Federal Inspections and Enforcement

2

Abstract

This chapter begins with the substantive discussion of food regulation by looking at the enforcement authority of the two primary food agencies in the US. By beginning with the enforcement authority, later subjects on prohibited acts will be placed in the context of risks and consequences. Introduction of the enforcement powers also enables instructors to test students using practical scenarios from Form 483s, warning letters, and regulatory control actions. This chapter covers the full suite of enforcement actions available to the FDA and FSIS. It includes a detailed examination of Constitutional and Statutory defenses to inspections and enforcement actions.

2.1 Introduction

This chapter will explore the inspection models used by the USDA/FSIS and the FDA. Inspections are the chief mechanism for the agencies to either remove troubled products or proactively prevent their release into the stream of commerce. As will be discussed in the sections below, the two agencies follow radically different models of inspection. Comparing and contrasting the two approaches will highlight the advantages and disadvantages of both agencies' enforcement mechanisms. From this viewpoint, a better understanding of the risks of non compliance along with strategies to solving enforcement issues will emerge.

When considering the regulatory landscape, activities of the primary agencies can be classified in two ways. On the one hand are the activities needed to bring new ingredients or additives on the market and on the others, the activities conducted to ensure products are safe, and consumers are not intentionally deceived. Typically, the dichotomy is referred to as pre market approvals and post market surveillance. This text begins with enforcement and inspection, post market surveillance activities, both because it constitutes the bulk of regulatory work and it provides insight into the statutory standards for ingredient and label integrity.

2.2 FSIS Inspection Authority and Enforcement Tools

2.2.1 Statutory Authority and Early Origins of Inspection Authority

Initial authority for meat inspections came in the Federal Meat Inspection Act (FMI) of 1906. It authorized the USDA to conduct continuous inspections of all domestic meat intended for human consumption. The FMI required the USDA to inspect all animals covered under the Act brought into a plant for slaughter or a processing facility. Processing plant activities included boning whole carcasses or creating meat products like

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sausages or ham. Poultry inspections were not included in the 1906 FMI. Prior to World War II, poultry production in the USA remained a small farm activity with sales limited to neighbors and local markets. Poultry sales were intrastate rather than interstate, and thus outside of any federal legislative awareness or authority. It was after the 1957 Poultry Products Inspection (PPI) Act that poultry inspections were also made mandatory. FSIS conducted all meat and poultry inspections from 1957 to 1995. Beginning in May 1995, the authority to inspected processed eggs under the Egg Products Inspection Act (EPI) was transferred from the USDA's Agricultural Marketing Services (AMS) to FSIS. For the past 20 years, FSIS has operated as the sole arm of the USDA with authority to conduct egg inspections.

FSIS enabling Acts are among the most stringent. The statutes governing the safety of meat, poultry, and eggs are designed to prevent contaminated (adulterated) or mislabeled (misbranded) food from reaching the market. This in part requires FSIS to ensure all regulated foods are slaughtered and processed under sanitary conditions. FSIS enjoys unfettered continuous accesses to facilities and the power to prevent uninspected or condemned products from entering the market. Understanding the scope, process, and coverage of FSIS, inspection and enforcement authority proves crucial in managing the agency's reach.

2.2.2 Continuous Mandatory Inspection Requirement

The 1906 FMI required the continuous presence of inspectors in all establishments providing meat for interstate commerce. This edict applied to both the slaughter and processing of meat intended for domestic sale and human consumption. What constitutes "continuous," however, varies between slaughtering and processing. FSIS personnel inspect all meat and poultry animals at slaughter with at least one federal inspector per slaughter-line during all hours the plant is operating. No slaughter or dressing can occur without an inspector on-site and on the slaughter-line. The system even accounts for instances of overtime or holiday shifts by utilizing a system allowing plants to pay a user-fee to bring an inspector on duty (CRS Meat and Poultry).[1] Inspectors at processing facilities in contrast remain on-site daily but do not require an FSIS inspector to monitor each product or process. Inspectors are on-site daily to ensure meat is processed in sanitary conditions, and regulations for ingredient levels, packaging, and labeling are followed. Processing plants are also considered under continuous inspection because of the daily visits and the presence of inspectors on-site at all times.

The 1906 crisis that sparked Congress action provides important context in evaluating the inspection model used by FSIS. In 1891, the USDA conducted limited ante- and post mortem inspections, but no inspection of processing plants. Upton Sinclair exposed the horrifying conditions in slaughter and processing plants in his book *The Jungle*. The FMI passed in 1906 largely because of the outcry from Sinclair's stories. It reflects not only a knee-jerk reaction to the crisis, but also a heavy emphasis on enforcement in order to restore public confidence.

In light of the strict prohibition against selling uninspected meat and poultry, the contours of FSIS jurisdiction become important. FSIS legal inspection responsibilities begin when animals arrive to slaughterhouses and end once products leave processing plants. The enabling acts provide the USDA and FSIS no further authority to engage in inspections of any type. This raises important questions about what happens to meat products when they leave the facility. Who monitors the shipping, storage, or preparation of these products? Such questions need not be rhetorical, but can often be the central issues of outbreak litigation.

2.2.3 Inspection Methods

Inspection with FSIS remained largely unchanged for 90 years. Meat inspection programs initially relied on organoleptic methods, namely sight,

[1] Congressional Research Service, "Meat and Poultry Inspection Issues" (Jean M. Rawson, 2003).

Fig. 2.1 Three marks of inspection utilized by the USDA/FSIS

touch, and smell, to determine the quality and presence of diseases. Inspectors stamp a mark of approval on each carcass and major cuts of meat passing their organoleptic inspection (see Fig. 2.1). Without the mark, the carcass cannot move on for further processing or enter the market. The purpose of this carcass-by-carcass inspection was originally aimed at reducing the potential for the transmission of diseases from sick animals to humans. This could arise either from a diseased animal brought to slaughter or via poor sanitary conditions in the slaughter and processing plants.

The processing plants experienced a similar inspection. Processing initially involved cutting and boning whole carcasses along with the production of meat products like ham or bacon. These functions were usually completed in a facility adjacent to the slaughtering facility. The focus for FSIS in processing was on the overall production line, not the individual products. The emphasis was on sanitary conditions, which would contaminate meat previously inspected and approved.

For nearly 90 years, the FSIS inspected for disease using organoleptic methods. As with the original passage of the 1906 Act only crisis compelled changes to how the USDA conducted inspections. The 1990 *E. Coli O157:H7* outbreak linked to the fast-food chain "Jack In the Box" brought a new inspection concept to FSIS. Prior to the outbreak FSIS explored ways to modernize its inspection system. The surge in establishments, the increasing range of products, and the emergence of new technologies, ingredients, and processes proved too complex for FSIS. FSIS simply was overwhelmed and the 1990 outbreak highlighted the extent of the gaps in its surveillance. In response, FSIS underwent structural changes and developed a new rule for inspectors known as "Pathogen Reduction/Hazard Analysis

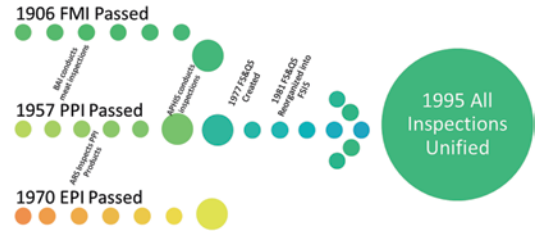

Fig. 2.2 Evolution of FSIS and unification of USDA inspections

and Critical Control Point System" (HACCP). More than two decades later, HACCP remains the industry standard for FSIS inspections.

2.2.4 Organization and Evolution of FSIS

FSIS did not start out with a clear name or mission. As discussed in Chapter 1 and shown in Fig. 1.7, FSIS began as the Bureau of Animal Industries. Inspection functions were housed in this sub agency from 1906 to 1953. President Eisenhower kicked off a lengthy series of changes; first, moving inspection functions to the Agricultural Research Service (ARS). In 1968, when poultry inspections were added, the sub agency was named Consumer and Marketing Services, a sub division within the ARS. In a short two-year-span, inspections were first moved to the Animal & Plant Health Service in 1971, renamed APHIS in 1972, and then moved to a new sub agency in 1982 called Food Safety & Quality Service (FS&QS). The final move came in 1981 when FS&QS was reorganized into FSIS (see Fig. 2.2). A great deal of upheaval for any organization, the sub agency experienced over five large organizational shuffles in less than 30 years.

Although FSIS's exercises a narrower scope of authority, it utilizes a complex organizational

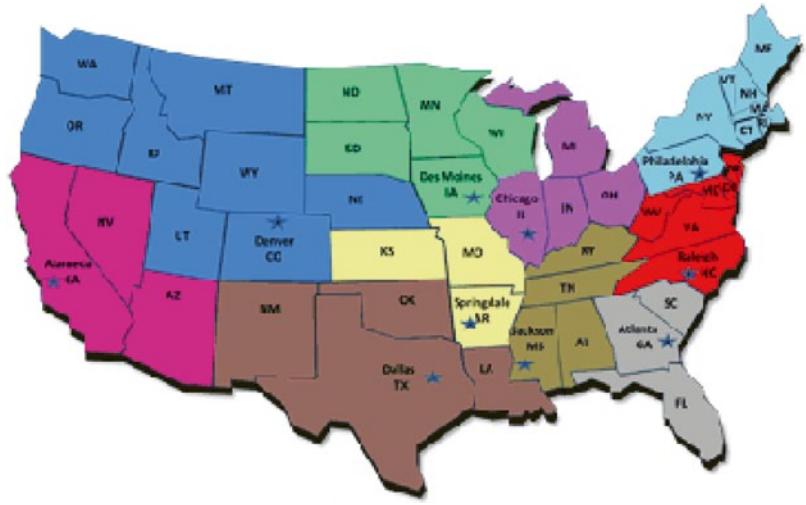

Fig. 2.3 US map broken into the ten OFO regions

structure. Visiting the FSIS's website and explaining its organization, one can become easily lost. The main office to focus on is the Office of Field Operations (OFO) and Office of Investigation, Enforcement and Audit (OIEA). The OFO manages all FSIS inspections and initiates the corresponding enforcement actions. FSIS deploys approximately 8000 FSIS inspectors and staff to about 6200 meat slaughtering and/or processing plants nationwide. The OFO, like the FDA's ORA, organizes its inspectors into districts (see, Sect. 3.2 below). FSIS operates ten districts (see Fig. 2.3). Each district is overseen by a district manager (DM) and deputy district manager (DDM). Both would be involved in serious enforcement actions.

The OIEA supports the OFO by conducting both criminal violations and investigating investigating outbreaks. While OFO is focused on in-plant activities OIEA casts its attention toward in-commerce products. In particular, it investigates criminal violations and instances of intentional contamination. It will also play a key role in investigating foodborne illness outbreaks. Since OFO is limited to inspecting domestic facilities OIEA also verifies imported meat, poultry, and egg products meet applicable standards. This is a small sampling of the primary activities charged to the OIEA.

2.2.5 Enforcement Toolkit

Overview of Types of FSIS Enforcement Actions

FSIS enforcement options can be divided into three groups. The three groups or classes of enforcement actions as defined in the regulations are: regulatory control action, withholding action, and suspension. Each is defined in 9 CFR 500.1 as provided below. As can be seen in the excerpt of 500.1 below the enforcement actions escalate in severity. There is a final enforcement action, which is irreversible and in many ways the culmination of FSIS enforcement. That is the Withdrawal of Inspection under 9 CFR 500.6. Once inspectors are withdrawn from a facility, the facility cannot operate or re-open.

9 CFR 500.1

a. A "regulatory control action" is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

b. A "withholding action" is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
c. A "suspension" is an interruption in the assignment of program employees to all or part of an establishment.

Regulatory Control Actions

Regulatory controls actions are the most commonly used by FSIS inspectors. Regulatory control actions function as a low-level enforcement action that allows inspectors to correct an issue before a product leaves the facility or an equipment is reused. The violations are minor and the enforcement action is taken immediately. There are four scenarios provided in 9 CFR 500.2 when a regulatory control action may be taken. The four scenarios are provided below.

9 CFR 500.2(a)(1)-(4)

1. Insanitary conditions or practices;
2. Product adulteration or misbranding;
3. Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or
4. Inhumane handling or slaughtering of livestock.

The focus for regulatory control actions centers on preventing non compliant products from leaving the facility. This includes potential contamination or adulteration as well as misbranding. The USDA FSIS Rules of Practice Regulation (RPR) provides examples of each of the four conditions (Rules of Practice).[2] The first three focus on ensuring that the products are safe and wholesome and the facility's compliance program fully functioning. For example, ensuring equipment is clean (500.2(a)(1)), water does not collect on or around meat (500.2(a)(2), or the facility is well lit in order to allow inspectors to assess products and processes (500.2(a)(3)).

Regulatory control actions only result in a temporary delay. Typically product is retained and potentially reinspected. In other cases, equipment or facilities are closed until cleaned or repaired. In most instances, slaughter or processing lines are slowed or stopped temporarily.

The final basis for a regulatory control action finds its roots in a second enabling act. Congress originally passed the Humane Methods of Slaughter Act in 1958 (7 U.S.C. 1901 *et. sEq.*)[3] The HMSA was updated in 1978 and provided the USDA FSIS authority to stop a slaughtering line until the abuses were corrected. The HMSA and 500.2(a)(4) do not apply to the slaughter of chickens or other poultry, only to livestock such as sheep, pigs, or cattle. The USDA/FSIS have issued a number of regulations, directives, and guidance to industry on how to humanely slaughter and handle livestock (9 C.F.R 313; FSIS Compliance Guide).[4] A word of caution, if a reader is new to FSIS inspections, then be aware of enforcement reports and regulations in this area, in particular on inhumane handling and slaughter, can often be unsettling and graphic.

Although regulatory control actions are immediate, the facility still must be notified. The RPR makes clear the notification, typically via a Noncompliance Record (NR), may be provided to the facility after the action is taken. This allows the hazard to be contained and the facility notified of a potential gap in its compliance program. In some cases, the facility may seek an appeal of the enforcement action. This appeal is taken to the next level of FSIS supervision.

[2] USDA FSIS Rules of Practice: Inspection Methods (June 23, 2013).

[3] 7 U.S.C. 1901 *et seq*.

[4] See e.g., 9 CFR 313; FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock—to support the Humane Methods of Slaughter Act (2013).

Withholding Action or Suspension Without Notification

The remaining two categories of enforcement action can occur under two scenarios. Withholding actions refer to withholding the marks of inspection, which every product requires to enter the market legally. Suspension of inspection activities as the name suggests involves suspending inspectors and effectively stopping all production. Suspension differs from the most severe enforcement action—Withdrawal of Inspection. The Withdrwal of Inspection terminates FSIS inspections permanently and shutters the facility. Suspensions and withholding actions are similar, but a suspension will be in effect for longer than a withholding action.

There are certain violations FSIS deems as requiring enforcement action in these two categories immediately and without any prior notification to the facility. Subsection 500.3 provides four triggers for a withholding or suspension action without prior notice. Those are provided below.

9 CFR 500.3(a)(1)-(4)

a. FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

1. The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;
2. The establishment does not have a HACCP plan as specified in Sec. 417.2 of this chapter;
3. The establishment does not have Sanitation Standard Operating Procedures as specified in Secs. 416.11–416.12 of this chapter;
4. Sanitary conditions are such that products in the establishment are or would be rendered adulterated;
5. The establishment violated the terms of a regulatory control action;
6. An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or
7. The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within 3 days of notification.

The most common basis for withholding or suspension actions involves a serious and imminent threat to public health. Protecting the public health provides the primary rationale for taking a significant enforcement step without notification. In the RPR, FSIS directs inspectors to document the imminent threat when taking action under 500.3(a). Inspectors are also required to notify the facility orally and in writing "as promptly as the circumstances permit…" (Rules of Practice).[5]

The decision to take withholding and suspension actions come from higher levels of authority. The decision to take a withholding action originates with inspectors in the plant, but must be made by the inspector in charge (ICC) or the frontline supervisor. In some cases, the decision is made by the district office. Suspension decisions on the other hand may only be made by the district office.

There are other grounds for taking enforcement action without prior notification that lack an urgency to protect public health. For instance, if any regulatory control action is not corrected or is repeated, then FSIS may take a withholding or suspension action without notification. In a sense, the facility already received notification through the regulatory control action and the regulations.

It is important to highlight instances where notification may be withheld that do not directly relate to food safety. Namely, the ability to withhold notification where FSIS personnel are

[5] *Id*. US FSIS Rules of Practice at 6.

confronted and possibly assaulted. Needless to say, it can be a contentious environment operating a facility with constant regulatory supervision. FSIS relies on the ability to work continually and freely in a facility. If an environment is created where inspectors do not feel comfortable to perform their duties, then enforcement action without notification works to restore the trust between FSIS and the host facility.

Withholding Action or Suspension with Prior Notification

If there is no immediate threat to public health then withholding or suspension actions require notification. Subsection 500.4 provides the criteria for withholding or suspension actions that require notification. Those are provided below. Prior to withholding the marks FSIS must provide written notice it intends to either withhold the marks of inspection or suspend inspections.

9 CFR 500.4(a)-(e)

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

a. The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;
b. The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;
c. The establishment has not maintained sanitary conditions as prescribed in §§ 416.2–416.8 of this chapter due to multiple or recurring noncompliances;
d. The establishment did not collect and analyze samples for Escherichia coli Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;
e. The establishment did not meet the Salmonella performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

Enforcement actions taken under 500.4 involve notification largely because it involves repeated non compliance. Unlike 500.3 where there is no HACCP or standard operating procedures (SOPs), 500.4 involve deficiencies in the compliance program. If these were one-off errors in the program, then they would most likely be caught in a regulatory control action. Section 500.4 instead aims for the gaps in the compliance program that result from inadequate procedures or processes. As such, the RPR directs inspectors to compile "extensive information" to provide both a factual basis for the facility to analyze and challenge and to demonstrate a pattern or history of failed corrective or preventative actions (Rules of Practice).[6] Once presented with the notification and supporting evidence a facility is given an opportunity to respond by identifying areas of disagreement or share an interpretation of the regulations. This is in many ways similar to the Form 483 used by the FDA, which will be discussed in the Section 3.4 below.

Withdrawal of Inspection

Withdrawal of FSIS inspectors represents the pinnacle of the agency's enforcement powers. There are several bases for withdrawing inspectors, which includes all of the previous actions that lead to withholding or suspension actions.

9 CFR 500.6

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform

[6] Id. US FSIS Rules of Practice at 7.

Rules of Practice, 7 CFR subtitle A, part 1, subpart H because:

a. An establishment produced and shipped adulterated product;
b. An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;
c. An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;
d. An establishment did not maintain sanitary conditions;
e. An establishment did not collect and analyze samples for Escherichia coli Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;
f. An establishment did not comply with the Salmonella performance standard requirements as prescribed in §§ 310.25(b) and 381.94(b) of this chapter;
g. An establishment did not slaughter or handle livestock humanely;
h. An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or
i. A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

The slaughter and processing of meat is uniquely viewed as a privilege not a right. Unlike other food facilities, FSIS regulated facilities must apply for a grant of inspection. Think of it as applying for a driver's license. And like a driver's license can be revoked, so can a grant of inspection. Abuse the privilege, lose the privilege. The process to take revoke the grant of inspection can be lengthy. It not only involves a documented history of non compliance, but a hearing before an Administrative Law Judge (ALJ). A hearing preserves due process (see, Sect. 2.2.6 below). This process, and truly the entire grant of inspection feature, is unique to FSIS. The FDA while requiring a facility register prior to beginning operations is unable to bar a facility from beginning operations like FSIS can. This level of control requires careful checks to ensure the privilege is properly revoked.

2.2.6 Lessons from FSIS's History—Food Law Is a Floor Not a Ceiling

There are a number of lessons to take away from the history of FSIS. In particular, note the slow pace of change in the inspection methods. Despite rapid changes in technology, demand, and the range of products, FSIS clung to outdated inspection criteria. There were rumblings of change prior to adopting HACCP, but it still took crisis to create change. If compliance is seen as a floor, then this can lead a facility into a false sense of security. As facilities struggle with the balancing marketability and compliance, it is important to look at the headlines. No facility wants to be associated with the crisis that leads to new rules or regulations.

Case Study: New Poultry Inspections Rule; First Change in Over 50 Years

An excellent example of the pace of change comes in a recent rule change announced by the USDA/FSIS. In the summer of 2014, the USDA/FSIS announced a new rule to poultry inspection. The new rule replaced the inspection model used when the PPI was adopted in 1957. For nearly 60 years, FSIS did not require facilities to test for *Salmonella* and *Campylobacter*. Under the new rule, known as the New Poultry Inspection System (NPIS), facilities will be required to take preventative

measure against *Salmonella* and *Campylobacter* contamination (NPIS Final Rule).[7] This will include mandatory testing at two points in the production process. The NPIS will leave unchanged the maximum line speeds, which are currently 140 birds per minute. Although the speed sounds dizzying, pilot programs set maximum line speeds of 175 birds per minute.

Startling to consider how much the scientific knowledge of these two pathogens changed over 60 years or to think how the industry developed in that timeframe. Yet rather than elect for incremental changes the current model of regulation waits and issues sweeping regulations in an attempt to catch-up.

The history of FSIS also provides insight into political priorities. As governmental agencies, the USDA and FDA are only as effective as properly funded. Shifting an agency around, renaming and altering responsibilities does not speak to a well-regarded agency. The numbers support the notion. Not only are meat and poultry inspections deemed suitable for shuffling, but also for basic funding. Numerous studies of budget appropriations conclude the meat inspection budget either remains stagnant or contracts even in the face of a swelling mandate. Simply, consumers are demanding more meat and poultry, but the budget appropriations to ensure the safety of that meat and poultry is not gaining approval.

If the goal of an agency is consumer confidence than the agency name matters. When one hears the name Food Safety and Inspection Service a clear mandate emerges without knowing anything else about the agency. A name like Agricultural Research Service or Animal and Plant Health Service signals little about what the agency does. Would one really expect an agency named Agricultural Research Service to ensure the safety of meat products? The US Federal government is vast and names matter. Names provide clarity to the public about an agency's mission and primary functions.

[7] USDA/FSIS, Modernization of Poultry Slaughter Inspection, Docket No. FSIS-2011-0012 (Final Rule 2014).

2.3 Overview of FDA Inspection Process and Enforcement Tools

2.3.1 Evolution of Inspection Authority

The FDA conducts warrantless inspections of the premises of regulated industries. The inspections may be "for cause" such as an inspection during a recall or adverse event or simply "surveillance" inspections as required by the Act. In either case, the FDA inspectors arrive unannounced and request total access to a facility for a period of four or more days. The FDA did not always enjoy the authority to inspect facilities. The 1906 Act, at only five pages, made no explicit reference to an ability to inspect facilities. An agent could arrive at a facility and request entry. If refused the FDA would need to go to court and obtain a warrant. With the 1938 Act Congress worked to patch-up this oversight. The 1938 Act created Section 704 to authorize the FDA to inspect facilities and added refusal to consent to inspect to the list of prohibited acts in Section 331. As a prohibited Act, a refusal became a crime, typically a misdemeanor (see, Chap. 7).

The Supreme Court struck down the penalty in the 1938 Act. The court determined the provision in Section 704 which allowed consent, but penalized for withdrawing consent, as too vague to be enforceable.

***UNITED STATES v. CARDIFF*, 344 U.S. 174 (1952)**

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Respondent was convicted of violating 301 (f) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. 331 (f). That section prohibits "The refusal to permit entry or inspection as authorized by

section 704." Section 704 authorizes the federal officers or employees "after first making request and obtaining permission… of the owner, operator, or custodian" of the plant or factory "to enter" and "to inspect" the establishment, equipment, materials and the like "at reasonable times."

Respondent is president of a corporation which processes apples at Yakima, Washington, for shipment in interstate commerce. Authorized agents applied to respondent for permission to enter and inspect his factory at reasonable hours. He refused permission, and it was that refusal which was the basis of the information filed against him and under which he was convicted and fined… The Court of Appeals reversed, holding that 301 (f), when read with 704, prohibits a refusal to permit entry and inspection only if such permission has previously been granted.

The Department of Justice urges us to read 301 (f) as prohibiting a refusal to permit entry or inspection at any reasonable time. It argues that that construction is needed if the Act is to have real sanctions and if the benign purposes of the Act are to be realized. It points out that factory inspection has become the primary investigative device for enforcement of this law, that it is from factory inspections that about 80% of the violations are discovered, that the small force of inspectors makes factory inspection, rather than random sampling… of finished goods, the only effective method of enforcing the Act.

All that the Department says may be true. But it does not enable us to make sense out of the statute. Nowhere does the Act say that a factory manager must allow entry and inspection at a reasonable hour. Section 704 makes entry and inspection conditioned on "making request and obtaining permission." It is that entry and inspection which 301 (f) backs with a sanction. It would seem therefore on the face of the statute that the Act prohibits the refusal to permit inspection only if permission has been previously granted. Under that view the Act makes illegal the revocation of permission once given, not the failure to give permission. But that view would breed a host of problems. Would revocation of permission once given carry the criminal penalty no matter how long ago it was granted and no matter if it had no relation to the inspection demanded? Or must the permission granted and revoked relate to the demand for inspection on which the prosecution is based? Those uncertainties make that construction pregnant with danger for the regulated business.

The alternative construction pressed on us is equally treacherous because it gives conflicting commands. It makes inspection dependent on consent and makes refusal to allow inspection a crime. However we read 301 (f) we think it is not fair warning… to the factory manager that if he fails to give consent, he is a criminal. The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid…may be as much of a trap for the innocent as the ancient laws of Caligula. We cannot sanction taking a man by the heels for refusing to grant the permission which this Act on its face apparently gave him the right to withhold. That would be making an act criminal without fair and effective notice…

This Supreme Court opinion led Congress to pass the Factory Inspection Amendment in 1953. The Factory Inspection Amendment remains a critical provision some 60 years later. The Amendment introduced several new concepts. First, it removed the consent requirement from the FDA's inspection authority. Instead, it required the FDA to present credentials and a written notice of inspection. This written notice is known as Form 482. The procedure created, and still used today,

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