

# LEGAL INFORMATION

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## HOW TO HANDLE AN FDA INSPECTION

**What Your Company  
Needs to Know About Inspection  
of Seafood Processing Establishments  
by the U.S. Food and Drug Administration (FDA)**

**An Educational Manual to Assist  
U.S. Seafood Processors**

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OF SEAFOOD PROCESSING ESTABLISHMENTS BY THE  
U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

**AN EDUCATIONAL MANUAL TO ASSIST  
UNITED STATES SEAFOOD PROCESSORS,  
PREPARED AT THE REQUEST OF**



VIRGINIA POLYTECHNIC INSTITUTE  
AND STATE UNIVERSITY

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**with additional support provided by:**

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## **How to Handle an FDA Inspection**

This document was created as an educational resource for Fish and Shellfish processors in the United States of America. Comments and advice presented herein are drawn from an analysis of applicable regulations as they existed at the time of printing. Users of this document should be aware that regulations and their applications are subject to change, and that this document should not replace the counsel of an attorney, or stand in the place of a thorough understanding of the applicable laws in their current form.

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# How to Handle an FDA Inspection

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## I. INTRODUCTION

The processing of seafood products in interstate commerce is subject to regulation by the federal government including especially the United States Food and Drug Administration (FDA). Accordingly, it is important for United States seafood processors to understand the procedures that are followed by FDA during inspections of processors, and to understand also the FDA's rights and obligations as well as a processor's rights and obligations.

Furthermore, regulatory requirements for seafood processors have expanded recently pursuant to FDA's issuance of new regulations to govern the manufacture of "fish and fishery products," including regulations that establish "Hazard Analysis Critical Control Point (HACCP)" requirements.<sup>1</sup> This manual includes coverage of changes in the law with respect to FDA inspections that result from the new HACCP requirements.

FDA inspections have a serious regulatory purpose. The inspector comes, usually, to determine whether the inspected processor is complying with the requirements of the Federal Food, Drug, and Cosmetic Act (FDC Act) and FDA regulations. The processor must regard the inspector as a policeman gathering evidence, evidence that ultimately could be used against the processor. Almost every FDA-initiated recall, civil seizure action, injunction action, and criminal prosecution has as its basis data acquired by an FDA inspector during an inspection. Therefore, it is critically important that a processor have a good understanding of FDA's rights and of the processor's rights during an inspection, and that the processor act accordingly to manage the inspection to protect itself as best it can.

Every seafood processor should have a standard operating procedure, a written plan, for coping with the FDA inspection. The plan should explain for affected personnel (A) FDA's rights, (B) the

company's rights, and (C) company policies and practices to be followed during the FDA inspection. This manual is intended to help U.S. seafood processors to develop such a plan, or to review and refine their existing plan.

A useful way to approach this subject is to review considerations with respect to a typical FDA inspection, from start to finish.

## II. RECEIVING THE INSPECTOR

Before beginning an inspection, an FDA inspector is required by the FDC Act to present (A) credentials identifying himself/herself and (B) a written notice of inspection (Form FDA 482) to the owner, operator, or agent in charge of the establishment to be inspected.<sup>2</sup> A seafood processor's inspection plan should designate the person (hereafter sometimes referred to as "the processor's representative") to receive and accompany the inspector. "Back-up" personnel should also be identified. These persons should be trained so that they understand thoroughly the extent of FDA's rights, the processor's rights, and the processor's policies with respect to the various matters that are likely to arise during an inspection.

## III. PROCESSOR'S RECORD OF THE INSPECTION

Upon receiving the inspector, the processor's representative should begin immediately to compile a comprehensive record of the inspection. This record should open with the notice of inspection provided by the inspector. The processor's representative should examine each inspector's credentials and record the full name of each inspector. If, later, FDA should institute an enforcement action based upon the inspection, the company will want to be certain of the identity of each FDA inspector, for depositions or other preparation of its defense.

#### IV. WHAT ABOUT A WARRANT?

The FDC Act provides that FDA inspectors are authorized . . .

to enter, at reasonable times, any factory, warehouse, or establishment in which food . . . [is] 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 . . . in interstate commerce; and . . . to inspect . . .<sup>3</sup>

The FDC Act makes no mention of requiring a warrant from a United States district judge or magistrate to authorize the inspection. Furthermore, the FDC Act provides that “refusal to permit entry or inspection” is a criminal offense.<sup>4</sup>

However, in 1978 the United States Supreme Court, in *Marshall v. Barlow’s, Inc.*, ruled that it is unconstitutional for inspectors of the Occupational Safety and Health Administration (OSHA) to conduct an inspection without a warrant unless the inspected company consents to the inspection.<sup>5</sup> In this decision, the Supreme Court stated that “warrantless searches are generally unreasonable” and that “this rule applies to commercial premises as well as homes.” Nevertheless, the Supreme Court also stated that warrantless inspections are permitted, as an “exception,” for “pervasively regulated” businesses “long subject to close supervision and inspection.” The Court identified the “liquor” and “firearms” industries as examples of the exceptional types of businesses for which warrantless inspections are permitted without the consent of an inspected firm.

FDA asserts that food processors that are subject to regulation under the FDC Act come within the exception in *Marshall v. Barlow’s, Inc.* that permits unconsented warrantless inspections of perva-

sively regulated industries. However, United States courts have ruled “both ways” on the issue of whether an unconsented and warrantless inspection under the FDC Act is constitutional in light of the *Barlow’s* decision.<sup>6</sup> Probably in part because FDA usually can easily obtain an inspection warrant anyway, simply by telling a United States district judge or magistrate that the Agency has not inspected a particular processing establishment for a while and that it wants to review the processing operations there, most processors permit an inspection without attempting to insist upon a warrant. This appears to be the most prudent and appropriate course of action in most circumstances.

FDA does not routinely obtain a warrant before attempting to conduct an inspection. If ever an FDA inspector should arrive at a processing establishment accompanied by a U.S. marshal armed with a warrant, this would be a most unusual and suspicious circumstance, requiring prompt and careful attention. If the warrant were to provide for photographs, for access to particular confidential records, or for other FDA activity that the processor otherwise would refuse to permit, it would be especially important to react immediately; a processor might find it necessary to comply with the warrant until the processor’s attorney could reach the judge or magistrate who issued the document.

#### V. BEFORE THE INSPECTION BEGINS

Before the inspector begins to examine a processing establishment, the processor’s representative should ask why the inspector is there, and what the inspector intends to review. It sometimes happens, for example, that the inspector is interested in a particular subject, and that a processor can immediately obtain and provide desired information without opening the door for the inspector to wander generally through the processor’s establishment.

Also, before the inspection begins, the processor’s representative should tell the inspector

of any company policies that will control the inspection. For example, a processor may want to tell the inspector (A) that company policy prohibits taking cameras into the plant and that the inspector must leave any camera in his/her car or in the company representative's office, and (B) that any questions or requests for information are to be directed only to the designated company representative and not to other company employees. (In sections XI.-XII. below, this manual reviews several policies that inspected processors should consider adopting.)

## **VI. CONDUCT OF THE INSPECTION— FDA'S RIGHTS OF ACCESS TO THE PROCESSOR'S OPERATIONS, PROD- UCTS, AND RECORDS; EFFECTS OF NEW HACCP REGULATIONS**

Suppose the inspector states that his/her purpose is to conduct a routine surveillance inspection of the processing establishment, including review of any HACCP plan and HACCP compliance records. What is the extent of FDA's inspection authority?

### **A. FDA's Basic Inspection Authority**

The FDC Act states that FDA is given authority

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.<sup>7</sup>

Note, however, what the Act does not state. It does not mention, for example, any FDA right of access to manufacturing records such as HACCP records, batch production records, results of laboratory analyses, or complaint files. Most food processors are not required to provide such records to the FDA.

### **B. Additional FDA Inspection Authority Resulting from FDA's HACCP Regulations— Generally**

However, seafood processors are subject to more rigorous manufacturing and inspection requirements than many other food processors.

In the Federal Register of December 18, 1995, FDA published new final regulations for "Fish and Fishery Products."<sup>8</sup> The new regulations became effective on December 18, 1997. The FDA press release that announced the issuance of these regulations characterized them as a major new development in advancing the cause of food safety and included the following statements:

The Clinton Administration today moved to increase the safety of the U.S. food supply by requiring that seafood processors use preventive controls to keep unsafe products from reaching consumers.

The new Food and Drug Administration regulations represent a revolution in the way food is protected. The regulations — based on principles of a system called Hazard Analysis Critical Control Point (HACCP) — replace the approach adopted in the early 1900s that addressed safety problems after the fact with new procedures under which food processors will take greater responsibility for preparing safe food, and government and industry will work more closely together to protect public health.

It is estimated that these regulations will prevent 20,000 to 60,000 seafood poisonings a year, which cost consumers up to \$116 million annually. . .

The key HACCP components of the system are: identification of potential problems that could make seafood hazardous; establishment and monitoring of targeted control points to minimize such risks; and keeping a record of the results.

Under the FDA rule, seafood processors will have to identify hazards that, without preventive controls, are reasonably likely to affect the safety of the products. If at least one such hazard can be identified, the firm will be required to adopt and implement an appropriate HACCP plan. For example, a highly mechanized processing line would be checked regularly for metal fragments in the food and records kept of those checks. In addition to helping ensure that the food is free of such contaminants, this process also helps manufacturers who subsequently have problems with their food determine how and when those problems could have occurred.

Seafood processors using the HACCP system will continue to be monitored under FDA surveillance and inspection programs. HACCP record keeping will enable FDA regulators to monitor product safety more closely and on a more continuous basis than through spot checks.<sup>9</sup>

The underlying legal premise of the HACCP regulations is that a seafood product that has been produced in violation of the requirements of the regulations or of a processor's HACCP plan may be deemed to be "adulterated," in violation of section 402(a)(4) of the FDC Act, in that it will have been prepared, packed, or held under insanitary con-

ditions whereby it "may" have become contaminated with filth, or whereby it "may" have been rendered injurious to health.<sup>10</sup>

It is of interest in this regard that the courts have held that a food may be deemed to be adulterated under section 402(a)(4) of the FDC Act without proof that the food actually is contaminated with filth or actually has been rendered injurious to health; the statute requires only that it be shown that a food "may" have become defective. (In a case that provides an instructive example of how FDA can use section 402(a)(4), the United States Court of Appeals for the Eighth Circuit, after describing conditions in a food processing establishment in which food had been held in open containers in a building in which pigeons were flying about, stated that the "pigeons were not housebroken" and condemned the food as adulterated in violation of section 402(a)(4), even though there was no direct evidence that pigeon droppings in fact had ever fallen into the food containers or touched the food.)<sup>11</sup>

FDA, in its explanatory preamble to the final HACCP regulations, says that it does not intend to seek unreasonable penalties such as destruction for technical HACCP violations. For example, FDA states,

The agency has heard considerable concern that it will automatically seek to seize or otherwise remove from commerce all products being produced under a HACCP system that is determined to be deficient in any respect. That concern is unfounded . . . FDA's reaction will depend . . . on the overall public health significance of the deficiency. . .

FDA has alongstanding practice of tailoring its regulatory response to the facts. A deviation from any of the



provisions of these regulations . . . carries the potential for regulatory action pursuant to section 402(a)(4) of the act. However, FDA intends to enforce these regulations in a manner that focuses on those deviations that have the greatest potential for causing harm. It is not FDA's intent to pursue regulatory action against a product or a processor exclusively for clerical errors or minor errors of omission. To do so would certainly not be an efficient use of agency resources, nor would it be in the best interests of the consuming public.<sup>12</sup>

Such statements by FDA are reassuring. It should be remembered, however, that if ever the agency disagrees with a company's view that a particular HACCP violation is not especially significant, and instead decides to pursue a serious enforcement action, the agency has written its regulations to enable it to assert that the affected seafood product is adulterated, which enables the agency thereby to assert that the food is subject to seizure and destruction, and also, to assert that responsible corporations and individuals are subject to an action for injunction, or even to criminal prosecution.<sup>13</sup>

Clearly, all of this is a major new regulatory program for the seafood processing industry.

### **C. Particular Records That Must Be Made Available to FDA Under the HACCP Regulations**

The purpose of this manual is to review FDA's inspection authority and to advise United States seafood processors about how best to handle an FDA inspection. This manual is not intended to be a primer about the requirements of HACCP for properly managing quality assurance operations in

a seafood establishment. U.S. seafood processors who have questions about applying HACCP requirements to their manufacturing, packaging, or other processing operations may wish to call the Virginia Polytechnic Institute and State University or to consult with appropriate experts in seafood processing operations. However, in order to provide guidance about certain FDA inspection matters, it is necessary at this point for this manual to review certain FDA HACCP requirements with respect to maintenance of certain types of records:

#### **1. "Hazard analysis"**

The new FDA regulations require each seafood processor to conduct, or to have conducted for it, a "hazard analysis" to determine whether there are food safety "hazards" that are reasonably likely to occur "for each kind of fish and fishery product processed by that processor," and to identify the "preventive measures" that the processor can apply to control those hazards.<sup>14</sup>

#### **2. "HACCP plan"**

The FDA regulations also provide that every seafood processor "shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur." There must be a "specific" HACCP plan for "each location where fish and fishery products are processed" and for "each kind of fish and fishery product processed" although the plan "may group kinds of fish and fishery products together, or group kinds of production methods together" if the hazards, critical control points, critical limits, and procedures that are required to be identified and performed are "identical for all fish and fishery products so grouped or for all production methods so grouped."<sup>15</sup>

#### **3. "Sanitation controls"**

The FDA HACCP regulations provide that "sanitation controls" "may be" (but are not required

to be) included in the HACCP plan.<sup>16</sup>

#### **4. “Corrective actions”**

FDA regulations provide that “whenever a deviation from a critical limit occurs,” a processor shall take one of several possible “corrective actions” specified in the regulations. The regulations then provide that “all corrective actions . . . shall be fully documented in records. . . .”<sup>17</sup>

#### **5. “Verification”**

FDA regulations require that every seafood processor “shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.” Requirements are established for reassessment of the HACCP plan at least annually, for ongoing verification activities such as regular review of consumer complaints, and for a review including signing and dating of records relating to monitoring of the critical control points, of the taking of corrective actions, and of the calibrating of any process control instruments.<sup>18</sup>

#### **6. Record retention**

The FDA regulations require that all HACCP-related records required by the regulations “shall be retained at the processing facility or importer’s place of business in the United States for at least one year after the date they were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.”<sup>19</sup> Furthermore, records that relate to the “general adequacy of equipment or processes being used,” including the “results of scientific studies and evaluations,” are required to be retained at the processing facility or the importer’s place of business in the United States “for at least two years after their applicability to the product being produced at the facility.”<sup>20</sup>

#### **7. FDA inspection of records**

FDA’s HACCP regulations require that “all records” and “all plans and procedures” required by the regulations, including the records described above in this manual, “shall be available for official review and copying” – i.e., including review and copying by an FDA inspector conducting an establishment inspection – “at reasonable times.”<sup>21</sup> This means that, in general, all HACCP records need to be readily available for review by an FDA inspector at all times.<sup>22</sup>

#### **8. Records concerning “sanitation control procedures”**

In addition, the new FDA regulations require certain “sanitation control” procedures and related record-keeping, and although these sanitation controls and records are not required to be part of the HACCP controls and records – see subsection VI.C.3. above – nevertheless, the regulations provide that these sanitation records also are subject to the requirements concerning maintenance and availability to FDA inspectors described above for HACCP records.<sup>23</sup>

#### **9. Summary**

In sum, as a part of the new FDA regulations concerning HACCP, FDA has required that a wide range of detailed records be maintained concerning hazard analysis, a processor’s HACCP plan, the procedures actually followed to control hazards, and sanitation controls, and, that these records be kept readily available for review and copying by FDA inspectors.

## VII. COMMENT: FDA'S REGULATIONS RE ACCESS TO A PROCESSOR'S HACCP RECORDS MAY EXCEED THE AGENCY'S AUTHORITY

The record-access provisions of the FDA's HACCP regulations, described above in section VI.C. of this manual, appear to be at odds with section 704(a)(1) of the FDC Act,<sup>24</sup> quoted above in section VI.A., which provides that in the case of "any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held . . .," FDA inspectors have authority "to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." (Emphasis added.) This provision does not appear to authorize FDA access to food manufacturing records.

Indeed, in the immediately-following sentence, this same section of the FDC Act states,

In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices [are in violation of the Act].<sup>25</sup>

Pursuant to this provision of the law, it has been assumed by many persons for many years that FDA's authority to require the production of manufactur-

ing records during an inspection generally is limited to drugs and devices and generally does not apply to foods.

Nevertheless, the situation is not quite so simple. FDA occasionally has relied upon other sections of the FDC Act to justify an asserted right of mandatory access to certain manufacturing records for its inspectors in situations where section 704 would not provide such access. For example, the agency's regulations that govern manufacture of low-acid foods that are packaged in hermetically sealed containers provide for such access, based ultimately on a threat of issuing a requirement for an emergency permit pursuant to section 404 of the FDC Act.<sup>26</sup> (There does not appear to be any judicial ruling upon whether the provision of FDA's low-acid food regulations requiring release of such records is valid, however.)

FDA asserted in its preamble to the final seafood HACCP regulations that agency access to manufacturing records is needed for FDA to verify that a company is complying with the HACCP requirements.<sup>27</sup> That, however, is not necessarily a sufficient justification for interpreting the statute to permit FDA to require such access. If the need to verify compliance with requirements were a sufficient basis to justify mandatory access to food manufacturing records, the limitation on FDA's right of access to such records in section 704(a)(1) of the FDC Act would be a largely-meaningless provision that the agency could almost always avoid, since it will almost always be the case that the most efficient way for FDA to verify compliance with requirements for foods is to have mandatory access to the manufacturing records – which section 704(a)(1) clearly does not authorize in the case of foods.

On balance, however, it appears that (A) although reasonable arguments can be made that FDA's asserted right of access to HACCP records exceeds the agency's authority, and, that if the agency truly believes it must have such access to seafood

manufacturing records, it should make its arguments to the Congress, which has the power to amend the FDC Act, nevertheless, (B) FDA may be able to make reasonable arguments for its conflicting point-of-view, and therefore (C) it is doubtful that any seafood processor will want to be the subject of a “test case” in court about the matter. In any event, it appears that most seafood processors let FDA inspectors review the processors’ HACCP records.

### **VIII. COMMENT RE CONFIDENTIALITY OF A COMPANY’S HACCP RECORDS WHEN REVEALED TO FDA**

One reason for concern about the matter of FDA access to HACCP and sanitation control records is that, once such records are in the agency’s possession, there is no guarantee that they will not subsequently become available to the general public (including competitors and the news media).

FDA’s regulations suggest that such records will be held in confidence by the agency to a degree. I.e., the regulations provide as follows:

. . . all plans and records required [by the FDA HACCP regulations and obtained by FDA] are not available for public disclosure unless they have been previously disclosed to the public . . . or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information. . . .<sup>28</sup>

However, the regulations then also provide:

. . . these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hard-

ship, such as generic-type HACCP plans that reflect standard industry practices.<sup>29</sup>

In response, it might be noted that FDA’s release of any HACCP plan (“generic” or not) for a particular processor would show to the processor’s competitors what that processor was doing in its manufacturing operations – information that would appear to be regarded as confidential by many processors. Furthermore, it is not at all clear that FDA will accept that HACCP records that document adverse events such as product contamination (i.e., records that could be highly damaging if the information were to become public and were to be featured in the press or referenced by competitors) will qualify as “trade secret or confidential commercial or financial information” and thereby be exempt from release to the public by FDA. However, at this early stage in FDA’s enforcement of the seafood HACCP regulations, it is too soon to tell how rigorous FDA will be in practice about resisting release to the public of a company’s HACCP records.

### **IX. TAKING OF SAMPLES**

The FDC Act provides that the FDA inspector is authorized to collect product samples.<sup>30</sup> During an inspection, FDA inspectors routinely take samples of finished and unfinished seafood products and of labeling, and processors generally permit the taking of reasonable samples of this type. The courts have recognized that this is an appropriate inspection function.<sup>31</sup> One may insist that the inspector pay for the fair value of samples taken, but many processors do not bother to do this unless the value is substantial.

### **X. “HOLDING” A SUSPECT PRODUCT**

While the FDA inspector may take samples of seafood products in a processor’s establishment, the inspector does not have the authority to detain or embargo seafood products that the inspector believes

to be in violation of the FDC Act (except, under certain established procedures, for items that are in the process of being imported into the United States). The inspector may, however, request that a processor voluntarily hold a seafood product that the inspector believes to be adulterated or misbranded.

“Seizure” of a seafood product in a processor’s establishment pursuant to the FDC Act generally requires the institution of a civil proceeding in a United States district court.<sup>32</sup> In general, before a seafood product can be “seized” under the FDC Act, the following chain of events must occur: The FDA district office recommends to FDA headquarters that a civil seizure be instituted, and if FDA headquarters agrees, the FDA chief counsel writes to the local United States attorney, requesting the initiation of a civil seizure action. Assuming the United States attorney agrees (as he/she usually does), he/she files a complaint for forfeiture in the local United States district court, and then the United States marshal serves upon the product a “warrant for arrest.” Service of this warrant upon the product accomplishes seizure. Thereafter, there will be a trial before the court to determine, on the merits, whether the food is adulterated or misbranded and should be condemned as alleged by FDA. (However, FDA may ask state health officials to detain foods until a federal civil seizure action is accomplished. State officials often can exercise authority under state law immediately to embargo food that is believed to be adulterated or misbranded.<sup>33</sup>)

## **XI. CONDUCT OF THE INSPECTION – PROTECTING THE PROCESSOR’S RIGHTS AND INTERESTS**

Let’s now consider several policies or procedures that a seafood processor should consider adopting to try to manage the conduct of the FDA inspection, in order to protect the processor’s rights and interests:

- Accompany the FDA inspector at all times. Do not allow the inspector to proceed unattended by a representative of the processor.
- Advise the inspector that any questions or requests for data are to be directed only to the processor’s designated representative.

(The FDC Act authorizes only “reasonable” inspections, and, surely, it is not reasonable to permit someone who is not an employee to roam unattended through a processing establishment asking questions of whomever he or she pleases. Such activity could be disruptive of production and perhaps even dangerous to someone who is not familiar with the plant.)

- Employees other than the processor’s representative should be instructed not to speak to the inspector. They should not volunteer conversation, and if asked a question by the inspector, they should respond that it is company policy not to discuss their work with visitors and that any questions should be directed to the representative designated to accompany the inspector.
- The company representative should keep a detailed record of all that the inspector says or does. This information may become important in the future, especially if FDA should undertake regulatory action based upon the inspection.
- Whenever the FDA inspector takes a sample of anything, the company representative also should immediately take a sample of the same article, to be maintained as a part of the company’s record of the inspection. For example, if FDA samples a particular lot of finished product, or a particular label, the processor will want to be certain that it has

taken an identical companion sample, which will then be available for efficient reference and review if FDA subsequently asks questions or undertakes regulatory action.

- Do not sign or initial “affidavits” or other documents. FDA inspectors frequently enter information that they believe to be important on a form entitled “Affidavit” and then ask a processor’s representative to sign or initial the form, thereby acknowledging the accuracy of the statement. There is no obligation to sign or initial any such affidavit, and there is no good reason to do so. Any admissions in the statement could be used against the processor in court.

(Many food companies have a standard policy that their employees are not authorized to sign or initial any documents for an FDA inspector. If the inspector asks for written acknowledgment with respect to a particular matter, the company representative can ask the inspector to submit a written request to the company, for review and consideration by management and company counsel. In practice, this often will be the end of the matter because FDA inspectors generally are loath to request anything in writing.)

- If the FDA inspector calls the company representative’s attention to a violation of law that is easily correctable, the company should try promptly to correct the situation during the course of the inspection.
- The company representative should not volunteer information. It may be reasonable to provide certain information in response to questions from an inspector, but there is no reason to suggest new

avenues of interest that otherwise might not be investigated.

- The company representative should always be scrupulously honest in everything that is said to the inspector. It can be entirely appropriate to tell an inspector that the inspector has no statutory right to require the processor to provide certain information, and to decline to provide it. It would be a very different matter, however, to give the inspector a potentially devious, or dishonest, response. The former should be understood and respected, and can be defended. The latter just invites trouble, and can be a criminal offense.<sup>34</sup>
- Finally, always be polite. A company representative may need to be firm in asserting company policies or in protecting a company’s rights in some other respect, but the representative should always remain courteous. Personal animosity cannot be helpful.

## **XII. PHOTOGRAPHS**

FDA asserts that it has a right to take photographs during an inspection, and the inspector probably will argue if told not to bring a camera into the processing establishment. The FDA Investigations Operations Manual (IOM) includes a section instructing the inspector to insist that he/she has a right to take photographs, and to cite particular judicial decisions if a company refuses to permit photography.<sup>35</sup>

However, a statement appearing earlier in the IOM, which the inspector is unlikely to mention, explains why FDA really wants the photographs: The IOM tells the inspector, “Photos. . . are one of the most effective and useful forms of evidence of violations.”<sup>36</sup>

There are two judicial decisions that the inspector probably will cite to a processor if the processor refuses to permit photographs: (A) *United States v. Acri Wholesale Grocery Co.* rules that if a company permits FDA to take photographs without objection, the photographs may be used in evidence against the company in a criminal prosecution<sup>37</sup>; and (B) *Dow Chemical Co. v. United States* upholds the authority of Environmental Protection Agency (EPA) inspectors to take photographs of company property from an airplane in public airspace.<sup>38</sup> However, it appears that no reported judicial decision has ever yet penalized a company solely for refusal to permit photographs during an FDA inspection.

It appears that many companies routinely do not permit photographs during an inspection. Photographs may overemphasize a particular detail in a misleading way, or may reveal trade secret manufacturing procedures that the processor does not want to release outside of its control. If the company representative is firm about the matter, the FDA inspector usually will put away his or her camera and proceed with the inspection, although he/she may report that the processor has “partially refused” to permit an inspection. A seafood processor should consider this matter together with its own legal counsel.

### **XIII. SHIPPING RECORDS**

The FDC Act provides that “persons receiving foods . . . in interstate commerce or holding such articles so received,” shall, upon written request, permit an FDA inspector . . .

at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food . . . or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof.<sup>39</sup>

Accordingly, if FDA so requests in writing, a processor must provide access to records concerning interstate shipment.

However, the same section of the Act also provides that information obtained in this manner may not be used in a criminal prosecution against the person from whom the information was obtained (although it may be used in a civil seizure action or injunction). Accordingly, if the inspector does request such information, the company representative should insist that the request be made in writing before providing the documents if the processor wants to assure itself of the protection afforded by the statute with respect to criminal prosecution.

### **XIV. THE “EXIT INTERVIEW”**

At the completion of the inspection, the FDA inspector usually will ask to meet with the “owner, operator, or agent in charge.” At this time, the inspector may provide an FDA form entitled “Inspectional Observations” (Form FDA 483), listing observations the inspector believes are violations.<sup>40</sup>

It is prudent to discuss with the inspector this list of observations. If the company representative does not understand an item, he or she should ask about it. If the company representative does not agree with a particular observation, he or she should explain his/her position. If the company has corrected an observation of a violation during the course of the inspection, the company representative should tell the inspector. The inspector should be asked to make any appropriate changes in the list of observations at this time. Also, if the company intends to correct certain observations, this should be explained. Even if the inspector does not amend the list of observations, he/she should include the company representative’s comments in the report of the inspection (the Establishment Inspection Report [EIR], discussed in section XVI. below). Such comments may affect the way the inspector and his/her superi-

ors at FDA evaluate the inspection. In essence, the company representative should try to satisfy FDA that the processor is taking all reasonable steps to manufacture proper seafood products.

Also, during the exit interview the FDA inspector should provide a "Receipt for Samples" (Form FDA 484) for all samples taken during the course of the inspection (unless he/she has already provided such documentation when the samples were taken). At this time, the company representative should confirm that the company has taken identical companion samples (for its own internal evaluation and future reference) of all articles sampled by the inspector.

If during an exit interview the company representative promises the inspector to make particular corrections, the company should be certain to do as promised. The next time an FDA inspector visits the plant, he/she can be expected to determine and report whether promised corrections have been made.

## **XV. AFTER THE INSPECTION**

Promptly after the inspection, appropriate company personnel should meet to review the inspection. Was the company in compliance with all significant requirements of law? If not, what corrective steps should be taken? Were the inspector's "Inspectional Observations" accurate? If the company representative disagreed with the inspector's observations during the exit interview, did the inspector make appropriate changes in the written list of observations? If the inspector noted violations, were they of such significance that some type of follow-up regulatory action might be expected from the Agency? Who in corporate management should be advised of the inspection and its outcome?

Depending upon the nature of the "Inspectional Observations" and the exit interview, after the inspection the processor may want promptly to send FDA a written response to the inspector's list of observations, thereby making certain that the

FDA record includes a complete statement of the processor's views.

## **XVI. THE "EIR"**

After departing, the FDA inspector may prepare a detailed Establishment Inspection Report (EIR). The EIR becomes FDA's primary comprehensive record of the inspector's visit to the firm, and it may be reviewed by FDA compliance officers looking for violations of law. (If product samples were taken, they may be examined in an FDA laboratory. Also, labeling taken by the inspector may be examined at FDA offices.)

A processor will, of course, be interested to know what the inspector has said about its establishment in the EIR, and the processor may obtain a copy of the EIR by filing a Freedom of Information Act request once FDA has closed its file on the inspection.<sup>41</sup> If FDA refuses to release a copy of the EIR concerning an inspection, the Agency may still have an "open" file on the matter, i.e., the Agency may still be considering whether to institute some form of regulatory action. (In the Federal Register of April 14, 1997, FDA announced that, effective April 1, 1997, a copy of the "narrative portion" of the EIR should "routinely" be provided to an inspected establishment "once the agency determines that the inspection is 'closed.'"<sup>42</sup>)

Note that EIRs are subject to release under the Freedom of Information Act to any member of the public, including competitors. Accordingly, a seafood processor may want to review the EIR from an inspection of the processor's establishment partly to determine whether FDA has inadvertently failed to purge the document of any trade secret or other confidential information before release. If a company finds FDA releasing an EIR that reveals trade secret or other confidential information concerning the company, the company should object to the Agency immediately.



## **XVII. FDA ANALYSES**

If FDA performs laboratory analytical work on a sample of an ingredient or finished product taken during an inspection, the processor is entitled to a copy of the results of analysis.<sup>43</sup> Note that the processor should be able to obtain such reports of analyses without waiting until FDA “closes the file” concerning the inspection.<sup>44</sup> Thus, one may be able to obtain analytical results before obtaining the EIR. (If FDA performs analytical work, one generally can also obtain from FDA a portion of the sample that was analyzed, so that the company may perform analytical work on the same sample tested by FDA.<sup>45</sup>)

## **XVIII. CONCLUSION**

If FDA should conclude that an inspection has revealed significant violations of the FDC Act or of FDA regulations, the Agency may initiate regulatory action (e.g., issue a warning letter, request a recall, or recommend a civil seizure action, an injunction, or even a criminal prosecution). It is precisely because of the serious enforcement actions that can result from an FDA inspection that it is so important for a processor to understand the governing law and to manage such inspections with attentive care. A seafood processor should never forget the potentially serious nature of an FDA inspection.

In order to protect their rights and interests, U.S. seafood processors should establish standard operating procedures for the management of FDA inspections, and affected company personnel should be thoroughly trained to follow the procedures. It is hoped that this manual will help U.S. seafood processors to establish effective inspection plans.



## REFERENCES

- <sup>1</sup> Title 21, Code of Federal Regulations (C.F.R.), Part 123; published in the Federal Register of December 18, 1995 (60 Fed. Reg. 65096-65202). These regulations became effective on December 18, 1997.
- <sup>2</sup> Section 704(a) of the FDC Act, 21 U.S.C. § 374(a).
- <sup>3</sup> Id.
- <sup>4</sup> Section 301(f) of the FDC Act, 21 U.S.C. § 331(f).
- <sup>5</sup> *Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978).
- <sup>6</sup> Compare *United States v. Roux Laboratories, Inc.*, 456 F. Supp. 973 (M.D. Fla. 1978) (ruling FDA may not conduct an inspection of a cosmetic establishment without a warrant if the company does not consent) with *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass. 1980) (ruling that neither a warrant nor consent was required for an FDA inspection of a grocery warehouse).
- <sup>7</sup> Section 704(a)(1) of the FDC Act, 21 U.S.C. § 374(a)(1) (emphasis added).
- <sup>8</sup> 21 C.F.R., Part 123; 60 Fed. Reg. at 65096-65202.
- <sup>9</sup> FDA Press Release No. P95-9, dated December 5, 1995, "Seafood Safety Regulations Announced." (Emphasis added.)
- <sup>10</sup> 21 U.S.C. § 342(a)(2)(4); 21 C.F.R. § 123.6(g); 60 Fed. Reg. at 65198.
- <sup>11</sup> *Berger v. United States*, 200 F.2d 818 (8th Cir. 1952).
- <sup>12</sup> 60 Fed. Reg. at 65170.
- <sup>13</sup> 21 C.F.R. § 123.6(g); 60 Fed. Reg. at 65198; 21 U.S.C. § 342(a)(4); 21 U.S.C. §§ 331-334.
- <sup>14</sup> 21 C.F.R. § 123.6(a).
- <sup>15</sup> 21 C.F.R. § 123.6(b).
- <sup>16</sup> 21 C.F.R. § 123.6(f).
- <sup>17</sup> 21 C.F.R. § 123.7(a), (d).
- <sup>18</sup> 21 C.F.R. § 123.8.
- <sup>19</sup> 21 C.F.R. § 123.9(b)(1).
- <sup>20</sup> 21 C.F.R. § 123.9(b)(2).
- <sup>21</sup> 21 C.F.R. § 123.9(c).
- <sup>22</sup> The FDA regulations provide that if a processing facility is "closed for a prolonged period between seasonal packs," or if "record storage capacity is limited on a processing vessel or at a remote processing site," records may be transferred to some other reasonably accessible location at the end of a seasonal pack "but shall be immediately returned for official review upon demand." 21 C.F.R. § 123.9(b)(3). Maintenance of records on computers can be acceptable. 21 C.F.R. § 123.9(f).
- <sup>23</sup> 21 C.F.R. § 123.11.
- <sup>24</sup> 21 U.S.C. § 374(a)(1).
- <sup>25</sup> Id. (Emphasis added.)
- <sup>26</sup> 21 U.S.C. § 344; 21 C.F.R. § 108.35(c)(3)(ii).
- <sup>27</sup> 60 Fed. Reg. at 65139.
- <sup>28</sup> 21 C.F.R. § 123.9(d)(1).
- <sup>29</sup> 21 C.F.R. § 123.9(d)(2).

30 Sections 702(b), 704(c), (d) of the FDC Act, 21 U.S.C. §§ 372(b), 374(c), (d).

31 *United States v. 75 Cases . . . Peanut Butter*, 146 F.2d 124 (4th Cir. 1944), cert. denied, 325 U.S. 856 (1945); *United States v. El Rancho Adolphus Products*, 140 F. Supp. 645 (M.D. Pa. 1956), aff'd, 243 F.2d 367 (3d Cir. 1957), cert. denied, 353 U.S. 976 (1957); *United States v. Roux Laboratories, Inc.*, supra, note 6.

32 21 U.S.C. § 334.

33 See, e.g., *United States v. An Article of Food . . . 345/50-Pound Bags*, 622 F.2d 768, 769 at note 1 (5th Cir. 1980).

34 18 U.S.C. § 1001.

35 FDA Investigations Operations Manual Subchapter 520, Section 523.1 "In-Plant Photographs" (October 1994).

36 FDA Investigations Operations Manual Subchapter 520, Section 523 "Photographs-Photocopies" (October 1994).

37 *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976).

38 *Dow Chemical Co. v. United States*, 476 U.S. 227 (1986).

39 Section 703 of the FDC Act, 21 U.S.C. § 373. (Emphasis added.)

40 Section 704(b) of the FDC Act, 21 U.S.C. § 374(b), states, "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, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

41 21 C.E.R. §§ 20.64, 20.101.

42 62 Fed. Reg. 18138 (April 14, 1997).

43 Section 704(d) of the FDC Act, 21 U.S.C. § 374(d); see also 21 C.E.R. § 20.105(c).

44 Id.

45 Section 702(b) of the FDC Act, 21 U.S.C. § 372(b); 21 C.E.R. § 2.10(c).

