

## **Enforcement: Follow Rules of Practice**

When a noncompliance determination is made, it may be necessary to take an **enforcement action** to prevent adulterated product from being produced and shipped. In accordance with the rules of practice, this enforcement action could be one of three types.

1. 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.
2. 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.
3. A “**suspension**,” is an interruption in the assignment of program employees to all or part of an establishment.

### **Regulatory Control Actions**

Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product. Examples of common regulatory control actions related to slaughter would be line stoppage, or carcass retention as a result of a zero tolerance finding.

***Regulatory Control Action Example 1:** You are performing beef carcass inspection procedures at the postmortem rail inspection station and you notice a fecal smear on the side of a carcass. The plant does not have an approved rail-out procedure, so you stop the production line and notify establishment personnel, who then proceed to trim the carcass.*

***Regulatory Control Action Example 2:** You are performing the 03B01 procedure at a fresh pork sausage operation, and have selected the monitoring requirement to verify. The HACCP plan states that product temperatures will be taken by QC personnel hourly and recorded. You take a product temperature measurement, which is not within the critical limits for this CCP. You review the monitoring record for this CCP and compare your result to the plant's most recently recorded check, which was also not within critical limits. You investigate further and see no evidence of action being taken to address this deviation. You see that no supervisors are present. You decide to notify the plant manager but are told, "All managers are in a big HACCP meeting at another location." You return to the production room and observe that production continues to operate. You decide to take regulatory control action, and put a retain tag on all available product. Employees stop production.*

### **Withholding Action Without Prior Notice**

There may be instances when it is necessary for you to take immediate enforcement actions to prevent imminent threat to public health, without giving the establishment prior notice. For example, if the establishment produced and shipped adulterated product, you would need to take an immediate withholding action. In these situations, first take the immediate withholding action, and then as soon as possible notify the District Office. For

further information, refer to the Rules of Practice module.

**Immediate Withholding Action Example:** *You are performing your regular duties when you become aware that a deviation from a critical limit took place yesterday afternoon, after you left the establishment for another plant on your patrol. A main refrigeration unit malfunctioned, and product was out of the critical limit for temperature for two monitoring checks. You decide to verify that all parts of corrective action have taken place, and ask for the corrective action log. You observe that the establishment documented that it identified and eliminated the cause, the CCP was brought under control, and that measures were implemented to prevent recurrence. However, you can find no evidence that the establishment identified or segregated any product affected by the deviation. You ask for any documentation that the safety of the product was verified, but nothing is provided. You verify that pre-shipment review was completed, and that all product produced has left the control of the establishment. You determine that the establishment produced and shipped adulterated or misbranded product. You notify the establishment that the marks of inspection are being withheld pending further instructions from your District Manager. You immediately page your supervisor and call the DO.*

### **Notify the District Office**

If you determine that an inadequate system may exist, you should notify the District Office. Provide the DO all of the information about the situation. You should request that a Notice of Intended Enforcement be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign a CSO to evaluate the establishment's HACCP system.

### **District Office Determines Enforcement Action**

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the rules of practice.

### **Withholding and Suspension Actions With Prior Notification**

Keep in mind that some withholding and suspension actions require prior notification according to the rules of practice. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is found inadequate due to **multiple or recurring noncompliances**. Withholding or suspending inspection for this cause does require prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

**Enforcement Action Example:** *On February 12, you issue an NR when you observe that the establishment did not conduct the monitoring procedures as specified in the HACCP plan. Instead of taking two temperatures of incoming product per load as the HACCP plan states, the establishment took one. On February 20, you document that the same monitoring personnel again took one incoming product temperature instead of two as specified in the plan, and on this NR you document that this noncompliance is linked to the one on February 12. Similar NRs are written on March 4 and 18. On each, you document the linkage that further planned actions are not effective or not*

*implemented, and discuss the NRs and the developing trend with plant management at the weekly meeting. On March 18, after providing the NR to plant management, you decide that documentation on NR's demonstrates that further enforcement actions are necessary to bring the establishment into regulatory compliance. You call the DO. You explain that repetitive NRs indicate a need to take further enforcement actions and request that a Notice of Intended Enforcement Action be issued to the establishment. The DO issues an NOIE to the establishment the next day.*