

GUIDANCE ON REQUESTING A WAIVER OF FOOD SAFETY AND INSPECTION SERVICE REGULATORY REQUIREMENTS FOR THE USE OF NEW TECHNOLOGY

I. Purpose

This *Guidance on Requesting a Waiver of Food Safety and Inspection Service (FSIS) Regulatory Requirements* informs meat and poultry establishments, egg product plants, companies that manufacture and sell technology to official establishments, and other interested persons of the procedure for obtaining a regulatory waiver for a limited period of time to test their new technology.

II. Background

FSIS has established flexible procedures to foster the development and use of new technologies in meat, poultry, and egg product establishments. Under these procedures, official establishments notify FSIS in writing of their intention to use a new technology. If the intended use of the new technology could affect any of four areas that are of interest to FSIS, specifically, if the new technology 1) affects product safety, 2) jeopardizes the safety of Federal inspection program personnel, 3) interferes with inspection procedures, or 4) requires a change in the Agency's regulations, then the establishment or company will need to submit to the Agency a protocol requesting an in-plant trial to gather data on the effects of use of the new technology.

When use of the new technology would not be possible without a change in the Agency's regulations, the submitter needs to request a waiver and obtain from FSIS a letter waiving provisions of the regulations for a limited period of time. FSIS regulations 9 CFR § 303.1 (h), §381.3 (b) and §590.10 allow meat, poultry, and egg product regulatory requirements to be waived for a limited period of time to permit experimentation.

The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. However, under these regulations, a waiver cannot be granted if the Administrator determines that a waiver would conflict with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031, et seq.).

III. Regulation Waiver

When the in-plant trial requires a waiver of any provision of FSIS' regulations, an establishment official or a representative of the company that intends to conduct

the trial needs to submit to the Risk & Innovations Management Division (RIMD) a written request for a waiver with data that demonstrate that the in-plant trial is scientifically sound; that the new procedure, equipment, or processing technique will facilitate definite improvements; or that there is a public health emergency; and that issuing the waiver will not conflict with the provisions of the relevant Act. Data that would justify a waiver would include: 1) validated laboratory results; 2) peer-reviewed journal articles; or 3) prototype production results.

When the RIMD completes its review, if it determines that the submitted data support the waiver, and that issuing the waiver will not conflict with the provisions of the Acts, the Administrator may issue a letter waiving provisions of the regulations for a limited period of time for the in-plant trial. The in-plant trial may not begin until the submitter has received the letter. If the waiver is granted, FSIS will review the data that is developed in the trial to determine whether they establish that the purpose of the waiver is being met.

For assistance in writing a protocol and waiver request, interested persons are advised to access following references from Federal Register Notice (00-011N), 68 FR 6073, February 11, 2003, "FSIS Procedures for Notification of New Technology" and revised document "Guidance Procedures for Notification and Protocol Submission of New Technology", by visiting the FSIS, New Technologies Website at:

<http://www.fsis.usda.gov/OPPDE/op/technology/guidance.pdf>

http://www.fsis.usda.gov/Regulations_&Policies/NewTechnologies/index.asp#NewTechnologyProcedures

Comments and questions regarding New Technologies should be directed to RIMD.

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