Obtaining Regulatory Waivers

FSIS knows there is scientific information that indicates that alternative parameters to regulations on time and temperature (9 CFR 381.66) and on off-line reprocessing (9CFR 381.91) also achieve the food safety objectives that FSIS is pursuing. To allow for new scientific findings, FSIS is allowing waivers of these two regulations in exchange for establishments to gather sufficient data to support changing the regulations through the Salmonella Initiative Program (SIP). Other existing waivers, such as HACCP-Based Inspection Models Project (HIMP), will also be included in the upcoming regulatory changes. The SIP basically requires daily Salmonella sampling by the establishment to determine they are maintaining process control and sharing data with FSIS.

Time and Temperature (9 CFR 381.66) Waiver:
If an establishment is considering alternative temperatures or times, it can request a waiver of the regulation. To obtain a waiver: submit a request to isabel.arrington@fsis.usda.gov the request should include the regulation to waive, the scientific basis for changing the regulation parameters, the alternative procedures the establishment will use in lieu of the waived regulation, planned in plant validation of the procedures and agreement to participate in the SIP.

Off-line Reprocessing (9 CFR 381.91) Waiver:
If an establishment is considering alternative reprocessing procedures such as online-reprocessing they may or may not need a waiver based on the location of the contamination. If carcasses are contaminated externally and not internally during evisceration, then the establishment does not require a waiver to use the antimicrobial. If the contamination (digestive tract contents) is inside the carcasses that are not condemned but remain on the evisceration line and not proceed to off-line reprocessing site, then the establishment will need a waiver of the regulation 381.91, to run On-Line Reprocessing (OLR). Antimicrobials used in OLR need to be on the list of Safe and Suitable ingredients found in FSIS Directive 7120.1, (latest amendment) “Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products”. If you have questions about the list contact Patrick.Burke@fsis.usda.gov.

To obtain a waiver: submit a request to isabel.arrington@fsis.usda.gov. The request should include the regulation to waive, the alternative procedures the establishment will use in lieu of the waived regulation, planned in plant validation of the procedures and agreement to enter the Salmonella Initiative Program (SIP). The details of this program can be obtained by contacting isabel.arrington@fsis.usda.gov or 1-800-233-3935

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