

Enforcement – Follow Rules of Practice

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.

Regulatory Control Action Example: You are performing the 03F01 procedure at a large snack stick establishment, and have selected the monitoring requirement to verify. The HACCP plan for the lethality CCP 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 look at the establishment's lethality log, and you observe that the most recent monitoring result was also not within critical limits. You observe no evidence that corrective action is being taken. You observe that there are no establishment supervisors in the area to notify about your findings. You take a regulatory control action, and put a retain tag on all available product in the area. Employees begin to 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 reviewing records at a canning establishment which produces a variety of chili products in glass jars. You observe that the establishment has noted in the records that the canning process was reassessed about two weeks ago because of a change of ingredients vendor. You see a note that a new type of starch was substituted for the previous thickening agent. You ask whether the processing authority evaluated the process for potential changes needed in the process schedule. You are told "no, the vender explained that this starch worked BETTER so we determined that the process authority did not need to evaluate the new formula." You review processing records and realize that the product being released for distribution today is the first product made with the new starch. You proceed to the shipping area and determine that the product is being loaded onto trucks. You verify that pre-shipment review was completed, and that some of the product produced has already left the control of the establishment. You cannot determine at this point whether the establishment has produced and shipped

adulterated product. You gather shipping information and any other details (product ID, amount, destination, etc.) you will need to communicate this situation to the District Office. You page your supervisor and call the DO. After discussion with District personnel, you notify the establishment that the marks of inspection are being withheld pending further instructions from your District Manager.

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 Action be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign an EIAO 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: You are a relief inspector and have been assigned to an establishment which produces several types of jerky. The lethality CCP for the jerky HACCP plan lists critical limits of a time and temperature combination of 141°F for 12 minutes, and the percent relative humidity maintained at 90 percent or higher throughout cooking until the lethality is reached. Your procedure schedule includes an 03F01 and you randomly select to verify recordkeeping. You review recent lethality records and observe that for one lot produced today, only time and temperature are recorded, not humidity. You ask the establishment whether it can support the safety of the product produced. The establishment cannot produce any record demonstrating that humidity was maintained as per the HACCP plan. You verify that the establishment is maintaining a hold on the affected product. You review recent NRs and find that there were two NRs written last week for the same reason, and that the regularly assigned inspector has documented the developing trend by

linking the two previous NRs. You issue an NR for not conducting monitoring procedures as specified in the HACCP plan. You add appropriate documentation to the NR to link this noncompliance to the previous one. When you provide the NR to the establishment, you explain that documentation on NRs demonstrates that further enforcement actions may be necessary to bring the establishment into regulatory compliance. You contact the District Office to 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. After gathering evidence that the establishment cannot demonstrate that its process does not produce adulterated product, the DO advises you to take an immediate withholding action. The DO issues an NOIE to the establishment the next day.