21 CFR 113.3(e)

complaints. CFSAN may periodically issue special assignments to address food economics issues or as targeted assignments for emerging issues . . . The current ORA Field Workplan provides resources primarily for “for cause” sample collection and analysis

Official Samples are to be collected “for cause” only (e.g., if inspectional conditions warrant or as part of investigations of illness outbreaks or consumer complaints. Investigators should not normally collect samples for pathogen testing if HACCP controls are clearly inadequate.

. . . where vector animals or evidence thereof is present, collect samples and submit to laboratory as filth exhibits.”

However, product samples are collected during the inspection of primary processors of farmed seafood “to evaluate compliance with regulations governing the use of chemotherapeutic agents in seafood.”⁴¹

A sample of a seafood product is an "Official Sample" if records or other evidence obtained shows the lot from which the sample was collected was introduced or delivered for introduction in interstate commerce, or was in or was received in interstate commerce, or was manufactured in a territory or the District of Columbia.⁴² FDA rules require that FDA inspectors “collect at least twice the quantity estimated by him to be sufficient for analysis”, and “a part of the sample . . . be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner.”⁴³ If practical, the inspector may collect “such further amount as he estimates will be sufficient for use as trial exhibits”

Investigational samples, on the other hand, are generally collected to document observations, support regulatory actions or provide other information and need not be collected from lots in interstate commerce or under federal jurisdiction. They may, for example, include raw materials, in-process and finished products to demonstrate manufacturing conditions, or filth exhibits and other articles taken for exhibit purposes during inspections to demonstrate manufacturing or storage conditions, employee practices, and the like (rodent excreta pellets, apparent nesting or other rodent gnawed material, and other evidence of rodent activity).

FDCA Section 704(c)⁴⁴ requires that the FDA inspector issue a “Receipt for Sample” (Form FDA 484) describing any samples obtained during of an inspection. This receipt must be issued prior to leaving the premises, and is not issued for labels, photographs, and records (including production, monitoring, sanitation, corrective actions and verification records). You may sign this receipt without any negative consequences.

⁴¹ “Chemotherapeutics in Seafood Compliance Program” (CP 7304.018)

⁴² “When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.” (21 CFR 2.10(a)(1))

⁴³ 21 CFR 2.10(b)

⁴⁴ 21 USC 374 (c)

FDCA Section 704(d)⁴⁵ also requires FDA furnish a “Report of Sample Analysis” (Form FDA 1551b) on any sample of food collected during an inspection of an establishment where such food is manufactured, processed, or packed if the sample is examined for compliance. The FDA laboratory is responsible for furnishing this report of analysis.

7. Photographs

FDCA Section 704 does not expressly authorize FDA inspectors to take photographs during an inspection over the objection of the owner or operator of a food facility. FDA inspectors, however, are advised to:

“Do not request permission from management to take photographs during an inspection. Take your camera into the firm and use it as necessary just as you use other inspectional equipment. . . .

“If management refuses, obtain name and contact information for the firm’s legal counsel, and advise your district management immediately. If the firm does not have legal counsel on retainer, collect the name and contact information for the most responsible individual.”⁴⁶

No court ruling grants FDA the authority to take photographs when the company objects, although there are comments (dicta) in two cases that suggest that FDA was granted implicit authority in Section 704. The two cases, which are cited in the IOM as the basis for FDA authority to take photographs, are:

- In *Dow Chemical v. United States*, 476 U.S. 227 (1986), the Supreme Court upheld the taking of aerial photographs as a valid exercise of EPA inspectional powers under the Clean Air Act saying “[w]hen Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission.” FDA interprets comment to apply to *any* regulatory agency taking photographs in *any* context. The *Dow* case, however, concerned aerial photographs of the open areas of an industrial complex, without physical entry into the facility. Saying that no specific statutory authority is needed to photograph areas open to public observation, however, is different than taking photographs inside a plant which is not open to public observation without permission.
- In *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976), the defendants did not object to the taking of pictures by the inspector and as a result, FDA photographs were subsequently admitted as evidence. This case, therefore, does not authorize FDA to take photographs, but does allow photographs to be used as evidence if no objection is made.

What the cases do stand for is the proposition that photographs inside a facility can be used as evidence against the facility, if the owner, operator, or agent in charge grants permission to take them.

If photographs are taken by a FDA inspector and you then object to further photos, the photographs that were taken are government property and the inspector will not provide disc,

⁴⁵ 21 USC 374 (d)

⁴⁶ IOM, 5.3.4.1

film, etc. Nor will copies be provided, except in response to a formal written request filed under the Freedom of Information Act.

Some states are allowed to take photographs under their laws (i.e., Alaska).

8. Affidavits

During an inspection of a facility the FDA inspector may ask you to record and sign a statement on an affidavit form regarding the products sampled by the inspector, the movement of products in commerce, or events affecting the condition of products. These documents include an "Affidavit" (Form FDA 463a), an "Affidavit (Dealer/ Warehouseman)" (Form FDA 1664),⁴⁷ an "Affidavit (Jobber)" (Form FDA 1664a),⁴⁸ and an "Affidavit (In-transit Sampling)" (Form FDA 1664b).

FDA's Investigations Operations Manual" explains that FDA inspectors should:

“. . . have the affiant read the statement and make necessary corrections before signing the affidavit. Mistakes, corrected and initialed by the affiant are an indication he/she has read and understood the statement. A handwritten statement by the affiant, declaring he/she read and understood the statement is a valuable tool to counter the possibility the affiant might later claim ignorance of what was signed.

Before the individual signs the statement, ask him/her to affirm the affidavit is true and accurate. A statement to that effect can also be added at the conclusion of the affidavit.

You should only sign the affidavit AFTER the affiant has signed it. . . .

Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in his/her own handwriting. Ask the affiant if the statement is true and correct. Ask him/her to write at the bottom of the statement "I have read this statement and it is true, but I am not signing it because..." in his/her own handwriting.

If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit. Include the actual situation, such as, you recorded the above facts as the affiant revealed them, the affiant read or refused to read the statement and avowed the statement to be true, and the affiant's reason for refusing to sign (e.g., "upon advice of corporate counsel", "per corporate policy", etc.). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit."⁴⁹

You are not required to sign an affidavit and refusing to acknowledge or sign an affidavit cannot be considered a refusal of inspection, although some FDA investigators may attempt to make it appear so.

⁴⁷ FDA 1664 is used to document the dealer or warehouseman identification of the lot and related records.

⁴⁸ Form FDA 1664a is used to document movement of goods from a jobber to a dealer.

⁴⁹ IOM, 4.4.8

B. Preparing for Inspection

Preparing for FDA inspections is very important. To ensure that each seafood facility of a company is prepared and will be properly represented during an inspection, a company should appoint a company representative for the facility, establish procedures for inspections, and adopt policies regarding how inspections should be conducted.

Warning

A visit by Special Agents from FDA's Office of Criminal Investigations is not an inspection. Contact legal counsel immediately if you are visited by FDA Special Agents.

1. Appoint a Representative

You should appoint someone to be the company representative for a facility who will be responsible for protecting your company's right to protect its trade secrets and other confidential information and for:

- Greeting the inspector(s);
- Participating in an initial (pre-inspection) meeting with FDA inspector(s);
- Accompanying FDA inspector(s) during the inspection;
- Participating in a closing (post-inspection) meeting with FDA inspector(s); and
- Supervising and providing the necessary communications, support personnel, and inspection follow-up.

This representative (e.g., plant manager, or quality assurance director) should know

- how product moves through the facility, from receipt of raw material to shipment of finished product;
- FDA's authority to conduct an inspection; and
- company policies regarding FDA inspections.

Also appoint at least one alternative representative.

2. Prepare an Inspection Manual

FDA inspections carry legal risk for the company and individuals. For this reason, it is wise to include legal counsel in key decisions surrounding the preparation of an inspection manual for your company and the management of FDA inspections.

An effective manual will include step-by-step procedures, clearly assign responsibilities for preparing and managing inspections, undertaking corrective actions and responding to observed deficiencies in a Form FDA 483, and provide for periodic reviews and adjustments.

Manuals also should include and explain company policies regarding FDA inspections so that the company representative can point to them during an inspection. For example, if an inspector requests confidential information that the company is not required to disclose, the company representative could respond:

“The information you seek is confidential. Company policy, based upon the advice of legal counsel, prohibits me from disclosing that information. However, if you wish to pursue the matter, you may submit a written request to me, the Company Representative, explaining why you feel you need the information, and I will forward it to the appropriate personnel for their consideration.”

The written policy can then be shown to the FDA inspector.

Here are some other topics that should be covered:

a) Escorting FDA Inspectors

Example of Policy Statement:

A representative of the company must accompany a FDA inspector throughout the entire inspection period (including being escorted to and from the restroom). This will help ensure that the inspector does not accidentally end up in an unsafe situation, contaminate food, inadvertently examine confidential data, cause a significant interruption of operations, or engage in unauthorized conversations with employees. If two inspectors are involved and decide to work independently, the alternate company representative will escort the second inspector.

b) Inspector Compliance with the Company’s Health and Safety Rules

Example of Policy Statement:

The inspector is expected to comply with all of the company’s safety and health rules at the facility being inspected and must wear and use appropriate protective clothing and equipment.

c) Only Designated Personnel May Respond to Questions and Requests

Example of Policy Statement:

FDA inspectors will be notified before an inspection begins that all questions should be addressed to the company representative or other designated company representative. The inspector is not permitted to conduct private employee interviews on company property. Employees will be notified that they are not permitted to respond to the inspector’s questions.

A preferred option when the FDA inspector wants to question an employee is for the company representative to ask the employee(s) the question(s) or obtain the requested information who can then provide to the inspector at a later time.

d) Employee Interviews

Example of Policy Statement:

The inspector is not permitted to conduct private employee interviews on company property. Employees are reminded that they are not permitted to respond to the inspector's questions.

FDA interviews of employees during inspections raise several concerns: it may compromise employee safety if distracted; potential misunderstanding of question by employee; a disgruntled employee may provide misinformation or confidential information.

e) Confidential Treatment for Incidental Exposure to Trade Secrets

Example of Policy Statement:

Confidential treatment for all confidential information obtained from areas of the plant that contain trade secrets should be orally requested and confirmed in writing to the investigator before the close of the inspection.

f) Disclosure of Information, Documents, and Other Records

Example of Policy Statement:

Except when authorized by company policy or a supervisor, employees will not permit the inspector to have access to or to obtain any confidential information. The following information is considered confidential:

- Corporate, unit, or department budgets or spending authority
- Corporate organizational structure
- Names or titles of any unit or corporate officers
- Names or titles of plant management

Provide copies of only those records FDA asks for. All FDA requests for records should be referred to a primary point of contact for these requests. This person should keep a record of all requests, when requested and when fulfilled. Copies of all records reviewed by FDA (whether or not copies are provided to FDA) should be made and notations made on them when they were copied and kept by FDA. If time permits, carefully review the document before providing it, to make sure it is responsive to the request. **DO NOT MAKE ANY CHANGES.** Supply **EXACTLY** what is in your files.

g) Affidavits and Similar Documents

Example of Policy Statement:

A FDA inspector has no legal right to require the execution of an affidavit or any other document. Therefore, XYZ company policy is for company representatives to avoid signing the affidavit, initialing the affidavit, reading the affidavit, having it read to them, making corrections to the affidavit, initialing corrections, or writing a statement at the bottom of the affidavit that the affidavit is not being signed because of company policy.

If a company's policy is to allow acknowledgement of affidavits, the affidavits should never be signed without approval of senior management following legal review.

h) Sound Recording Equipment

Example of Policy Statement:

The inspector is not authorized and, therefore, not permitted to take a tape recorder or other sound recording equipment beyond the reception area.

i) Photographic Equipment

Example of Policy Statement:

The inspector is not entitled and, therefore, not permitted, to take photographic equipment beyond the reception area. This includes cell phones or other devices with photographic or video recording capability.

Given the lack of specific statutory authority, definitive case law, and the FDA guidance to inspectors, it is essential that a seafood facility address the issue of handling inspection photographs in a written policy. This policy should be posted throughout the facility.

FDA investigators are directed to obtain the name and contact information of your legal counsel if they are told they may not take photographs and advise their District Office of your policy. It is especially important therefore that your legal counsel be involved in developing your policy on photographs and be prepared to support the policy if contacted by FDA after a FDA inspector is advised that no photographs will be allowed.

If a company decides to permit photography, it should also consider if there should be exceptions for areas of the facility containing proprietary machinery. The company should include the photography allocation and any associated limitations in their inspection policy, along with the underlying justification for the policy.

FDA, however, may obtain a search warrant, which could expressly authorize the use of photographs. In view of FDA's more adamant position on photographs in the IOM, the likelihood of FDA requesting a warrant authorizing photographs has increased. If an inspector arrives at a facility with a warrant, legal counsel should be contacted immediately.

The manual also should indicate who can take photographs so it is clear in the event of a court case. For example, it may cite the company can take photos for training purposes, documentation of corrections for submission to FDA following issuance of a Form FDA 483 Inspectional Observations.

j) Sampling

Example of Policy Statement:

Upon providing a written receipt (Form FDA 484) and a promise of compensation if requested, the inspector may take samples of product, packaging, and labeling. Compensation is typically requested only if a large number of samples is collected.

During an inspection, a company should, within reason, be able to duplicate every sampling procedure performed by the inspector. Appropriate sampling equipment should be on hand and in good working order with all necessary supplies.

If sampling is performed, these procedures should be followed:

- An employee familiar with sampling techniques should accompany the inspector to examine the inspector's techniques and to perform sampling on behalf of the company.
- The employee should determine and note the sampling procedure and technical instruments or equipment the inspector is using.
- The employee should ask the inspector if these procedures and equipment are formally approved by FDA and note his or her response.
- The employee should ask the inspector when and by what procedures the equipment was last calibrated and note his or her response.
- The employee should note the number of samples taken, when they were taken, and the operations and locations sampled.
- The employee should take duplicate samples for each sample taken by the FDA and retained it for the company.
- The employee should use company test equipment to duplicate the procedure used by the inspector and, where appropriate, use an alternative procedure which would provide similar data.
- All samples should be labeled to permit identification and ensure that they do not become lost or contaminated.
- Samples should be retained for one year unless a decision is made by the company to have the samples analyzed.

The company also should consider placing a hold on the distribution of any lots sampled by the FDA inspector until the samples are tested and the results are known.

3. Conduct Training

Training is important to ensure that both company managers and key personnel understand the content of the FDA inspection manual, and carry out their duties correctly. Good training will improve staff confidence and reduce the amount of supervision required. Training should include "mock inspections" and be tested and recorded.

4. Conduct Exercises

The company should conduct practice exercises, including mock inspections, before an inspection occurs.

Mock FDA inspections are a role-play that casts an individual in the role of an FDA investigator who conducts an inspection and helps your staff experience a simulated FDA inspection. The person you select to be the mock investigator should have experience with FDA inspections, as well as an in-depth understanding of the relevant FDA guidelines. If you are selecting from your internal resources, this would usually be someone in your quality assurance group. Mock inspections will:

- help you identify potential problems and give you a chance to mitigate them before an inspection;

- give you an opportunity to rehearse logistics for managing FDA presence on site; and
- provide staff with an opportunity to practice answering questions.

Ensure that relevant personnel know the answers to the following questions:

When an inspector calls to schedule a visit–

- Who should take the call?
- Who else should be notified?
- What other actions should be taken right away?

When an inspector arrives at the facility –

- What should the receptionist do?
- Who else should be notified immediately?
- What other actions should be taken right away?

If an inspector asks to see records –

- Who should take the request?
- Which records are permissible or impermissible to disclose?
- Who should provide the records and make copies if requested?
- When should a supervisor be notified?

If an Inspector takes a sample of a product or the plant environment ---

- Who should take the request?
- Who else should accompany the inspector and witness the sampling?
- Who from the company should also take samples?
- When should a supervisor be notified?

If an inspector indicates photos and/or videos will be taken ---

- Who should take the request?
- When should a supervisor be notified?

What could or should be done in these scenarios?

- The company representative and the alternate are unavailable the day of the inspection;
- The inspector arrives after normal working hours;
- The inspector refuses to wear required safety gear;
- The inspector asks about items noted for improvement in previous inspection reports;
- The inspector pressures an employee to reveal information not required for disclosure;
- An emergency occurs during the inspection;
- The inspector overhears employees talking about a recent safety violation.

C. During the Inspection

FDA may inspect your facility for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem.

1. Arrival of Inspector

In many instances the FDA will send two or more investigators or inspectors to a facility. One will be the team leader, usually an investigator, while the others may be inspectors with a particular expertise. It is also possible that one of inspectors is receiving on-the-job training.

a) Receptionist

The receptionist or other person who typically greets visitors must know what to do when an inspector or investigator arrives.

- Be sure the inspector is escorted at all times;
- Know which employee has been designated as the company representative and which employees have been designated as alternatives;
- During normal office hours: Notify the company representative that the inspector has arrived;
- After or before normal office hours: Make every effort to have the inspector return during normal office hours. If the inspector insists on performing the inspection, advise him that he will have to wait for the company representative and notify the company representative. If the inspector continues to insist on inspecting and there are ongoing operations, consult with company management and counsel.

b) Company Representative

The person appointed to be the company representative should:

- Escort the FDA inspector(s) to a separate room for an initial meeting;
- Ensure that appropriate personnel are notified that a FDA inspector has arrived;
- Ensure that all working areas are prepared for an inspection and that all appropriate employees make themselves available for consultation.

c) Set Aside a Work Room

A work area for the FDA inspector(s) should be set aside for the duration of the inspection. The inspector generally will not want the company representative in the room while he/she works, but this person should be readily available to the inspector at all times. The room in which the inspector will be located should not contain any records other than the records that the inspector has requested.

2. Initial Meeting

This meeting can set the tone of the inspection and should be considered a very important part of the inspection process. The company representative should handle all conversations with the inspector and ask the inspectors why they are at the facility and what they plan to review.

Although FDA inspectors are not required to participate in a pre-inspection meeting, such a meeting is typically used by inspectors to present their credentials and Notice of Inspection and to inform the company as to the purpose and scope of the inspection. Most inspectors will participate in such a meeting if requested.

a) Credentials and Notice of Inspection

Before beginning an inspection, the FDCA requires an inspector to present “*appropriate credentials and a written notice to the owner, operator, or agent in charge*” of a facility.⁵⁰

In the event the FDA inspector does not present his credentials and "Notice of Inspection" (Form FDA 482) at the initial meeting, the company representative should ask to see them.

The company representative should examine the credentials of each FDA inspector and record their full name. If the inspection leads to subsequent enforcement actions, the company may need to know the inspector names to take their depositions or otherwise prepare a defense.

The Notice of Inspection is a printed form with spaces to be filled in, showing the date, the name and title of the responsible member of the firm to whom the notice is being issued, the firm name, and location of the plant. The Notice of Inspection also quotes the language from the FDCA which grants FDA its inspection authority.

The Notice of Inspection should be signed by all FDA personnel participating in the inspection and should bear the name and address of the District Office from which he or she operates. This notice should be kept on file for later reference. Any revisit after the conclusion of the inspection (verbal closure or issuance of Form FDA 483), requires issuance of a new Form FDA 482.

Prior arrangements are required for the FDA inspector to bring non-FDA personnel on the inspection. If they are approved, they do not sign the Form FDA 482. Some state or local officials may not present this notice; in such cases, the company representative should write down all pertinent information provided regarding his or her inspection authority.

FDA may conduct an inspection for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem. However, the Notice of Inspection form does not specifically supply the reason for the inspection.

At the same time the Notice of Inspection is issued, FDA inspectors are instructed to provide a facility with a copy of an Information Sheet – Assessment of Re-Inspection User Fees that outlines the violations for which a facility may be charged a re-inspection fee.⁵¹ Examples of

⁵⁰ 21 USC 374(a)(1)

⁵¹ FDCA Section 743 (21 USC 379j-31) provides FDA with the authority to assess and collect fees from: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection, to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food recall activities associated with such order; and (3) each importer subject to a re-inspection to cover re-inspection-related costs.

violations that would result in a re-inspection are: foodborne pathogens in ready-to-eat products, failure to declare allergens on product labeling, or failure to have adequate hazard controls.

b) Clarify Purpose and Scope of the Inspection

From a company's viewpoint, the main purpose of the meeting is to learn, to the extent possible, why the inspector is there and what the inspector plans to do.

The FDA inspector may inform you of the purpose of the inspection (e.g., routine, compliance, HACCP, LACF etc.). The FDA Investigations Operations Manual directs the inspector to outline in general terms the scope of the inspection, including the physical inspection of the operations, records review, any complaints received, and the nature and purpose of the exit or closing meeting.

If the company representative does not believe the inspector has been sufficiently informative, he or she should not hesitate to ask for additional details. Ask about the nature of the inspection.

The company representative also should discuss the potential length of the inspection and develop a schedule if necessary. Inspections can be very lengthy and disruptive to company operations.

c) Communicate Company Inspection Policies

The company representative also should advise the inspectors of the company policies regarding FDA inspections.

Company policies, especially those refusing FDA with access, need to be communicated in a way that underscores full cooperation with the legal requirements, and to avoid creating an adversarial relationship with the inspector. The company representative should make it clear they are not refusing inspection, just exercising their rights under the law.

If the company prohibits photography inside the facility, the company's policy regarding photography should be explained during the pre-inspection conference, and an inspector carrying a camera should be asked to leave it outside.

An example statement is:

Thank you for presenting us with Form FDA 482 Notice of Inspection. You are welcome to inspect the facility during our normal work hours which are ____ to _____. We will have [designated staff] accompany you at all times during the inspection. Our policy requires that visitors present their credentials and sign in on the visitor log as part of our facility security plan. We are also presenting you with a copy of our written photo/video policy. Please read the policy, and let us know if you have any questions.

d) Clarify What Records Are Requested

The FDA inspector is likely to ask to review certain records during the inspection.

Certain documents must be disclosed to an inspector, even in a routine inspection. Be sure you are familiar with what documents must be disclosed, the circumstances under which they are to be disclosed, and where they are located at your facility.

Most likely, the FDA will ask to review your HACCP plan for certain products and the records associated with your plan.

Shipping records covering receipt of seafood shipped in interstate commerce must be made available to an FDA inspector for review and copying but you can ask for a written request from the inspector specifying the nature or kind of seafood to which the request applies. None of the information obtained by FDA pursuant to a written request, including any evidence which is directly or indirectly derived from the shipping records disclosed, may be used in a criminal prosecution of the company or employees of the company which made the records available to FDA. This defense is not available unless FDA's request is in writing. Be sure you get the request in writing.

If FDA believes there is a reasonable probability that consumption of a seafood, and any other seafood that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, FDA may access all records "*relating to [the seafood] that are needed to assist [FDA] in determining whether there is a reasonable probability that consumption of the seafood will cause serious adverse health consequences or death.*" Written notice is required, which should be made by the inspector on Form FDA 482c.

Only documents specifically requested by the inspector should be provided for review. When documents are copied for inspectors, make an extra copy for your FDA inspection file. (It is very important to keep a copy of every record/document that is provided to the Inspector during the inspection.)

FDA should not ask to look at Financial and Sales Data, Personnel Information (besides qualifications), Audit Reports, and Management Reviews.

3. Escorting the Inspector

The inspector may inspect areas where seafood products are stored, processed, or packaged, as well as storage areas for packaging and labeling. However, this authority does not extend to any other area of the plant. So, for example, access to offices and other areas not related to food processing or storage can be restricted.

Typically, the FDA inspector conducts a walk through visual inspection of the premises to become familiar with the operation, learn about products and processes, identify sources of manufacturing records and identify potential areas of concern such as: general housekeeping, state of operation for processes and processing equipment, and people dependent operations. These inspections also include areas used for product sampling and testing, product reworks, return goods, and product quarantine areas for obvious potential product problems.

When accompanying the inspector, you should be courteous and respectful, while at the same time firmly standing up for the company's rights and viewpoints. Do NOT let the inspector roam freely in the facility and do NOT leave the inspector alone.

When answering the FDA inspector's questions, listen to the question carefully. If you do not understand the question, ask the inspector to explain. Answer the question that was asked in an honest and complete manner. If you do not know the answer to a question, do not be afraid to tell the Inspector. Defer to others if you do not know the answer to a question. Stop when the question is fully answered, and wait for the next question. Follow these five rules: Be truthful; be concise; answer only the question that is asked; do not speculate or guess; and do not argue.

Immediately involve legal counsel whenever the question of a refusal is raised by a FDA inspector. For example, if you are asked by an FDA Investigator "Are you refusing me...?" you should respond:

"No, I am not refusing you [whatever] but before I comply with your request I need to consult with our legal counsel and senior management. Please accommodate my request."

Keep these points in mind.

- The company should act promptly on any valid suggestion made by the inspector that is related to food safety, either at the time of the inspection or shortly thereafter.
- The company should not volunteer information that might be used to form the basis for a citation.
- Be certain to point out any misinterpretations and unwarranted safety concerns on the part of the inspector.
- The inspector may provide useful advice but is primarily there to review regulatory compliance.
- The company representative must exercise caution in disclosing information, and must not let an inspector make you feel defensive about following company policy or exercising legal rights.
- Do not admit any violations of any laws or regulations.
- Avoid making any statement which could be construed as an admission of a violation.
- Do not volunteer information to impress the inspector with your knowledge.
- Restrict your conversation to matters covered by the inspection.
- Do not initiate discussion of an incident or complaint which involved the products of the company or its competitors. Use discretion in responding to the inspector's questions regarding such incidents or complaints. Generally, you should provide sufficient information to demonstrate to the inspector that there never was a health hazard or that there is no continuing hazard (if accurate) and that the company is dedicated to food safety and quality, without providing any evidence which would indicate possible violations.

4. Taking Samples

If the FDA inspector takes samples during the inspection the company representative should request the FDCA Section 704.2(b) part of each sample be provided to the company after FDA analysis. This section requires that if seafood "is collected for analysis . . . [FDA] shall, upon request, provide a part of such official sample for examination or analysis by any person named

on the label of the article, or the owner thereof, or his attorney or agent”.⁵² This refers to the Section 704.2(b) part of the sample which is provided to the company after FDA analysis.

The company representative also should collect two duplicate samples (one for possible testing, one reserve sample). Duplicate samples may be valuable in case of litigation.

a) Samples of Products and Food Contact Surfaces

FDA rules require that “*all reasonable precautions*” be taken “*to ensure that production procedures do not contribute contamination from any source*” and that “*chemical, microbial, or extraneous-material testing procedures . . . be used where necessary to identify sanitation failures or possible food contamination.*”⁵³

FDA takes the position that if a pathogen such as *Listeria monocytogenes* is detected on either a food contact surface or a finished seafood product, the “*reasonable precautions*” a seafood processor must take are: (i) segregate and hold the product; (ii) take appropriate corrective actions, which may include listericidal treatments, reprocessing, diverting or destroying product, and recalling finished refrigerated or frozen product that has been distributed, and (iii) keep records of corrective actions.⁵⁴

If the FDA inspector collects a sample of finished RTE product (i.e. cold smoked salmon), you should collect side by samples and have them tested by a recognized 3rd party laboratory. These test results should be reported directly to you. Also, you should stop production of the lot sampled by FDA and:

- 1) Clean and sanitize all the production lines and their areas, and note in daily records;
- 2) Change production codes to isolate the product(s) sampled;
- 3) Hold and segregate the lot(s) sampled by the FDA; and
- 4) **Do not release this HOLD until you receive written notification that FDA's laboratory tests are negative.**

If FDA advises you that it has made an adverse finding in the samples collected, you should consult with FDA and third-party experts and either destroy the suspect product on HOLD under FDA's observation, or reprocess the suspect product in a manner acceptable to FDA.

b) Plant Environment Samples

If FDA collects samples for pathogen testing from nonfood contact surfaces in a plant's environment, you should collect side by samples and have them tested by a recognized 3rd party laboratory. These test results should be reported directly to you.

The “*reasonable precautions*” a seafood processor must take if an environmental sample taken by the FDA tests positive are fact-specific and depend upon the circumstances. For example, a

⁵² 21 USC 372(b)

⁵³ 21 CFR 110.80(a); Similar wording is in the revision of this provision proposed by FDA in January 2013 (21 CFR 117.80(a))

⁵⁴ FDA recommends that "any processor of a refrigerated or frozen RTE (RF-RTE) food" follow their *Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance.*

facility that finds a pathogen during environmental monitoring of non-food contact surfaces typically tests surrounding surfaces and areas to determine the potential source of contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the pathogen is found on retest, the facility conducts more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts.

5. Preparing a Record of the Inspection

Accompanying an inspector is a significant undertaking. For this reason, two employees should accompany each inspector: one to answer questions, and the other to carefully note all activities.

An employee who is not the company representative should carefully observe and note all activities of the inspector—including areas visited, sampling, records inspection, investigator's questions, company's responses, discussions, and corrective action taken or promised.

Any notes taken may later be used in legal proceedings. It is important, therefore, that they do not contain any statements you would not want to be seen by people outside the company.

6. Correcting Deficiencies Noted by the Inspector

During the inspection, the FDA inspector may point out conditions which he or she considers to be in violation.

In appropriate situations, the company representative should direct employees to modify or begin modification of those conditions. Factors to be considered in making this determination are:

- The potential hazard presented by the by the condition;
- The likelihood that the condition does constitute a violation;
- Whether the modification can be accomplished without undue interference with normal operations.

7. “Notice of Inspectional Observations” (Form FDA 483)

At the conclusion of a facility inspection, the FDA inspector may prepare a written list of discrepancies noted during the inspection and present it at an exit, or close-out, meeting. This list will be on a “Notice of Inspectional Observations” (Form FDA 483).⁵⁵ In case no serious discrepancies are found in the investigation, the inspector will not issue a Form FDA 483.

The Form FDA 483 includes this preprinted instruction:

⁵⁵ FDCA Section 704(b) provides: "Upon completion of any such . . . establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food . . . in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary." (21 USC 374(b))

“This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address [on the form].”⁵⁶

There also are several fields in a typical Form FDA 483. These include:

- Issuing FDA field office and address;
- Dates of inspections (may be more than one day)
- Firm Establishment Identifier or FEI
- Manufacturer’s contact info
- List of Observations (typically, between 5 and 10)
- Names and titles of the investigators (usually 1 or 2)

The observations listed on a Form FDA 483 do not cite FDA rule violations, but they should contain observations that are directly linked to a violation of regulations ---not ideas, remarks, or other direction. FDA’s Field Management Directive 120 explains:

“All FDA 483s should have the following characteristics to be useful and credible documents:

1. *Each observation should be clear and specific.*
2. *Each should be significant. Length is not necessarily synonymous with significance.*
3. *Observations should not be repetitious.*
4. *The observations should be ranked in order of significance.*
5. *All copies of the FDA 483 should be legible.*

If an observation made during a prior inspection has not been corrected or is a recurring observation, it is appropriate to note this on the FDA 483.”

8. Exit Meeting

Typically, the FDA inspector will ask to have a closing meeting with the company representative. At least one other company employee should attend the conference and take detailed notes of the discussion.

FDA’s Investigations Operations Manual provides this guidance for inspectors:

“After completion of the inspection, meet with the highest ranking management official possible to discuss your findings and observations. The FDA 483 is not a substitute for such discussion since there may be additional questionable practices or areas not appropriate for listing on this form.

“During the discussion be frank, courteous and responsive with management. Point out the observations listed on the FDA 483, are your observations of

⁵⁶ See also IOM 5.2.3.1.4

objectionable conditions found during the inspection, and explain the significance of each. Try to relate each listed condition to the applicable sections of the laws and regulations administered by the FDA. You should inform management during the closeout discussion the conditions listed may, after further review by the Agency, be considered to be violations of the Food, Drug and Cosmetic Act or other statutes. Legal sanctions available to FDA may include seizure, injunction, civil money penalties and prosecution, if establishments do not voluntarily correct serious conditions.

“Do not be overbearing or arbitrary in your attitude or actions. Do not argue if management voices a different view of the FDA 483 observations, or of your opinions. Explain, in your judgment the conditions you observed MAY be determined by the FDA, after review of all the facts, to be violations. Make clear the prime purpose of the discussion is to call attention to objectionable practices or conditions, which should be corrected.

Obtain management's intentions regarding correcting objectionable conditions. They may propose corrections or procedural changes and ask you if this is satisfactory. If this involves areas where your knowledge, skill, and experience are such that you know it will be satisfactory, you can so advise management. Do not assume the role of an authoritative consultant. In areas where there is any doubt, you must explain to management you cannot endorse the proposed corrections. Advise the individuals their firm's response may impact FDA's determination of the need for follow-up action, if FDA receives an adequate response to the FDA 483 within 15 business days of the end date of the inspection. . . . FDA will supply comments . . . if the establishment will submit its request and its proposed corrections or procedures in writing to the district office.

Concentrate on what needs to be done rather than how to do it. Do not recommend the product or services of a particular establishment. If asked to suggest a product or consulting laboratory, refer the inquirer to a classified directory or trade publications and or organizations.

Report in your EIR all significant conversations with management or management representatives. In most instances it is not necessary to quote management's response verbatim. Paraphrasing the replies is sufficient. However, if the situation is such that quoting the reply or replies is necessary, enclose them in quotation marks.⁵⁷

During this meeting, the company representative should inform the FDA inspector of any corrective action taken, and ask that it be included in the inspector's notes. Any clear mistakes should be pointed out to the FDA inspector, who should be asked to correct the 483 immediately. However, "policy" disagreements are best handled at a later stage, rather than arguing with the FDA inspector.

As a matter of corporate policy, some firms will not respond verbally at all to the inspector's concerns. The firm's response is made in writing to the local FDA District Office.

⁵⁷ IOM, 5.2.7

The company representative also should confirm that the FDA District Office will give your company a copy of the Establishment Inspection Report (EIR), which the inspector will write after the inspection, without the need to make a formal Freedom of Information Act request.

D. Post Inspection

1. Responding to Inspectional Observations

Receiving a Form FDA 483 is the first step in what can become an escalating enforcement process. Responding to it effectively, therefore, is the key to preventing further regulatory action.

Typically the FDA inspector presents the Form FDA 483 during the exit meeting at the conclusion of the inspection. Companies have an opportunity to make an initial oral response during this meeting. They also are given **15 days to respond in writing after the closing meeting with the FDA inspector.**

Although the law does not require any response, most companies send a formal written response because it:

- Demonstrates an understanding and acknowledgement of the observations;
- Demonstrates a commitment to correct deficiencies (voluntarily comply);
- Establishes credibility with FDA

Indeed, failing to respond might be viewed as unusual by the FDA. Hence, a written response should always be prepared (unless legal counsel advises against it).

Suggestions for addressing Form FDA 483 observations

- (1) Include a commitment/statement from senior leadership
- (2) Address each observation separately
- (3) Note whether you agree or disagree with the observation
- (4) Provide corrective action accomplished and/or planned; tell FDA the plan
 - Be specific (e.g. observation-by-observation)
 - Be complete
 - Be realistic
 - Be able to deliver what you promise
 - Address affected products
- (5) Provide time frames for correction
- (6) Provide method of verification and/or monitoring for corrections
- (7) Submit documentation of corrections where reasonable and feasible

An effective outline for responding to each deficiency would be worded as follows:

In response to this observation, we are taking the following actions: [list what you are doing]

We believe this approach is reasonable because [state]:

- Your assessment of the reason(s) why the observation occurred;
- Your assessment of the impact on product safety;

Your assessment of the scope of impact (other lots, other products) and how you determined the scope
 We will complete these actions by [date]
 We will take the following steps to ensure these actions have the intended effect
 [list; generally, this will be audit or monitoring]

Pitfalls to avoid:

(1) Do not use excuses such as:

- No one objected to this during our last inspection
- Everyone in the industry does it this way
- The investigator is out to get us
- The investigator is inexperienced

(2) Do not admit that a condition or practice represents a “violation” and avoid comments that condemn the actions of your company or colleagues

(3) Do not provide FDA with documents that exceed the scope of FDA’s inspection authority

FDA Field Management Directive 120 includes this guidance to FDA District Offices regarding their response:

“Districts will issue a timely reply to all contact and correspondence from firms regarding FDA 483s. The type and depth of the reply will be based on the content of the contact or correspondence received.

The firm may request clarification, criticize FDA 483 items, disagree with the FDA 483, or raise other questions or issues. In these cases, the District will evaluate the firm’s information and send the District’s conclusion to the firm. A copy shall also be sent to the official establishment file.

Do not prepare a response which can be construed by the firm as an endorsement of its actions unless such a response is appropriate (which should usually be reserved until after verification). Be cognizant of the effect a reply may have on anticipated or ongoing regulatory actions against the firm.”

Timing is important. A timely and effective response to a Form FDA 483 may change the recommendations of the FDA inspector, which will be made in the inspector’s Establishment Inspection Report (EIR) and FDA management. This report, which is written after an inspection, expands on the inspection observations and links the observations to the evidence collected to support them.

Senior FDA officials review the EIR, and if they decide the conditions it describes are serious enough, they may issue a Warning Letter.

2. Obtain Copies of the Establishment Inspection Report

The FDA inspector’s Establishment Inspection Report (EIR) is usually a detailed report of all aspects of the inspection, the answers to all questions, a summary of all observations—favorable as well as unfavorable—and a recital of company responses to the adverse observations.

Under a Field Directive, the FDA District Office will provide a redacted copy of the EIR to your company when it decides that an inspection is "closed".⁵⁸ Only the narrative report is provided (no exhibits or photographs are provided. Failure to receive a copy of the EIR within a reasonable time period (e.g., 30-60 days after inspection), therefore, may suggest that FDA has further concerns.

FDA posts EIRs and Form FDA 483s in the ORA Electronic Reading Room on its website when a high level of public interest is anticipated. FDA also posts "frequently requested" EIRs as defined by the Electronic Freedom of Information Act Amendments of 1996. FDA redacts non-public information, such as trade secrets, from these documents before posting them. EIRs and 483s also are available to the public upon request under the Freedom of Information Act (FOIA).

Both the Form FDA 483 and the EIR will be available to the public under the Freedom of Information Act. The Form FDA 483 is immediately available, regardless of the status of the inspection. The EIR is available, but only after the investigation is closed.

To protect against improper disclosures, therefore, you should consider filing a FOIA request for an unpurged copy (available only to the inspected firm) and a purged copy (proprietary information deleted, available to public). Let FDA know immediately if firm disagrees with purging. If not yet available, renew your FOIA request in another 30 days

Finally, if an inspector does take photographs of the facility, regardless of whether the photography is contrary to the company's expressed policy, you should obtain copies of all photographs taken during the investigation. These photographs may be obtained through the company's FOIA requests to FDA.

3. Monitor FDA's Classification of the Inspection

FDA will classify an inspection based on the observations noted during the inspection, the investigator's report, and recommendations of the FDA District Office supervisory personnel into one of these classifications:

- "No Action Indicated" or NAI, signifying that no objectionable conditions were found during the inspection;
- "Voluntary Action Indicated" or VAI, signifying that objectionable conditions were found but were not sufficient to warrant regulatory or administrative action; and
- "Official Action Indicated" or OAI, signifying that objectionable conditions were found that warrant regulatory or administrative action.

FDA Field Management Directive 86 provides:

"Lowering an OAI classification will be based upon a lack of evidence to support the proposed action, corrective actions taken by the establishment or based on an agency decision to use regulatory discretion."

⁵⁸ FDA Field Management Directive 145 provides guidance and criteria for releasing a copy of the establishment inspection report to the establishment that was the subject of an FDA or FDA-contracted inspection when the Agency determines the inspection to be "closed." FDA rules provide that a matter is closed "If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded." (21 CFR 20.64 (d) (3))

FDA may also change a classification if a facility promises during an inspection to make corrections and FDA subsequently determines that the facility did not make those corrections during follow up inspection.

These classifications are posted on the FDA website on its Inspection Classification Database.

4. Warning Letters

FDA Warning letters are mailed to firms with alleged violations of “*regulatory significance*” threatening them and responsible individuals with legal action if they don't comply. FDA advises its District Offices that before issuing a letter they “*should consider whether*”

- a. *Evidence shows that a firm, product, and/or individual is in violation of the law or regulations and that failure to achieve adequate and prompt correction may result in agency consideration of an enforcement action;*
- b. *The violation(s) are determined to be of regulatory significance, and the issuance of a Warning Letter is appropriate and consistent with agency policy, as described in Compliance Policy Guides or elsewhere; and,*
- c. *There is a reasonable expectation that the responsible firm and persons will take prompt corrective action.*⁵⁹

Warning Letters are issued “*to achieve voluntary compliance*” and “*are based on the expectation that most individuals and firms will voluntarily comply with the law.*” Typically companies are given 15 days to respond to issues raised in a letter.

FDA posts these letters each week on its website. So investors, competitors, and customers may hear about them and start asking questions.

a) Responding to a Warning Letter

A Warning Letter differs from a Form FDA 483 in two ways. A 483 represents the observations of the individual FDA inspector, not the agency. A Warning Letter communicates the decisions of higher level FDA officials who have concluded that the observations in the FDA 483 warrant further formal notification to the inspected company that FDA believes serious violations may exist.

If you receive a warning letter, you should:

- Call FDA and advise them that you received the letter and are assembling a response team to address all violations. Inform FDA you will respond in 15 working days or give a justified reason for a later date for their consideration;
- Assemble a team and designate a leader who understands the issues raised in the letter (usually not a lawyer);
- Determine if you have the in-house knowledge and expertise to address the issues, if not seek outside help.

⁵⁹ FDA, Regulatory Procedures Manual, 4-1-3

In your written response begin with a statement of commitment to comply with applicable laws and regulations. Make it clear that your company understands its obligation under the law and is serious about its intent to follow the law.

Address each item in the warning letter individually. For convenience, quote each specific citation verbatim and follow with your reply.

Describe the scope of your corrective action plan. Include a report of the corrective action for each of the specific examples listed in the observation, the steps taken to address any other area which may be subject to the same deficiency, and the measures taken to prevent the reoccurrence of the problem in the future.

Only commit to what you are sure you can accomplish, and keep time lines and milestones realistic. In many cases, FDA will agree to extensions of time when original objectives turn out to be unreasonable. If an extension of time is needed, communicate your request to the agency as soon as possible; be absolutely certain the proposed new date is attainable; clearly articulate the reason(s) the extension is needed; and demonstrate that there is no significant risk to the product or the consumer arising from the delay. Finally, set and meet a new date. FDA may lose confidence if there are repeated requests for modifications to corrective action plans or for extensions of time.

If you take a policy position different than that expressed in a warning letter, include documentation and scientific papers as attachments to your written response that support your position.

If you have amended you HACCP or sanitary procedures in response to FDA concerns, include records and documentation to demonstrate that corrective actions were taken.

Take steps to ensure that a promised corrective action is properly carried out. A company's most valuable regulatory asset is its credibility with the FDA. Credibility is built through ensuring that problems do not reoccur.

In deciding whether to take regulatory action, FDA looks for repeated patterns of noncompliance. Where they exist, future promises of corrective action are unlikely to be believed, and the risk of further enforcement action is increased.

You will receive acknowledgement that your reply has been received.

In the meantime, you should discuss matters with the FDA District Office to be sure your corrective actions meet their expectations. Disagreements about "policy" matters (e.g., whether a firm's practices are consistent with CGMPs) are appropriately pursued at CFSAN or in the Commissioner's office, but only after an impasse is reached with the local FDA District Office.

You will know the matters have been resolved if you receive a copy of the EIR report.

b) Completed Corrective Actions

Corrective action may be undertaken or promised during an inspection or addressed in correspondence to the FDA inspector after an inspection, but before a warning letter is issued.

FDA's Regulatory Procedures Manual provides that as "*a general rule, a Warning Letter should not be issued if the agency concludes that a firm's corrective actions are adequate and that the violations that would have supported the letter have been corrected.*" In this instance, a response letter to the responsible individuals at the firm to supplement the record of the violation(s), indicate that the agency is relying on the firm's corrections, and warn that if FDA inspectors later observe that these or similar violations have not been corrected; regulatory action may be taken without further notice.⁶⁰

c) Promised Corrective Actions

FDA's Regulatory Procedures Manual provides that while "Ongoing or promised corrective actions generally do not preclude the issuance of a Warning Letter" a FDA District may nevertheless decide not to issue a Warning Letter after considering these factors:

- 1) *"The firm's compliance history, e.g., a history of serious violations, or failure to prevent the recurrence of violations;*
- 2) *The nature of the violation, e.g., a violation that the firm was aware of (was evident or discovered) but failed to correct;*
- 3) *The risk associated with the product and the impact of the violations on such risk;*
- 4) *The overall adequacy of the firm's corrective action and whether the corrective action addresses the specific violations, related violations, related products or facilities, and contains provisions for monitoring and review to ensure effectiveness and prevent recurrence;*
- 5) *Whether documentation of the corrective action was provided to enable the agency to undertake an informed evaluation;*
- 6) *Whether the timeframe for the corrective action is appropriate and whether actual progress has been made in accordance with the timeframe; and,*
- 7) *Whether the corrective action taken ensures sustained compliance with the law or regulations."*

d) Close Out Letters

If FDA and the company reach agreement on how to handle all the issues raised, and corrections are verified in a follow-up inspection, FDA will post a "close-out" letter on its website.

A warning letter close-out letter will not be issued based on representations that some action will or has been taken. The corrective actions must actually have been made and verified by FDA.

If a subsequent inspection reveals problems with the adequacy or sustainability of the corrections that were taken in response to a warning letter, such violations would be considered serious. If FDA observes violations during subsequent inspections or through other means, FDA may take enforcement action without further notice.

e) Untitled Letters

FDA may issue an untitled letter when the violations are not significant enough to meet the criteria for the issuance of a warning letter. Untitled letters summarize the inspection's findings but do not include a warning statement that failure to make prompt correction may result in an

⁶⁰ Section 4-1 Warning Letters

enforcement action. They also request that the facility respond within “a reasonable amount of time,” such as 30 days.⁶¹

FDA posts these letters on its website.⁶²

E. Possible FDA Enforcement Actions

FDA may initiate enforcement in situations involving violations that may not be resolved through voluntary compliance, including administrative detention, seizure, injunction, and prosecution.

1. Administrative Detention

If an “officer or qualified employee” of FDA finds during an inspection, examination, or investigation that there is “*reason to believe*” that food is adulterated or misbranded he may order the seafood detained. Such an order requires approval of the FDA District Director.⁶³ Seafood may be detained “*for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to . . . institute an action*” of seizure and forfeiture.

An order “*may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate.*”

FDA may approve a request for modification of an administrative detention order to allow for the destruction of the seafood or its movement to a secure facility, to maintain or preserve its integrity or quality, or for any other purpose that the authorized FDA representative believes is appropriate in the case.⁶⁴ Requests for modification of a detention order must be submitted in writing to the FDA official who approved the original detention order.

2. Seizures and Injunctions

FDA initiates seizure actions by asking the Department of Justice to file a complaint with the U.S. District Court where the facility holding the product is located.

A seizure is the attachment of products through Court order by a U.S. Marshal pursuant to FDCA Section 304.⁶⁵ It can be a:

- Lot-specific seizure: Seizure of all units in a specific lot or batch of a product.
- Open-ended seizure: Seizure of all units of a specific product, regardless of lot or batch.
- Mass seizure: Seizure of all products and equipment at a facility.
- Multiple seizures: Seizure of the same product in more than one district court.

⁶¹ FDA, Regulatory Procedures Manual, 4-1-10

⁶² FDA began posting untitled letters issued by the Center for Food Safety and Applied Nutrition (CFSAN) in December 2011, this includes violations from manufacturing controls or labeling that do not meet the threshold of regulatory significance for a Warning Letter, or that are issued to Internet websites (cyber letters).

⁶³ 21 USC 334(h)(1)(A); 21 CFR 1.378. Prior to FSMA, FDA could order an administrative detention only if it had credible evidence or information that the food presented a threat of serious adverse health consequences or death to humans or animals.

⁶⁴ 21 CFR 1.381(c)

⁶⁵ 21 USC 334

Seized product is subject to forfeiture *in rem*. This means there is no pre-seizure hearing, nor any need for notice or a prior judicial finding of probable cause. Courts also tend to accord the FDA great deference and often resolve challenges of seizures in the FDA's favor.

An injunction is an order issued by a Court requiring a defendant to perform an act which he is obligated to perform but refuses to do, or forbidding him from doing a specified act which he is threatening or attempting to do.⁶⁶

To support a permanent injunction under the FDCA, the Government must show that the defendant violated the statute, and that there is "some cognizable danger of recurrent violation."⁶⁷ This likelihood of future violations may be inferred from past unlawful conduct.

3. Registration Suspensions

If the FDA Commissioner determines that seafood that is processed, packed, received, or held by a registered facility "*presents a threat of serious adverse health consequences or death to humans or animals*", the Commissioner may suspend the FDA registration of a facility that:

- Created, caused or was otherwise responsible for such reasonable probability;
OR
- Knew of or had reason to know of such reasonable probability AND packed, received or held such food.

This authority may not be delegated by the FDA Commissioner.⁶⁸

Violation of a suspension order is a prohibited act under FDCA Section 301(d),⁶⁹ subject to injunction proceedings under FDCA Section 302⁷⁰ and penalties under Section 303.⁷¹ Also, no person may import, offer to import, or introduce into interstate or intrastate commerce food from a foreign facility whose registration has been suspended.⁷²

4. Re-Inspections

FDCA Section 743 authorizes FDA to assess and collect fees to recover 100% of the costs related to certain domestic and foreign food facility re-inspections from the responsible party for each domestic facility and the U.S. agent for each foreign facility.

FDCA Section 743(a)(2)(A)(i) defines the term "reinspection" with respect to domestic facilities as "*1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.*"

⁶⁶ 21 USC 332

⁶⁷ United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953)

⁶⁸ 21 USC 350d(b)(7)

⁶⁹ 21 USC 331(d)

⁷⁰ 21 USC 302

⁷¹ 21 USC 333

⁷² 21 USC 350d(b)(4)

The FDCA does not define “reinspection” specific to foreign facilities, but FDA has defined it in its rule as “1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified noncompliance materially related to a food safety requirement, specifically to determine whether compliance has been achieved to FDA’s) satisfaction.”

The fee for re-inspection is to cover re-inspection related costs when an initial inspection has identified violations “materially related to food safety requirements” of the FDCA with a final classification of Official Action Indicated (OAI). The re-inspection must be conducted specifically to determine whether compliance has been achieved.

These fees are effective October 1, 2012 through September 30, 2013

- \$221/hour if domestic travel is required
- \$289/hour if foreign travel is required.

FDA is developing a guidance document to outline the process through which firms may request such a reduction of fees. FDA does not intend to issue invoices for reinspection fees until this guidance document has been published.

5. Criminal Prosecution

Most violations of the FDA rules carry criminal penalties although few are imposed each year.

In deciding whether to pursue criminal charges, the FDA usually considers: “continuing violations of law (e.g., continuing insanitary conditions); violations of an obvious and flagrant nature (e.g., food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentionally false or fraudulent violations.”

One distinctive feature of these criminal penalties is their “strict liability” nature. For example, if someone in a food facility violates a FDA rule, the person in charge of the facility is held criminally liable without FDA proving any knowledge, intent, or negligence. In *U.S. v. Park*, the U.S. Supreme Court explained why:

“The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.”⁷³

FDA’s Regulatory Procedures Manual outlines several factors FDA officials must consider before recommending a “Park doctrine prosecution” to the FDA’s Office of Criminal Investigations, including whether the official in question actually did know of or participate in the violation, and the seriousness of the violation.

⁷³ The two leading cases upholding this doctrine are *U.S. v. Dotterweich*, 320 U.S. 277 (1943) (misbranded drugs) and *U.S. v. Park*, 421 U.S. 658 (1975) (rats in a warehouse). These cases involved misdemeanor violations and relatively small fines, which helps explain why the U.S. Supreme Court upheld the doctrine.

Another factor is the extent to which a company executive cooperates in — or obstructs — an FDA inspection or investigation. How a company or individual reacts to an inspection or investigation can have a dramatic impact on the discretion to recommend or charge a misdemeanor. And given that false statement and obstruction charges are typically felonies, even if avoiding obstruction cannot prevent a misdemeanor Park doctrine prosecution, it can mean the difference between a misdemeanor and a felony prosecution.

Once a person has been convicted of a misdemeanor under this standard, any subsequent violation is a felony, even without proof that the defendant acted with the intent to defraud or mislead.

FDA rules provide that “*a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.*”⁷⁴

6. Private Enforcement

Federal law does not expressly authorize a private cause of action for violations of FDA rules, and the U.S. Supreme Court has ruled that only the FDA may file them. Thus, a citizen cannot function as a private attorney general to supplement FDA enforcement. A private party injured by unsafe food, however, can bring a common law tort claim against the manufacturer. As a result, tort litigation provides an important tool to compel industries to ensure food safety.

7. FDA Ombudsman

If you do not agree with the actions being taken by the FDA or if you have a question about the jurisdiction of the agency in a particular matter, you can contact the FDA's Office of the Ombudsman to seek a resolution.

FDA Office of the Ombudsman
10903 New Hampshire Avenue
WO 32, Room 4231
Rockville, MD 20903
Telephone: 301-796-8530
Fax: 301-847-8628
E-mail: ombuds@oc.fda.gov (sending confidential information by electronic mail is not recommended)

⁷⁴ 21 CFR 7.84

References

FDA Investigations Operations Manual <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>

FDA Regulatory Procedures Manual
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Seafood Processor Inspection Program - Domestic and Foreign Facilities (7303.842)
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm073125.pdf>

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Seafood HACCP Alliance Course, Sanitation Control Procedures Manual
<http://nsql.gso.uri.edu/flsgp/flsgpe00001/flsgpe00001index.html>

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<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/SeafoodHACCP/ucm194434.htm>

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Environmental Sampling for the Detection of *Listeria monocytogenes*
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