

Regulatory Shift to Performance Standards-"Layering"

I. Objective of Proposal

The goal of the Pathogen Reduction/HACCP Proposed rule is to adopt and implement an integrated, HACCP-based inspection system that clarifies and maintains a distinction between industry and FSIS responsibilities, targets the most significant hazards, and fosters flexibility, innovation and accountability for improving food safety. However, FSIS recognizes that to achieve this goal, it must also eliminate unnecessary and redundant regulations.

II. Description of Comments

Some commenters argued that the proposed pathogen reduction and HACCP requirements layer an additional set of regulations, and subsequently an additional program of inspection, on the current meat and poultry inspection regulations and inspection activity. Some commenters recommended that, prior to publishing the final rule, FSIS review and revise or eliminate current regulations, directives, and other FSIS guidances so that they are compatible with the proposed pathogen reduction/HACCP requirements.

Some commenters cautioned FSIS not to alter or eliminate current regulatory requirements and inspection procedures until more effective ones are operating in their place.

III. Issues Raised by Comments

FSIS recognizes the need to articulate how regulatory requirements and inspectors' roles would change under the regulatory system that would emerge from the proposed regulatory reforms. Key issues of concern raised by the comments include:

- HACCP clarifies the mutually exclusive roles of industry and Government and, along with responsibility, affords individual plants the flexibility to innovate and make site-specific decisions. The current inspection system makes the inspector responsible for "approving" production-associated decisions. How will inspection change under HACCP?
- Under what circumstances will FSIS continue to issue command-and-control-type requirements?
- How should the regulatory system be changed, and at what pace, to eliminate redundant and obsolete requirements, such as prior approval systems and command-and-control requirements?

- Has FSIS identified the regulations that need to be eliminated or changed to be compatible with HACCP? Given that the current inspection system is embedded in current regulations, the essential changes are likely to be extensive. Can all necessary changes be adopted prior to HACCP implementation?
- Will inspectors' roles change as a result of the shift from step-by-step, command-and-control requirements to performance standards? How? How will the transition to the new regulatory system--with plants accountable for meeting FSIS's requirements by methods not necessarily listed in the regulations or inspectional guidelines--be managed?
- What methods of dispute settlement should be available to handle the more complex decisions that need to be made about compliance with regulations under HACCP?

IV.FSIS' Current Thinking about Changes Needed to Address These Issues

Under the proposal in conjunction with the regulatory reforms now in progress, industry would assume full responsibility for production decisions and execution, and FSIS, having set food safety standards and public health objectives, would monitor and enforce plants' compliance with those standards and related requirements and, under HACCP, would verify process control. This would appear to imply the following:

- FSIS must review and revise or eliminate current regulations, directives, and other FSIS guidances to ensure their compatibility with HACCP requirements and the regulatory philosophy HACCP represents (see attachment).
- Performance standards could be used to eliminate certain command-and-control requirements.
- With the distinct roles and responsibilities of FSIS and industry clearly defined, FSIS would be able to relieve inspectors of many tasks that should be performed by establishments, enabling inspectors to focus on, HACCP-related oversight tasks.
- In-plant inspection would have to be managed so that the skills necessary to evaluate the plant's performance under HACCP would be available in every plant.
- Lines of FSIS supervision and decision making would need to be shortened, clarified, and publicized, particularly with respect to fair, prompt, and effective dispute resolution.
- Unnecessary and redundant regulations would need to be eliminated.