

## FSIS Administrative Withdrawal of Inspection: Overview of Case Referral and Disposition Process

### I. Introduction

This attachment provides additional guidance to Office of Field Operations (OFO) District Office personnel, Office of Investigation, Enforcement and Audit (OIEA), Enforcement Operations Staff (EOS), and other designated FSIS personnel related to the procedures for the administrative withdrawal of Federal inspection service. The attachment provides additional guidance on the case referral, evaluation, and disposition process, such as the filing of an administrative complaint, resolving a case by a consent decision and order, or proceeding to an administrative hearing. FSIS applies this methodology when taking or initiating action to withdraw the grant of Federal inspection from an establishment receiving inspection services under the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*). The attachment supplements the general instructions in [FSIS Directive 8010.5, Case Referral and Disposition](#). OFO and OIEA personnel should keep in mind that this attachment does not show the full scope of FSIS activities related to each process or the actions in every case; each case is distinct, and the actions in each case are highly dependent on the unique facts and circumstances of the case.

### II. Overview of the Administrative Withdrawal Process

As described in [FSIS Directive 8010.5](#), FSIS may withdraw the grant of Federal inspection service, when necessary, from an establishment under FSIS regulations (9 CFR [500.6](#)). The withdrawal process includes four parts:

1. In-Plant Verification and Enforcement;
2. Case Review and Disposition;
3. Administrative Complaint and Hearing; and
4. Consent Decision and Order.

Together, these four parts comprise the “administrative withdrawal process.” See *Figure 1*.

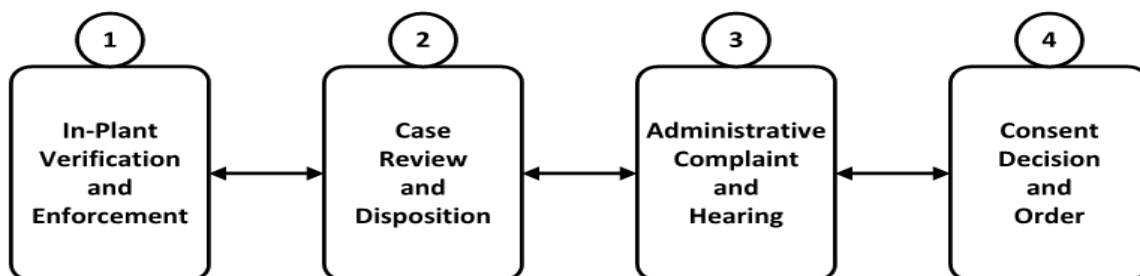


Figure 1



The administrative withdrawal process and each of the four parts of the process are described more fully below.

### III. Parts of the Administrative Withdrawal Process

#### 1. In-Plant Verification and Enforcement

The first part of the administrative withdrawal process is *In-Plant Verification and Enforcement*. The administrative withdrawal process begins with OFO personnel verifying compliance day-to-day in a Federal establishment in accordance with the relevant FSIS Directives, and concludes, when necessary, with a case referral from OFO to EOS in accordance with [FSIS Directive 8010.5](#). See *Figure 2*.

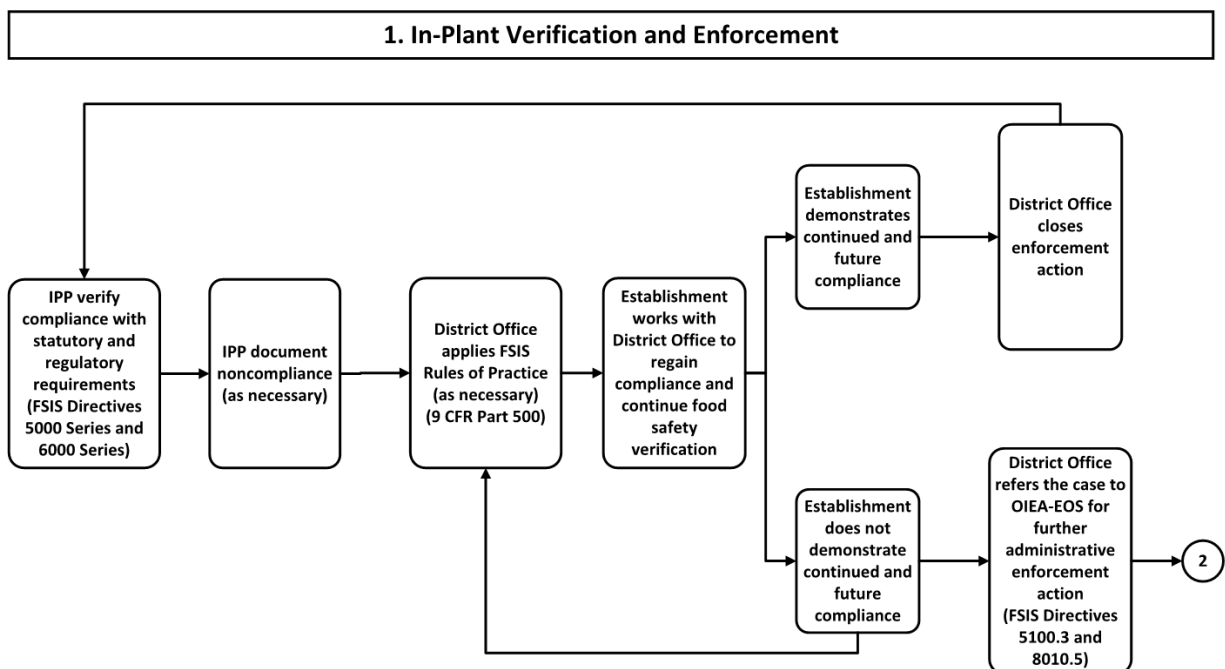


Figure 2

#### A. Verifying Compliance

OFO personnel (specifically, Consumer Safety Inspectors, Public Health Veterinarians, and Enforcement, Investigations, and Analysis Officers, and other inspection program personnel (IPP)) carry out inspection activities in official establishments to verify compliance with food safety, humane handling and slaughter, and other regulatory requirements. These personnel conduct inspection and verification activities according to the instructions in various [FSIS Directives](#).

#### B. Documenting Noncompliance

Each time IPP make a noncompliance determination, they are to inform the establishment of the findings, generally, through documenting a Noncompliance Record (NR). The NR notifies the establishment of the noncompliance and that it should take action to remedy the situation and prevent recurrence. The establishment should acknowledge receipt of the NR. Should IPP



document repetitive or egregious food safety or other noncompliance, FSIS may take actions to control products and/or may take administrative enforcement action under the FSIS Rules of Practice (9 CFR [Part 500](#)).

### C. FSIS Rules of Practice

The FSIS Rules of Practice define the type of administrative enforcement actions taken by FSIS, the conditions under which these actions are appropriate, and the procedures FSIS follows in taking these actions. Administrative enforcement actions may include a regulatory control action (9 CFR [500.2](#)), issuance of Notice of Intended Enforcement (NOIE) (9 CFR [500.4](#)), or suspension of the assignment of inspectors, without prior notice, for a specific or, in some instances, multiple food safety processes (9 CFR [500.3](#)). When this occurs, FSIS provides Federal establishments with due process by providing them with opportunity to respond to the notice or action, to propose corrective and preventive measures, to appeal the action, and/or to contest the action at an administrative hearing (9 CFR [306.5](#), [381.35](#), [590.310](#), and [500.5](#), respectively).

### D. Compliance Demonstrated

If the establishment demonstrates the ability to return to compliance, the OFO District Office may, in the case of an intended enforcement action, defer action, or, in the case of a suspension action, hold the action in abeyance (9 CFR [500.5](#)). During the deferral or abeyance period, the District Office is to develop a verification plan for IPP to verify that the establishment is complying with its proffered corrective actions and is ensuring food safety and regulatory compliance. The District Office may close the enforcement action after a time period (typically, a minimum of 90 days) in which the establishment demonstrates compliance.

### E. Continued or Future Noncompliance

In other situations, establishments are not able to return to compliance or ensure food safety, or there is future noncompliance by the establishment. When this occurs, the District Office is to take action under the FSIS Rules of Practice, such as reinstate suspension or take new or additional enforcement actions, to ensure food safety and protect public health. In some cases, OFO may decide that it is necessary to refer the case to EOS, in accordance with [FSIS Directive 5100.3](#), *Administrative Enforcement Action Decision-Making and Methodology*, and [FSIS Directive 8010.5](#) to evaluate for further action.

This takes us to the second part of the administrative withdrawal process, *Case Review and Disposition*.

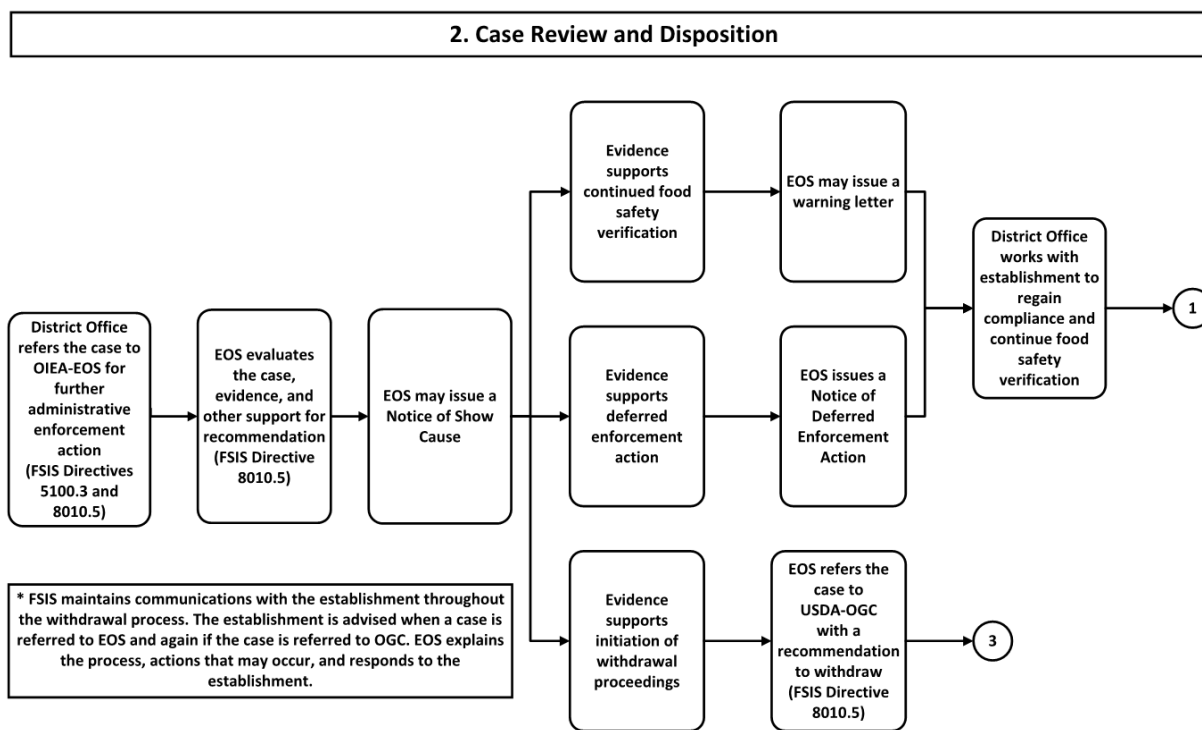
## **2. Case Review and Disposition**

The second part of the administrative withdrawal process is *Case Review and Disposition*. This part includes activities carried out by EOS. EOS evaluates alleged violations of the FSIS statutes and regulations and, when necessary, takes or initiates action, including criminal, civil, or administrative action, to enforce FSIS requirements. In addition, EOS supports OFO personnel in enforcing food safety regulations and other requirements in federally inspected establishments.

The *Case Review and Disposition* process begins when the OFO District Office refers a case to EOS to evaluate for further administrative enforcement action and concludes with a final case



disposition. Disposition outcomes may include continued compliance verification, warning letters or deferred enforcement, or referral to USDA's Office of the General Counsel (USDA-OGC). See *Figure 3*.



*Figure 3*

#### A. FSIS Authority for the Withdrawal of Inspection

When case history shows an inability or unwillingness by a Federal establishment to ensure food safety, prevent repetitive or egregious humane handling or slaughter violations, or otherwise comply with the FSIS statutes and regulations, FSIS has the authority, under these statutes, to initiate action to withdraw the establishment's grant of Federal inspection. When withdrawn, the establishment is prohibited from conducting any slaughter and/or processing operations that require Federal inspection. The FSIS Rules of Practice specify the situations for which FSIS can move to withdraw inspection service (9 CFR [500.6](#)). These rules also specify the situations for which FSIS can seek to deny inspection service (9 CFR [500.7](#)). The processes for both withdrawal and denial are generally similar.

#### B. Case Referral and Disposition

[FSIS Directive 8010.5](#) provides instructions to FSIS personnel on the referral of cases, including referral by OFO District Offices of cases to EOS for administrative action to withdraw inspection services from an establishment. FSIS Directive 8010.5 also describes the work methods EOS uses for the evaluation and disposition of cases, and the actions EOS may take on a case.



### C. Case Review

When evaluating whether to initiate action to withdraw Federal inspection services from an establishment, EOS is to consider a variety of factors, each case- and evidence-dependent. These factors include, but are not limited to, the type (or nature) of the violation (e.g., does the case involve food safety violations, insanitary conditions, Hazard Analysis and Critical Control Point (HACCP) plan design or execution); the seriousness (or gravity) of the violation (e.g., does the case involve adulterated product, consumer illness outbreak); the number and/or repetitiveness of violations (e.g., does the case involve multiple and/or recurring noncompliance issues, such as HACCP, sanitation, and humane slaughter, and/or repeated violations); the degree of culpability (e.g., is there evidence showing the violations were negligent, reckless, knowing, or intentional); the establishment's compliance history (e.g., does the case involve repetitive violations, previous suspension actions); and the establishment's compliance efforts (e.g., prior or current actions taken by the establishment to correct, restore, or maintain compliance). EOS may also consider actions it has taken in similar cases. Of primary importance is the Agency's objective to ensure food safety and protect public health.

### D. Notice of Show Cause

In some, but not all, cases, EOS may decide to issue a Notice of Show Cause letter (SCL) prior to initiating action. A SCL notifies the establishment that FSIS is considering initiating action to withdraw its grant of Federal inspection. The SCL provides the establishment with opportunity to present its views and other information regarding the allegations, as well as steps taken by the establishment to rectify the situation. EOS is to consider all responsive information submitted by the establishment in case disposition decisions. EOS is to engage OFO in the process and may engage other FSIS experts, such as staff in the Office of Policy and Program Development (OPPD) or in the Office of Public Health Science (OPHS). EOS may also communicate, at this point, with attorneys in USDA-OGC.

### E. Communications

EOS and OFO are to maintain communications with the establishment throughout the administrative withdrawal process. The establishment is to be advised if/when the case is referred to EOS and again if/when the case is referred by EOS to USDA-OGC. EOS is to explain the case referral and administrative withdrawal process to the establishment and to advise the establishment of actions that may occur and what steps the establishment can take to rectify the situation. EOS is to ensure the establishment understands its rights, including appeal and hearing rights. EOS and OFO also are to respond to any inquiries or proposals, such as for reinstatement of inspection, submitted by the establishment.

### F. Case Disposition

As stated in [FSIS Directive 8010.5](#), and shown in *Figure 3* above, case actions can take various paths. In general, EOS (i) may determine that withdrawal of Federal inspection is not supported at the time and that further food safety verification is more appropriate (i.e., continued verification), (ii) may defer withdrawal action based on new actions by the establishment and subject to future compliance (i.e., deferred enforcement), or (iii) may refer the case to USDA-OGC with a recommendation to initiate inspection withdrawal proceedings (i.e., referral to USDA-OGC).



i. *Continued Verification*

Some cases support providing the establishment with additional opportunity to demonstrate and achieve compliance. Typically, this includes FSIS outreach and engagement with the establishment, continued food safety verification, and/or other actions alternative to withdrawing its grant of Federal inspection. In these situations, the District Office is to work with the establishment to determine if it can regain compliance and resume operations. This is usually done as part of the District Office holding a suspension or reinstatement action in abeyance. When necessary, EOS is to issue a letter to the establishment urging compliance and advising that future violations may result in inspection withdrawal proceedings. If the establishment maintains compliance going forward, the District Office is to close the action. If the establishment does not maintain compliance or if there are new or additional violations, OFO is to refer the case back to EOS for action.

ii. *Deferred Enforcement*

In other cases, EOS may determine the evidence supports deferral of immediate inspection withdrawal proceedings, so that an establishment can have further opportunity to demonstrate and maintain compliance. Generally, deferred enforcement action occurs when an establishment has taken or proffered new or additional corrective and preventive measures, often of an extraordinary measure, to ensure immediate as well as future compliance. In these situations, EOS is to issue a formal Notice of Deferred Enforcement Action. Usually, deferred enforcement occurs following issuance of a SCL.

iii. *Referral to USDA-OGC*

Some cases support referral to the USDA-OGC for initiation of formal administrative proceedings to withdraw the grant of Federal inspection from an establishment. This decision may be made by EOS without issuance of a SCL, when supported by the evidence and the Agency's public health objectives. In other cases, referral to USDA-OGC may occur after an establishment has been given opportunity to respond to a SCL and the response has been considered by the Agency.

When cases are referred by EOS to USDA-OGC, the administrative withdrawal process proceeds to the next step, *Administrative Complaint and Hearing*.

### **3. Administrative Complaint and Hearing**

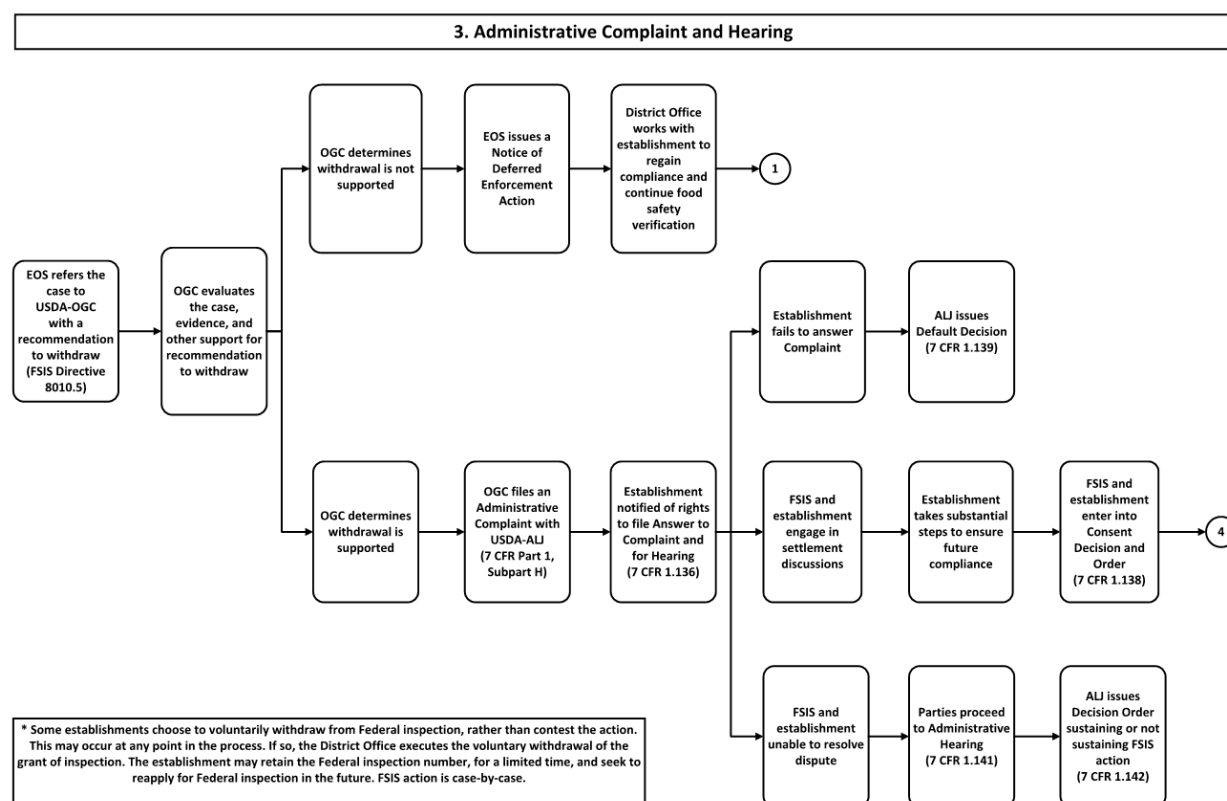
The third part of the administrative withdrawal process is *Administrative Complaint and Hearing*. This part of the process includes activities carried out by USDA-OGC and the USDA Office of Administrative Law Judges (USDA-OALJ), as well as by OFO and EOS.

USDA-OGC is an independent legal agency that provides legal advice and services to the Secretary of Agriculture and USDA agencies with respect to USDA programs and activities. Within USDA-OGC, the Marketing, Regulatory, and Food Safety Programs Division represents FSIS in most legal matters, including those involving the withdrawal of inspection services under the FSIS statutes.



Administrative Law Judges (ALJ) in USDA-OALJ preside over administrative withdrawal cases. ALJs hear and receive testimony and documentary evidence, make rulings, issue case decisions, and approve consent decisions negotiated by parties. The Hearing Clerk's Office, within USDA-OALJ, manages the formal case record, including serving complaints on the parties and docketing other case activities.

The *Administrative Complaint and Hearing* process begins when EOS refers a case to USDA-OGC, and includes the steps in the formal administrative, legal process for the withdrawal of Federal inspection services. These steps are governed by USDA Rules of Practice (7 CFR [Part 1, Subpart H](#)), and may include, depending on the case, the filing of a complaint, negotiation of a consent decision and order, and/or an administrative hearing. See *Figure 4*.



*Figure 4*

## A. USDA Rules of Practice

Much like the FSIS Rules of Practice (9 CFR [Part 500](#)), which define the procedures for administrative enforcement actions, such as suspensions, that FSIS may take at establishments, the USDA Rules of Practice, known formally as the USDA Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary (7 CFR Part 1, Subpart H) (7 CFR [1.130 – 1.151](#)), define the procedures that USDA-OGC and FSIS must follow to withdraw the grant of Federal inspection from an establishment. In simple terms, the FSIS Rules of Practice cover actions up to the filing of a complaint, while the USDA Rules of Practice cover the procedures starting with the filing of a complaint until case resolution.



## B. Administrative Complaint

When necessary, EOS refers cases to USDA-OGC to determine whether the withdrawal of Federal inspection service is appropriate and supported by law and evidence. If USDA-OGC agrees that the withdrawal of inspection is appropriate, it will file an administrative complaint, which is the first, formal step in the withdrawal of inspection proceeding.

The administrative complaint will briefly state the nature of the proceeding, the legal authority and jurisdiction for the withdrawal action, the factual allegations that form the basis for the complaint, and the relief sought by FSIS (7 CFR 1.135). The complaint also identifies the Complainant and the Respondent to the proceeding – in withdrawal of inspection actions, this is, respectively, the FSIS Administrator, who signs the complaint, and the Federal establishment to which the action applies.

After the complaint is signed by the Administrator, USDA-OGC files it with the Hearing Clerk (7 CFR 1.133(b)). The Hearing Clerk assigns a docket number to the case (7 CFR 1.134) and serves the complaint on the parties (7 CFR 1.147). Service of the complaint and other documents is typically made by certified mail. The Hearing Clerk also sends the establishment the USDA Rules of Practice and a letter that briefly explains how to answer the complaint as well as the Respondent's hearing rights (7 CFR 1.136).

## C. Consent Decision and Order

Many withdrawal of inspection cases are resolved by a settlement agreement, known as a Consent Decision and Order (Consent Decision) (7 CFR 1.138). A Consent Decision allows the establishment to resume federally inspected slaughter and/or processing operations under terms negotiated with FSIS. A Consent Decision is an entirely voluntary alternative to the withdrawal action going to hearing, in cases where the establishment demonstrates a willingness and ability to take substantial steps to ensure present and future compliance.

A Consent Decision is a legal order that contains specific terms that the establishment agrees to implement and maintain for the length of the agreement. The OFO District Office, in consultation with EOS, may develop a verification plan based on the specific conditions of the Consent Decision. These conditions are in addition to the general statutory and regulatory requirements that all establishments must meet to have and maintain Federal inspection services.

A Consent Decision holds the withdrawal action in abeyance and allows the establishment to receive Federal inspection services, under a conditional grant of Federal inspection – conditioned upon compliance with the FSIS statutes and regulations, the general conditions of inspection, and the specific conditions of the Consent Decision.

Consent Decisions are case-specific and are negotiated based on the facts, circumstances, and violations that led FSIS to seek withdrawal of inspection services from the establishment. Consent Decisions may require the establishment to develop and implement new food safety systems, to make facility repairs and/or improvements, to implement product sampling and testing, to make management or other personnel changes, to conduct training for managers and/or employees, to conduct and respond to compliance audits, and/or to take other actions designed to ensure the safety of products produced and shipped.



Consent Decisions are signed by the establishment, FSIS, and the ALJ, and then filed with the Hearing Clerk. Consent Decisions contain findings and stipulations as agreed to by the parties. The establishment is not, however, required to admit to the violations to resolve a case by a Consent Decision. Consent Decisions have the same force and effect as a decision entered by the ALJ after a hearing and are fully enforceable.

#### D. Administrative Hearing

Some cases are not resolved by a Consent Decision and proceed to an administrative hearing. Under the USDA Rules of Practice, either party in a withdrawal of inspection proceeding can request a hearing by including a request in the complaint or answer, or by filing a separate, written request with the Hearing Clerk (7 CFR 1.141). In practice, USDA-OGC generally requests a hearing in the complaint and most respondents will request a hearing in their answer to the complaint. These actions preserve both parties' rights to a hearing.

If the case is not resolved, USDA-OGC or the establishment may file a motion for a hearing and the ALJ will gather the parties and set a hearing date. At the hearing, FSIS and the establishment will have the opportunity to present testimony and documentary evidence and make legal, factual, and procedural arguments (7 CFR 1.141). FSIS is represented by USDA-OGC at the hearing. The establishment also has a right to legal counsel.

After the hearing, the ALJ will issue a written Decision and Order that will either sustain or not sustain the Agency's withdrawal of inspection action (7 CFR 1.142). Either side may appeal the decision to the USDA's Judicial Officer (7 CFR 1.145). Otherwise, the ALJ's decision becomes a final decision (7 CFR 1.142).

#### E. Default Decision

In some cases, the establishment may fail to answer the complaint after being served by the Hearing Clerk. When this occurs, USDA-OGC files a motion for the ALJ to issue a Default Decision (7 CFR 1.139). A Default Decision becomes a final case decision unless the establishment files objections or appeals the decision. If the decision becomes final, FSIS proceeds with withdrawing the establishment's Federal grant of inspection.

#### F. Voluntary Withdrawal

In some cases, an establishment may decide to voluntarily withdraw from Federal inspection, rather than contest the Agency's withdrawal of inspection action. An establishment may request to voluntarily withdraw from inspection at any time during the process, before or after a complaint is filed. If this occurs, FSIS is to process the withdrawal of inspection. The establishment may retain its inspection number for a limited period. The establishment also can seek to reapply for Federal inspection services in the future. However, in many cases, FSIS would contest the reapplication based on the violations that led FSIS to seek to withdraw inspection (9 CFR 500.7).

#### G. Expedited Hearing

In addition to this path to an administrative hearing, an establishment may request a hearing, under the FSIS Rules of Practice, if FSIS takes a suspension (or reinstatement of suspension) action (9 CFR 500.5). The written suspension notice issued by the OFO District Office includes language to advise the establishment that it can request a hearing by making a written request



to the Director of EOS. Upon receiving a request for hearing, EOS is to contact the establishment and ask USDA-OGC to file a complaint and, in accordance with the Rules of Practice, a motion for an expedited hearing on the suspension action.

#### H. Communications

As in other parts of the administrative withdrawal process, FSIS and USDA-OGC are to remain in communication with the establishment, its management, and its legal counsel, if any, or other representatives. EOS and USDA-OGC are to communicate with the establishment about the administrative withdrawal process, the complaint and hearing process, and the establishment's rights and responsibilities. EOS and USDA-OGC are to discuss case resolution options with the establishment or its legal counsel, including the Consent Decision and Order process, and are to respond to questions or proposals submitted by the establishment or its representatives.

This takes us to the fourth step of the administrative withdrawal process, *Consent Decision and Order*, which is the path that many withdrawal cases follow.

#### **4. Consent Decision and Order**

The fourth part of the administrative withdrawal process is *Consent Decision and Order*. This part includes activities related to the establishment implementing and maintaining compliance with the Consent Decision, and FSIS verifying compliance and enforcing the Consent Decision including, if necessary, through the legal process. See *Figure 5*.

This *Consent Decision and Order* part of the administrative withdrawal process applies only to those cases where FSIS and the establishment have entered into a Consent Decision to resolve a withdrawal action; though, not all cases are resolved by a Consent Decision.



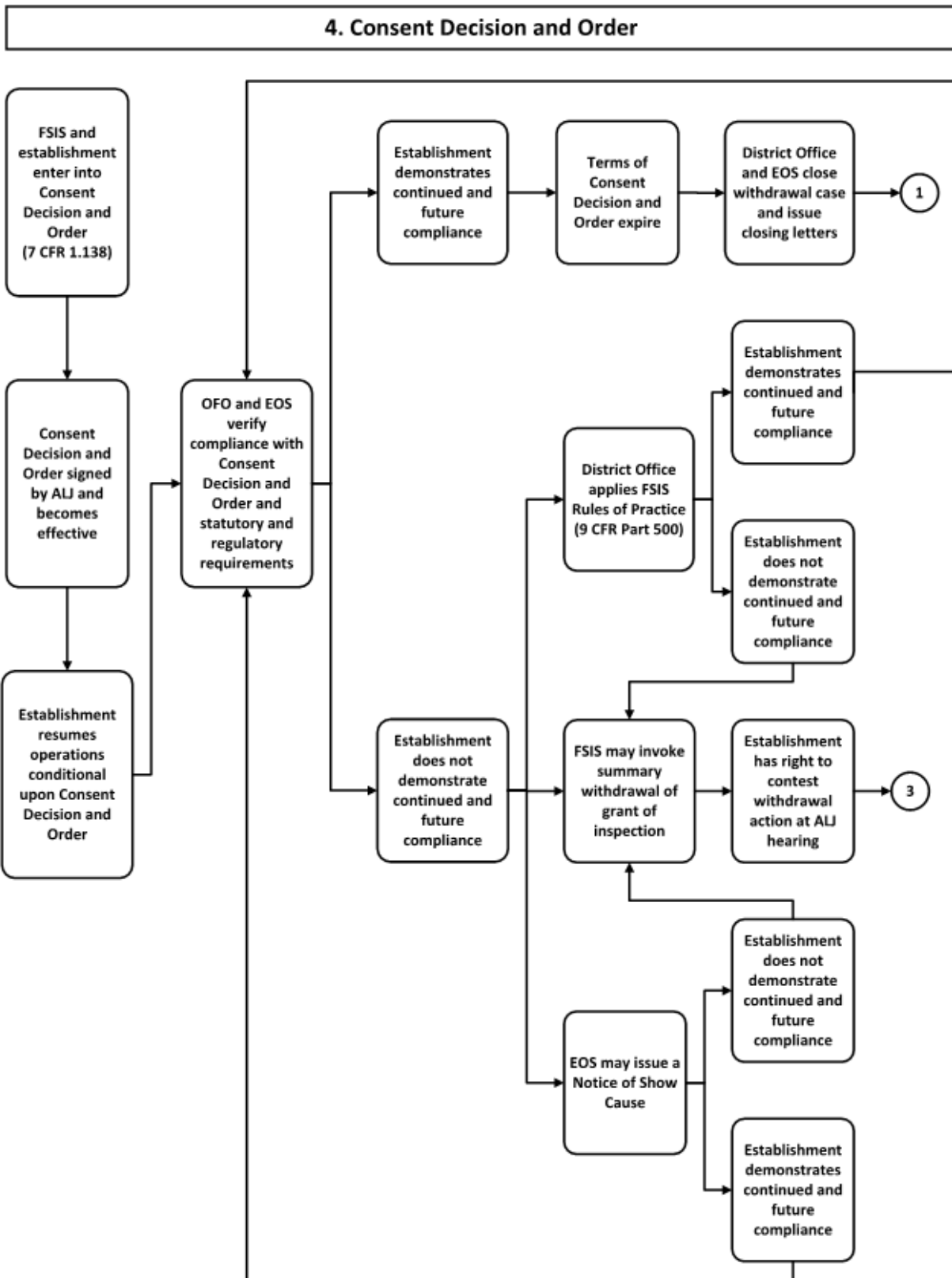


Figure 5



### A. Operations Resume

A Consent Decision becomes final and enforceable once it is signed by the parties and the ALJ. The effective date of the terms of the Consent Decision may vary depending upon the specifics of the agreement. Some Consent Decisions start upon signature of the ALJ. Other times, the terms apply from the date Federal inspection services resume at the establishment.

Once the Consent Decision comes into effect, it is the responsibility of the establishment to implement and maintain compliance with the terms of the Consent Decision as well as with FSIS statutes and regulations. Many Consent Decisions require a variety of actions by the establishment both before and after operations resume.

As part of the Consent Decision process, EOS and the OFO District Office are to meet with the establishment to review the terms of the Consent Decision, to outline expectations, to discuss verification of the Consent Decision terms, and to address any questions the establishment may have. This is generally referred to as a Consent Order meeting.

### B. Consent Order Verification

Throughout the length of the Consent Decision, EOS, OFO District Office personnel, and IPP are to verify the establishment's compliance with the terms of the Consent Decision. In addition, OFO personnel are to continue to verify the establishment's compliance with FSIS statutes and regulations, and, if needed, document noncompliance and/or initiate action under the FSIS Rules of Practice.

If there are violations or other compliance concerns identified during the length of the Consent Decision, OFO and EOS are to advise the establishment, and take necessary enforcement steps, generally, but not always, after first providing the establishment an opportunity to address the concerns.

### C. Summary Withdrawal

Consent Decisions typically include an enforcement provision known as the Summary Withdrawal. The Summary Withdrawal provision provides that FSIS has the right to summarily withdraw inspection services upon a determination by FSIS (typically, the Director of EOS, or his/her designee) that one or more conditions of the Consent Decision has been violated.

In situations where an establishment demonstrates continued noncompliance with the Consent Decision, with FSIS statutes and regulations, or the establishment's continued operations impact public health, FSIS may invoke the summary withdrawal provision contained in the Consent Decision.

Prior to invoking this provision, EOS may issue a SCL or other correspondence to the establishment to provide the establishment an opportunity to present its views as to why inspection should not be summarily withdrawn.

If FSIS determines summary withdrawal is warranted, the establishment retains the right to request an expedited hearing pursuant to the FSIS Rules of Practice, concerning any violation alleged as the basis for the withdrawal. However, inspection is withdrawn pending the hearing and a decision by the ALJ.



If summary withdrawal is not invoked, OFO and EOS are to continue to monitor the establishment's compliance with the Consent Decision and FSIS statutes and regulations.

#### D. Expiration of Consent Order

Should the establishment demonstrate compliance with the Consent Decision and FSIS statutes and regulations for the duration of the Consent Decision period, the Consent Decision will expire by the terms of the agreement. EOS and the OFO District Office are to then close the case and issue closing letters.

Thereafter, the District Office and IPP are to continue verifying the establishment's compliance with food safety regulations and other conditions of Federal inspection service as described in various FSIS Directives and the *In-Plant Verification and Enforcement* section above.