**VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS**
**FOOD SAFETY CONSUMER PROTECTION DIVISION**
**Meat Inspection Service**
**MONTPELIER, VT**
**Anson Tebbetts, Secretary**

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| # MIS DIRECTIVE<br>**Adopted from FSIS Directive 5100.3.1Rev.3** | 5100.3<br>Revision 3 | 2/16/17 |

## ADMINISTRATIVE ENFORCEMENT ACTION DECISION-MAKING AND METHODOLOGY

### CHAPTER I – GENERAL

### I. PURPOSE

A. The VT Agency of Agriculture (VAAFM) has statues and policies in place to ensure that all actions are supportable and properly documented. VAAFM has differing roles and responsibilities versus the defined roles in USDA FSIS.

The purpose of this directive is to explain the system and procedures used in the Meat Inspection Office for documenting and maintaining case files supporting administrative enforcement and other actions taken under the authority of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and VT State Statutes and regulations. The VT Meat inspection program maintains electronic case files on the VAAFM server.

### II. CANCELLATION

FSIS Directive 5100.3, Revision 2, *Administrative Enforcement Report (AER) System*, 10/18/11

## III. BACKGROUND

A. Sections 603 and 608 of the Federal Meat Inspection Act (FMIA) and Section 456 of the Poultry Products Inspection Act (PPIA) authorize the Secretary to require meat and poultry establishments to be maintained and operated in a sanitary manner to prevent adulterated products from entering commerce. The Humane Methods of Slaughter Act (HMSA) requires that humane methods are used for handling and slaughtering livestock.

B. 6 V.S.A. §1, §15, and §16 authorize the Secretary to institute appropriate proceedings in the name of the Agency in order to enforce any law or regulation administered by the Secretary and require the Agency to provide opportunity for fair hearing prior to assessing any proposed administrative penalty.

6 V.S.A. §§3304, 3305, 3307, and 3318 authorize the Secretary to adopt rules, conduct investigations and otherwise enforce the provisions of 6 V.S.A. Chapter 204 in law and equity, including enforcement of the licensing requirements of 6 V.S.A. §3306, the prohibited acts of 6 V.S.A. §3308-3310, and the detention of any livestock product under 6 V.S.A. §3314, when there is reason to believe the livestock product is adulterated or misbranded as those terms are defined in 6 V.S.A. §3302.

6 V.S.A. §1(a) (10) and 6 V.S.A. §3304 and 6 V.S.A. §3305 authorize the secretary to adopt, prescribe and enforce rules for the preparation of livestock, including the rules set forth in the federal meat inspection act and codified at 9 C.F.R. §§300.1 et seq.

B. When an official establishment is not meeting the provisions of the FMIA, PPIA, the HMSA (the Acts), 6 V.S.A. Chapter 201 or chapter 204, or the regulations promulgated under these Acts, personnel may carry out inquiries and investigations to support administrative enforcement. When the Agency decides to pursue an enforcement action under 9 CFR 500.3, *Withholding or suspension without prior notification*, it issues a Notice of Suspension (NOS) letter. When the DO decides to pursue an enforcement action under 9 CFR 500.4, *Withholding action or suspension with prior notification,* it issues a Notice of Intended Enforcement (NOIE) letter. In connection with these enforcement actions, VAAFM prepares a case file to include supporting documentation, and evidence collected to support the enforcement action.

C. As a case progresses, VAAFM updates the case file to include the new information that it gathers or generates. The information is maintained on the VAAFM server in a specific folder designated for each licensed state establishment.

D. EIAOs or Food safety specialists may provide the initial supporting documentation for an administrative case file. However, the VAAFM meat inspection chief or head of service is responsible for maintaining the file on the server. The Food Safety Consumer Protection Director and Agency Counsel are responsible for approving enforcement and other action.

## CHAPTER II – DECISION-MAKING AND ENFORCEMENT METHODOLOGY

### I. ENFORCEMENT ACTIONS

A. Enforcement recommendations can originate from inspection program personnel (IPP), EIAO, DVM, and other sources. Enforcement actions are taken in accordance with the ROP, 9 CFR 500 and 6 V.S.A. §1(a) (10) and 6 V.S.A. §3304 and 6 V.S.A. §3305.

B. Examples of situations when IPP recommend enforcement actions include when establishments have multiple, recurring noncompliances; implement ineffective corrective actions; receive multiple adulterant positive results from VAAFM testing; or ship adulterated product. An example of a situation when an enforcement action is recommended by the EIAO includes when the EIAO identifies that the establishment's HACCP system is inadequate. An example of a situation when an enforcement action is recommended by the DVM includes humane handling violations.

### II. FIELD PERSONNEL RESPONSIBILITIES

A. IPP are to contact their supervisor when noncompliance findings may warrant intended enforcement or enforcement.

B. IPP are to review enforcement or enforcement-related letters, including FSA findings.

C. IPP are to verify the implementation of the establishment's corrective actions and preventive measures as described in the verification plan.

D. IPP are to document findings of noncompliance in the PHIS from performing directed PHIS verification tasks and share the findings with their supervisor.

E. IPP are to maintain copies of enforcement letters, completed and active verification plans, and supporting documents in the government office.

F. The IPP are to document and share timely findings with the supervisor DO that may indicate the establishment is unable or unwilling to perform or implement the corrective actions and preventive measures.

### III. ENFORCEMENT, INVESTIGATIONS, AND ANALYSIS OFFICER (EIAO) RESPONSIBILITIES

A. Before scheduling or starting each food safety assessment (FSA), the EIAO is to evaluate and document the background findings of an establishment's food safety system in a Public Health Risk Evaluation (PHRE), as described in FSIS Directive 5100.4*, Enforcement, Investigations, and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology.*

B. The EIAO is to construct a regulatory rationale and make enforcement recommendations based on the PHRE or FSA findings or other investigations, as described in this directive.

C. The EIAO is to assist in the documentation and verification of activities that follow the enforcement action (Figure 1).

## IV. CHIEF OF INSPECTION

A. The Meat Inspection Chief or Head of Service plays a key role in developing the case strategy and in ensuring that the case file contains documentation that supports the enforcement or other action taken.
B. In addition to ensuring that the evidence that forms the basis for initiating the enforcement action has been included in the case file, they ensures that all relevant documents after the issuance of the NOIE or NOS letter are added to the case file. The relevant documents include the following:
1. Enforcement letters (e.g., NOIE, Notice of Suspension, Letter of Deferral, Letter of Warning) issued by the DO to propose, initiate, defer or put in abeyance, or close an enforcement action;

2. Letters and documentation submitted by the establishment or industry officials concerning the enforcement matter, such as responses to a NOIE or to a NOS letter;

3. Written plans or programs or excerpts from these documents, included as part of the establishment response to the enforcement action;

4. Correspondence between the office and the establishment during the life of the case; and

5. Verification reports from in-plant inspection personnel and EIAOs or other relevant records collected during a deferral or abeyance period.

C. The Meat Inspection Chief or Head of Service is responsible for issuing the enforcement letters, which should contain: a background summary of the facts supporting the enforcement action and the statutory and regulatory authority for proposing or taking the action, appropriate contact information, including the address and telephone number of the office, so that the establishment can contact and provide a written response in a timely manner, the appeal rights and hearing rights and to whom the appeal or hearing request should be directed.

D. As new information is gathered during the administrative process, this information is to be added to the case file. Attachment 1 provides guidance on what should be the first exhibit and the final exhibit in each type of case file. Additional guidance is also provided on the various types of documentation to be included as exhibits on the most common case file types.

E. The Chief, in consult with legal counsel, is to ensure cases are referred to the VT Attorneys General Office, as appropriate.

## V. DIVISION DIRECTOR OR DESIGNEE

A. The Director or designee is to sign enforcement letters, as appropriate, described in this directive.

## VI. DVM OR STATE VET RESPONSIBILITIES RELATED TO HUMANE HANDLING ENFORCEMENT

A. The state vet or designee (Vet) has a primary role in the evaluation, documentation, 6
and recommendation of enforcement action and preparation of verification plans when there is an inhumane handling incident or an action based on a history of humane handling violations by the establishment.

B. Based on information provided by IPP or, in some cases, first-hand observational knowledge, or the history of humane handling noncompliance by the establishment, the Vet makes recommendations on the appropriate enforcement action. The documented recommendation is to specify the regulatory requirements that have not been met and the relevant statutory authorities.

C. As the investigation and other administrative activities are being conducted, the Vet needs to confirm that the MOI provided by IPP with first-hand observational knowledge of the inhumane incidents clearly and fully provide all relevant information that supports taking the enforcement action. Additionally, all relevant communications concerning the inhumane incidents with or by supervisory personnel (e.g., Mini-IPPS Supervisory PHV) and establishment personnel need to be documented in a MOI. These documents are to be included as separate exhibits in the case to provide support for the enforcement actions described (e.g., Notice of Suspension or Notice of Intended Enforcement), and copies are to be provided to establishment management. In the case of a noncompliance history leading to the enforcement action, the Vet needs to provide the analysis of the trend in noncompliance of inhumane incidents and work with the Meat Inspection team on the enforcement strategy.

D. If any scientific or technical issues are raised that need further clarification, before making the enforcement recommendation, the Vet is to seek expert advice from professional channels The Vet also needs to ensure that he or she documents any guidance received and includes the documentation in the case file.

E. Given that the administrative enforcement process calls for enforcement to be initiated in a timely manner, the Vet is also expected to assist in drafting the NOIE and NOS letter or other documents, as needed, associated with the enforcement action.

F. When the FSCP Director decides to defer enforcement, or to hold a suspension in abeyance, because the establishment agrees to take corrective and preventive measures, the Vet is expected to assist in preparing the verification plan that will be used to ensure that the corrective and preventive measures proffered by the establishment are effective. The Vet also is to discuss the verification plan with the IPP to ensure that there is a clear understanding of the noncompliance issues and of the specific verification procedures IPP are to conduct to verify the effectiveness of the corrective and preventive measures provided by the establishment.

G. In addition, the Vet or PHV is expected to conduct periodic follow-up verification visits (e.g., at 30 day intervals) to the establishment during the deferral or abeyance period. During these visits, the Vet or PHV is to evaluate the data and information that has been generated by establishment personnel and the documented verification activities performed by in-plant IPP to determine whether the corrective and preventive measures that were proffered by the establishment have been effective. When a follow-7
up visit is performed by a PHV, theVet is expected to communicate with the PHV regarding any questions or issues that the PHV identifies during the visit where the Vet’s subject matter expertise may be needed. The Vet is to document all follow-up visits and to provide the

documentation to the case file.

H. The Vet is also expected to provide recommendations to the Meat Inspection office to help decide when an enforcement action should be closed, or if additional action is needed. An inhumane handling suspension action is not to be closed without one or more on-site visits by the Vet during the abeyance period.

I. The Vet is expected to follow the procedures in this directive pertaining to collecting evidence (e.g., copies of plant records or other records, photographs taken), and he or she is to ensure that the information is submitted to the case file.

## VII. STATUTORY AUTHORITY TO EXAMINE FACILITIES AND COPY RECORDS

A. The FMIA, PPIA, EPIA, and state statutes provide state personnel with the authority to examine facilities, inventory, and records at Federal establishments and at warehouses, distribution centers and other in-commerce facilities subject to those statutes (21 U.S.C. 460, 642, 1034, and 1040). FSIS regulations also provide access and examination authority (including 9 CFR 310.25, 320.4, 416, 417. 430.4, 590.200, and 590.220). These statutory and regulatory provisions also provide state personnel authority to copy certain business records.

E. At the entrance meeting before a Food Safety Assessment (FSA) or other investigation, EIAOs or other involved state personnel are to explain to the establishment management the statutory and regulatory authorities that allow them to access to examine and copy records during the course of their duties.

F. Employees are to use government-issued cameras or scanners to make needed copies in accordance with FSIS Directive 8010.3. Alternatively, in the event an establishment copy machine is available, they are to request that management provide a copy of any records needed or are to request permission to use the establishment's copy machine.

## VIII. SUPPORTING ENFORCEMENT ACTIONS AND CASE REFERRALS

A. The EIAO and Chief are to analyze the hazard analysis, supporting documentation, HACCP plan, Sanitation SOP, Sanitation Performance Standards (SPS), and prerequisite program findings to determine if an enforcement action is supported.

B. The rationale and factual basis for all enforcement actions and description of supporting documents for inclusion that would enable a person unfamiliar with the facts or with the establishment's processes, to understand the sequence of events that led to the noncompliance findings and the enforcement action. Enforcement actions should be based upon violations of the statutes and supported through descriptions of regulatory noncompliance. For example, a regulatory rationale may state:

1. “The establishment is preparing, packing, and holding product under insanitary conditions whereby it may become contaminated with filth, or whereby it may have been rendered injurious to human health,” or

2. The establishment is producing product that is adulterated, which has rendered the product injurious to health.”

C. The relevant adulteration provisions under 21 USC 601 (m) (1)-(4) of the FMIA or 21 USC 453 (g) (1)-(4) of the PPIA, humane handling and slaughter provisions of 7 U.S.C. 1901 *et seq.*, under the HMSA, and 6 V.S.A Chapter 201 and 204, as well as the findings that support the adulteration/humane handling violation determination and the impact from a public health perspective. Violations to statutory and regulatory requirements should be linked(e.g., the Acts, 9 CFR 6 V.S.A).

D. If the establishment implements corrective and preventive measures during the course of the FSA, investigation, or incident, this action does not negate the recommendation to issue an enforcement action. These deficiencies represent the findings of the FSA, investigation, or incident and it typically requires time for the establishment and VAAFM to verify the effectiveness of corrective actions and preventive measures.

E. If the EIAO or DCS find noncompliance that would warrant an intended enforcement or a suspension recommendation, but there is no information that would suggest that multiple or recurring noncompliances have occurred, the EIAO or DCS is to explain how the findings establish a basis for concern about the safety of product being produced and why these findings support the recommended enforcement action.

F. Noncompliance Records (NRs) are not to be mentioned that are not used to support the regulatory rationale or how the conditions have resulted in adulterated product or the creation of insanitary conditions that may cause product to be adulterated in the NOIE, NOS, or Notice of Reinstatement of Suspension (NROS) letter. IPP are to issue these NRs separately as described in FSIS Directive 5100.1.

G. VAAFM is to seek expert advice when information related to policy, technical or scientific issues is needed before documenting findings or making an enforcement recommendation.

H. When appropriate, the case is to be referred to compliance or the State’s AG’s Office.

## IX. VERIFICATION PLAN DESIGN AND EXECUTION

A. The verification plan is a tool designed to verify the effectiveness of the establishment’s proposed corrective actions and preventive measures that were proffered and led to the decision to defer enforcement or hold a suspension in abeyance. A verification plan is designed to provide detailed instructions to IPP, the EIAO, and the DVM for verifying the establishment’s proposed corrective actions and preventive measures (Figure 2). Verification plan results are to be recorded in PHIS.

B. Do the establishment’s proposed corrective actions and preventive measures that were proffered contain the following elements:

1. Procedures or assessment methods the establishment will use to address the cause of the regulatory noncompliance;

2. Specific actions the establishment will use to eliminate and prevent the cause of the regulatory noncompliance;

3. Monitoring activities the establishment will use to ensure that changes are implemented and effective to address the regulatory noncompliance; and

4. Scientific support the establishment provides, for new or modified interventions or processes used to support decisions in the hazard analysis, to support that corrective actions and preventive measures are effective. The scientific support should identify the critical operating parameters necessary for the intervention or process to function as intended and the establishment's current processes should incorporate those parameters as required in 9 CFR 417.4.

C. After determining that the establishment's proposed corrective actions and preventive measures contain the elements described in B. above, the a verification plan is to be developed and determine whether to issue a deferral or abeyance letter.

D. Describe the Agency's verification responsibilities in a verification plan that covers a minimum of 90 calendar days when an enforcement action has been deferred or held in abeyance.

E. Analyze the establishment's previous enforcement history to ensure that the current proffered corrective actions and preventive measures are substantially different and meaningful.

F. The bi-weekly verification plan, at a minimum, is to include:

1. The background that led to an enforcement action and deferral or abeyance of that action;

2. The organized list of the establishment's proposed corrective actions and preventive measures;

3. The documents, processes, products or programs that are required to be verified;

4. The frequency of the verification in 3 above;

5. The directed PHIS task associated with each verification activity in 3 above;

6. Free text space to record additional information as needed;

7. A statement to inform the establishment that VAAFM is to be informed of any changes to corrective actions and preventive measures during the verification period. For example, if an establishment decides to buy an additional piece of equipment or implement an additional monitoring activity after the implementation of the verification plan, VAAFM is to be informed of these changes and the

verification plan is to be revised before the establishment implements the changes; and

8. The IIC is to ensure scheduling of the corresponding directed tasks in PHIS for the verification tasks and frequencies listed in the verification plan. IPP are to use the justification "*Verification Plan for Enforcement Actions*" to justify the scheduling of the directed task.

G. During the 30-, 60-, and 90-day visits, the EIAO is to review the PHIS report for verification activity results (e.g. Task Summary and List for an establishment) and assess whether corrective actions are effective and make recommendations and add any additional information as appropriate.

## CHAPTER III – ENFORCEMENT ACTIONS AND LETTERS

### I. THE RULES OF PRACTICE (ROP)

A. The ROP; 9 CFR 500 regulations identify the conditions under which the Agency can take enforcement actions and include the criteria for when those actions are warranted. These regulations were issued to ensure that all establishments are afforded due process.

B. 9 CFR 500.3, *Withholding action or suspension without prior notification*, gives FSIS the authority to take a withholding action or impose a suspension without providing the establishment prior notification (an NOIE).

C. 9 CFR 500.4, *Withholding action or suspension with prior notification*, gives FSIS the authority to take a withholding action or suspension with prior notification.

D. 9 CFR 500.6 and 9 CFR 500.7, respectively, gives the FSIS Administrator the authority to file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H and to refuse to grant Federal inspection to an applicant.

### II. BASIC STRUCTURE AND COMPONENTS OF ENFORCEMENT LETTERS

A. The information in enforcement letters is to explain the findings in a manner that encompasses all defining aspects of the alleged violation in chronological order (earlier to most recent).

B. The findings should link the alleged violations to statutory and regulatory requirements and that enforcement letters describe who is involved, what happened, when it occurred, where noncompliance was found in the establishment's food safety system, and why the Agency is taking action. Ensure the findings that support the adulteration determination and a description of the public health impact is included.

C. The enforcement letter should describe the facts in a manner that makes clear any past noncompliance and how previous noncompliance relates to present noncompliance. When applicable, the describe whether the establishment's previously proposed corrective actions and preventive measures were ineffective to address the noncompliance.

D. Suspension letters (NOV, NOS, NROS) contain hearing rights as defined under 9 CFR 500.5(d), 6 V.S.A. §16, 3 V.S.A. Chapter 25. Inform the establishment in the enforcement letter that it may request a hearing pursuant to the request a hearing, and that it will be conducted under Vermont's Administrative Procedure Act.

**NOTE:** Use the third person when writing enforcement letters and EIAOs are to use first person when writing FSA and PHRE reports.

E. Promptly deliver enforcement letters to the establishment after finalization. Methods to deliver enforcement letters include e-mail delivery of a scanned, signed PDF file; hand delivery of a hardcopy by VAAFM personnel or overnight delivery of a hardcopy by a carrier. A means to ensure Delivery confirmation should accompany any delivery method.

### III. NOTICE OF INTENDED ENFORCEMENT LETTER

A. Document an intended enforcement action in a Notice of Intended Enforcement (NOIE) letter. An intended enforcement action, as described in 9 CFR 500.4, provides an establishment with prior notification that VAAFM may take a withholding action or impose a suspension of the assignment of

inspectors at the establishment and provides the establishment opportunity to present its views and demonstrate or achieve compliance.

B. Ensure the NOIE letter includes all information as required by 9 CFR 500.5(b), including:

1. VAAFM's authority under the Acts and Statutes;

2. An explanation of the findings and basis for action in a chronological order of events;

3. Findings linked to the statutes (e.g., the Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. The expected format for the establishment's response and a three (3) business day timeframe for the establishment to respond to the DO; and

7. The VAAFM contact information.

## IV. LETTER OF DEFERRAL

A. Issue a Letter of Deferral (LOD) after it decides to defer the decision to take an enforcement action and allow the establishment the opportunity to implement the proposed corrective actions and preventive measures. Ensure the issuance of the LOD is accompanied by a verification plan.

B. During deferral, the Chief is to review any changes to the establishment's corrective actions and preventive measures and ensure that the VAAFM concurs prior to implementation of the changes. After concurrence with changes to the establishment's corrective actions and preventive measures, update the verification plan accordingly.

C. A LOD is to contain:

1. A brief explanation of the findings and basis for action that led to issue the NOIE, including the dates of issuance of the NOIE letter;

2. The establishment's processes or products that are affected by the NOIE action;

3. Findings from the review and acceptance of the establishment's proposed corrective actions and preventive measures;

4. contact information; and

5. Reminder that VAAFM has the authority to take a suspension or withholding action if the establishment fails to implement its proposed corrective actions and preventive measures or if the corrective actions and preventive measures are not effective.

D. Take further enforcement action, such as suspension of the assignment of inspectors, in accordance with 9 CFR Part 500, if the establishment is unable or unwilling to perform or implement the corrective actions and preventive measures.

## V. NOTICE OF SUSPENSION LETTER

A. 9 CFR 500.3, outlines conditions under which FSIS may take a withholding action or impose a suspension of the assignment of inspectors at the establishment without prior notification.

B. A suspension may be issued to an establishment following a NOIE letter because the establishment failed to provide corrective actions and preventive measures or those corrective actions and preventive measures were ineffective. Personnel are to document a suspension in a Notice of Suspension (NOS) letter that provides the establishment with an explanation of the findings that led to the decision to take enforcement action.

C. A NOS letter is to include all information as required by 9 CFR 500.5(a), including:

1. authority under the Acts;

2. An explanation of the findings and basis for action in a chronological order of events;

3. Findings linked to the statutes (The Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. Expected format for the establishment's response;

7. contact information; and

8. Appeal rights and hearing rights.

## VI. NOTICE OF REINSTATEMENT OF SUSPENSION

A. A suspension may be reinstated during the abeyance period. Document a reinstatement of suspension in a Notice of Reinstatement of Suspension (NROS) letter that provides the establishment with an explanation of the findings that led to the District's decision to reinstate the suspension.

B. 9 CFR 500 outlines the conditions under which FSIS may impose a reinstatement of suspension. VAAFM may reinstate a withholding action or reinstate a suspension without or with prior notification.

C. A NROS letter is to include all information required by 9 CFR 500.5(a), including:

1. FSIS's authority under the Acts;

2. An explanation of the findings and basis for action in a chronological order of events, including the findings from the previous suspension action;

3. Findings linked to the statutes (e.g., the Acts) and regulatory requirements (9 CFR) and a description of how the findings relate to the establishment's ability to produce safe, wholesome, and unadulterated products, including the impact on public health;

4. The establishment's previous enforcement history, including the previous suspension action, and how the history relates to the effectiveness of the establishment's food safety system;

5. The establishment's processes or products that are affected by the action;

6. Expected format for the establishment's response;

7. contact information; and

8. Appeal rights and hearing rights.

## VII. NOTICE OF SUSPENSION HELD IN ABEYANCE AND NOTICE OF REINSTATEMENT OF SUSPENSION HELD IN ABEYANCE

A. Issue a Notice of Suspension Held in Abeyance (NOSA) or Notice of Reinstatement of Suspension Held in Abeyance (NROSA), after the establishment responds with acceptable corrective actions and preventive measures, to permit the establishment the opportunity to implement the proposed corrective actions and preventive measures. Issuance of the NOSA/NROSA is also to be accompanied by a verification plan.

B. A NOSA/NROSA letter is to contain:

1. A brief explanation of the findings and basis for action that led to issue the NOSA or NROSA including the dates of issuance of the enforcement letter;

2. The establishment's processes or products that are affected by the enforcement action;

3. The findings from the review and acceptance of the establishment's proposed corrective actions and preventive measures;

4. The contact information; and

5. A reminder that VAAFM has the authority to reinstate the suspension or withholding action if the establishment fails to implement its proposed corrective actions and preventive measures or if the corrective actions and preventive measures are not effective.

## VIII. RECALLS AND RECALL EFFECTIVENESS CHECKS

A. Exhibits for recall case files may include, but are not limited to, recall worksheets, Memorandum of Information (MOI), decision memorandums, laboratory reports, consumer complaints, list of consignees, company press release, USDA press release, recall notification report, VT Form 8400-4, *Report of Recall Effectiveness*.

B. Refer to FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, and FSIS Directive 5100.2, *Enforcement, Investigations, and Analysis Officer (EIAO) Responsibilities Related to Recalls and Consumer Complaints,* for additional information regarding recalls and recall case file documentation.

## IV. PROHIBITED ACTIVITIES

A. Prohibited activities case files are to be created within 48 hours of issuance of the prohibited activities letter to the establishment.

B. For prohibited activities (e.g., adulterated product deliberately distributed into commerce), the exhibits may include:

1. MOI with responsible officials;
2. Photographic evidence;
3. decision memorandum;
4. Information of how the product was shipped or received; and
5. Copy of the prohibited activities letter issued to the establishment.

## V. TRACEBACK

A. Traceback case files are to be created promptly.

B. The exhibits may include:

1. Positive sample results from FSIS or another Federal or State agency's testing of ground beef or bench trim;
2. Supplier and source material information collected by IPP at the time of sample collection;
3. Evidence that shows product is in commerce;
4. Any pertinent PHIS reports or data;
5. Report documenting traceback investigation that includes a written analysis of findings and any additional recommendations for action (FSIS Directive 10,010.3, *Traceback Methodology for* Escherichia coli *(*E. coli*) O157:H7 in Raw Ground Beef Products and Bench Trim*).

## VI. STANDARD RETENTION OF REPORTS IN ANET

A. Retention of records should follow the statutory requirements of Vermont.

## QUESTIONS

Refer questions regarding this directive to the office at 802-828-2426.

Katherine M. McNamara DVM

Head of Service
VT Meat Inspection Service