



United States
Department of
Agriculture

Food Safety
and Inspection
Service

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20250

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To: District Managers
Deputy District Managers

From: Dr. Kenneth E. Petersen
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Subject: Clarification on In-Plant Validation Requirements

This is to follow up on some issues that have been discussed over the past few months, concerning in-plant validation requirements for plants that are currently operating under a grant of inspection as well as for those operating under a conditional grant of inspection. The purpose of this message is to ensure we are all clear on the current Agency approach to enforcement of the regulatory requirements outlined in 9 CFR 417.4 (a) (1).

OPPD intends to issue guidance to establishments, so that they are aware of available means to demonstrate that their CCPs and interventions are achieving the anticipated effect under actual in-plant conditions. OPPD also intends to issue a *Federal Register* notice to explain validation requirements under the regulations and to provide a deadline for establishments to comply with the requirements as they apply to in-plant conditions. Finally, OPPD intends to issue instructions to the field on how to verify that establishments have adequate in-plant validation data.

As you know, validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe unadulterated product. There are two distinct elements to validation: 1) the scientific or technical support for the HACCP system and 2) the initial practical in-plant demonstration proving the HACCP system can perform as expected. The establishment has to provide scientific or technical support for the CCP's and critical limits it has established and/or interventions or processes it uses as support for its HACCP system decisions. According to 9 CFR 417.4 (a) (1), it must also test its system to make sure these controls, interventions, or processes achieve the expected results in the plant's own setting, with its own employees and equipment.

Until the Agency issues the *Federal Register* Notice and related documents referred to above, OFO will defer writing NR's or basing enforcement actions solely on the lack of the in-plant validation. We will, however, issue NR's if the scientific or technical support is lacking or inadequate, which includes that the plant is not following the parameters of the study or documentation it has identified as its support for the CCP, intervention or process. We will issue an NOIE if taken together with other relevant findings, the scientific and technical

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support is lacking and we can support a determination that the system may be inadequate. If an EIAO conducting an FSA finds that the scientific support is adequate, but the in-plant validation is lacking, he/she should note this in the FSA, but should not instruct that an NR be written nor should an enforcement action be taken if this is the only finding.

With regard to plants operating under conditional grants of inspection, the same approach holds true. Before they are issued the permanent grant, they must have in place their scientific and technical support for their system's controls, and they must be meeting the parameters of the scientific or technical documentation on which they are relying. However, the grant will not be held up because they have not completed the in-plant validation – a repeated test of their controls to show that they achieves the result they are designed to achieve, in their operation. These plants will be expected to complete the in-plant validation in accordance with the upcoming Agency guidance, when issued, along with all other plants.

Also, please note that we are not in support of a routine requirement for an FSA being completed prior to a permanent grant being issued. Unless there is a “for cause” reason to conduct an FSA at one of these new plants in their first year of operation, we would expect them to fall into the 4-year cycle we will start this summer.

cc:

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