

Sanitation Standard Operating Procedures (SOPs)

I. Objective of Proposal

The objectives of the sanitation standard operating procedures (SOP) provisions clarify that plant management is responsible for daily maintenance of good sanitation and to focus both plant management and FSIS inspectors on sanitation issues that relate to the possibility of direct product contamination.

II. Description of Comments

Commenters generally supported the proposed sanitation SOP requirements. Some commenters noted that proper sanitation is a prerequisite to improving consumer confidence in food, reducing the risk of harmful contamination and successfully implementing HACCP.

Some commenters expressed concerns about the lack of specificity in the proposal regarding the requirements of a written SOP. Commenters had questions on the following topics: the role of inspectors in SOP development and approval; who would conduct preoperational sanitation inspections - the establishment or inspector; how inspectors would document "deficiencies" and what actions would be taken; the relationship between sanitation SOPs and HACCP plans; and whether additional requirements will be proposed. To address these questions, some commenters requested that FSIS provide guidelines and other types of technical assistance, and that FSIS provide a more detailed explanation of respective roles and responsibilities.

Some commenters objected to some of the example cited in the proposed procedures that might be incorporated in a sanitation SOP on the grounds they would be impractical to institute in current slaughter operations (e.g., hand washing between each carcass skinning and evisceration, and washing livestock prior to slaughter).

Some commenters who supported the shift of responsibility for sanitation from the inspector to the plant expressed concern about how the SOPs would be enforced and urged that FSIS mandate microbial testing of equipment and certain other critical sanitation measures.

III. FSIS' Current Thinking on Issues Raised by Comments

FSIS agrees that it must provide guidelines for what the SOP should contain. It does not expect SOPs to track all the requirements related to sanitation in the current regulations. It does expect that the guidelines would be similar to good

manufacturing practices (GMPs) in that they would reflect currently accepted good sanitation procedures, and that they would focus on the daily sanitation tasks the plant must undertake to prevent the occurrence of insanitary conditions, both at the time of start-up and during operation, that could result in direct product contamination. FSIS does not intend to prescribe a format for the SOP or SOP records; however, it will provide guidelines, as noted above.

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FSIS considered, before it proposed SOPs, the alternative of dealing with sanitation through HACCP plans. The agency believes it may be appropriate, once a plant establishes a HACCP plan, to monitor and verify some sanitation areas under the critical control points (CCPs) included in a plant's HACCP plan. Those sanitation areas that are not appropriate to monitor under CCPs of a HACCP plan would continue to be monitored in the SOP. Thus, FSIS would expect SOPs to continue on a parallel basis with HACCP plans after HACCP implementation. However, FSIS does not expect duplicate monitoring by the plant under both systems.

Given that most sanitation areas would not be included in HACCP plans, FSIS has not identified, nor have the comments produced, any alternatives to the proposed SOPs that are as effective in clarifying industry / government responsibilities and that permit the agency to improve the productivity of sanitation inspection so that resources will be available to focus on CCPs.

FSIS intends to focus its inspectional oversight and enforcement on whether a plant has a sanitation SOP that follows good manufacturing practices, is following the SOP on a daily basis, and is successfully preventing insanitary conditions that could result in product contamination.

Failure to have a sanitation SOP, or to consistently follow it, or the presence of insanitary conditions that could result in product contamination, would require immediate regulatory action, including consideration of whether particular lots of product have been rendered adulterated and should be retained or recalled. These conditions would be identified by the inspector and documented by the inspector and, as necessary, by compliance personnel. In cases of observable product adulteration or the high probability of product adulteration, the inspector would stop operations in the plant. In other cases, the correct regulatory action would be decided on a case-by-case basis. Repeated violations of SOP requirements or a persistent pattern of insanitary conditions would be the basis for withdrawing inspection.

Specific Economic Considerations and Issues

I. Objective of Proposal

The Pathogen Reduction/HACCP proposal acknowledged that the proposed requirements would have significant economic impact, particularly on small entities. Comments were requested on cost estimates for these impacts as well as on alternative regulatory approaches that could lessen this economic impact.

II. Description of Comments

Several themes emerged from the written comments received and oral statements made during public meetings on the Pathogen Reduction/HACCP proposed rule. A primary concern was that the proposal would have several negative economic impacts on small businesses. Some commenters opposed mandatory HACCP, daily microbial testing, and stringent time and temperature requirements.

While most commenters supported HACCP in principle, small businesses expressed concern about hazard analysis and plan development costs, equipment purchases, plant personnel training, and records maintenance. Suggested alternatives included voluntary HACCP, a 5-year implementation period, increased financial and technical support, alternative training options, inplant demonstration projects and generic HACCP plans.

Daily microbial testing of carcasses from each species slaughtered and of each type of raw ground product was cited as an unfair burden on small plants that slaughter only a few animals, a variety of species, or produce several different raw ground products. Some commenters proposed a frequency of microbial testing based on production volume or simply once per week or month in small plants. It was also suggested that federally-subsidized laboratories conduct the testing, an indicator organism instead of *Salmonella* be selected, and that either FSIS inspectors or, in the case of State-inspected plants, State inspectors conduct the sampling.

In response to the proposed carcass cooling time and temperature mandates, small businesses voiced a need for more realistic standards that reflect small plant product variety, processing operations, and shipping norms. Some said they would need to purchase additional refrigeration equipment for compliance with the proposed requirements. Others cited the "command and control" nature of these proposed standards and argued that they are impractical restrictions on a variety of their operations. A common theme was that these proposed controls should be restated as guidelines.

Commenters also voiced economic objections to the anti microbial treatments and asked for greater scientific justification. Comments also included cautions about

worker safety and environmental hazards, and requested a change from mandatory to voluntary implementation.

Some commenters asserted that within the small plant category is a subgroup of State-inspected plants with the same concerns as those stated above and additional ones due to their very small size and diverse operations. These commenters requested identification of a "very small" sub-category of plants defined as those with annual sales less than \$1 million, fewer than 20 employees and limited production volume. Exemptions and implementation delays were requested for plants in the proposed "very small" category.

Another issue raised was State-provided implementation assistance for State-inspected plants and whether matching Federal funds would cover State programs that provided more help than USDA regulations required.

III. Issues Raised by Comments

After reviewing the small business concerns expressed in the comments, FSIS is considering whether the food safety and public health objectives of this proposal can be accomplished by means that would reduce the regulatory burden and resulting costs of the proposed requirements on small businesses.

FSIS continues to believe that mandatory HACCP is central to the FSIS food safety strategy and reform of the meat and poultry inspection system. Given this, can FSIS significantly reduce the economic impacts on small business by any of the generally applicable modifications to the proposed rule or by using its available resources to provide implementation assistance?

For example, small business objections to the burden of daily microbial testing of each species and ground product for *Salmonella* require FSIS to determine whether another microorganism, reduced frequency of testing, and/or FSIS assumption of a greater testing role would be equally effective in verifying process control and attaining pathogen performance standards and, at the same time, reduce the economic burden.

Raw product time and temperature specifications and anti microbial treatments for carcasses are techniques for pathogen reduction that have been criticized as command-and-control regulatory approaches. FSIS is considering whether these proposed requirements can be replaced by a performance standard or otherwise modified to achieve the food safety objectives while mitigating the economic burden on industry, including small plants.

After publication of final Federal meat and poultry Pathogen Reduction/HACCP regulations, all State inspection programs must establish requirements "at least equal to" the Federal requirements. Due to variations in State regulatory processes,

some intrastate inspection programs may match the Federal regulations within a year while others may take two years in cases where inspection program regulations must be approved by the State legislature. Once new regulations are in place, State plants would have to be given adequate time to meet the new requirements. In particular, State implementation of the near-term initiatives would likely occur on a longer time line than the proposed for Federal plants. FSIS is considering ways to minimize any inequity between Federal and State-regulated plants.

Another State-specific concern relates to Federal matching funds for up to 50 percent of State inspection program budgets. The HACCP proposal raises questions about what activities will be covered by matching funds. For example: If State inspection programs provide HACCP training for industry employees in State plants, assist State plant owners in HACCP plan development and implementation, or offer ongoing technical assistance to State plant operators, can/shall Federal matching funds be provided?

A further question is whether certain small businesses should be separately identified from others by defining a new "very small" business category. Available data indicate, for example, that among *all* state-inspected plants, approximately 75 percent employ fewer than 8 employees. Given the likelihood of longer implementation times for most intrastate plants due to the normal process of State compliance with Federal inspection program changes, is there a reasonable justification for longer times for all such "very small" plants in terms of attainment of national pathogen reduction and process improvement requirements?

IV. FSIS' Current Thinking on Issues Raised by Comments

To address small business concerns, FSIS proposes to use a three-part regulatory policy that would apply to every Federal and State-inspected plant: (1) Fundamental public health and food safety principles must not be compromised, (2) Regulatory flexibility will be provided to plants by establishing performance standards, and (3) Direct and indirect assistance will be provided by FSIS to small plants that need help in reaching those goals.

FSIS is considering appropriate regulatory flexibility options that would minimize small business impacts as they attain performance goals. In the other issue papers on carcass cooling requirements, antimicrobial treatments, and microbial and testing standards, FSIS has outlined alternatives that could mitigate both the technical and economic considerations raised by small businesses about these proposed requirements. Remaining concerns to be addressed are focused on the HACCP implementation schedule and technical assistance.

HACCP Implementation Schedule

As noted above, FSIS is considering ways to adjust the implementation schedule to ensure that small businesses under Federal; regulation and those under State

regulation are treated equitable with respect to the time period allowed for compliance with the provisions of the final rule.

HACCP Implementation Assistance

Federal Assistance to Industry: FSIS is considering a program to develop implementation aids that should greatly reduce the uncertainty small plants have expressed about a mandatory HACCP program. These aids would include: (1) information publications, such as a HACCP Handbook that explains how a plant can effectively and economically incorporate the seven HACCP principles into its operations; (2) training videos and computer programs that present HACCP implementation guidance in alternative formats; (3) models for onsite HACCP training of plant employees; and (4) a catalog of hazards with examples of control measures and generic plans for each slaughter and processing category described in the proposed rule. These materials would provide the means for all plants to meet HACCP regulatory requirements.

FSIS is also planning to sponsor inplant demonstration projects to generate real-world information and guidance about near-term and HACCP implementation issues in small businesses.

Federal Assistance to States: FSIS would continue its technical assistance to State programs by including State training officials in Federal training efforts, by facilitating State access to and use of Federal computer support systems, and by expansion of state/federal cooperative efforts through the Conference for Food Protection, the National Association of State Departments of Agriculture, the Association of Food and Drug officials, and the Meat and Poultry Inspection Advisory Committee. Also, FSIS' plans for inplant demonstration projects referenced above would focus on small plants under State regulation as well as those under Federal regulation.

Specific Product Considerations Involving Religious, Ethnic, and Cultural Food Handling Practices

I. Objective of Proposal

The objective of the Pathogen Reduction/HACCP proposed rule is to take a comprehensive approach to improving the safety of meat and poultry products.

II. Description of Comments

Many commenters identified unique product considerations that they felt were threatened or undermined by certain requirements in the proposed rule. These unique product considerations principally involved religious, ethnic, and cultural issues centered around three product types: kosher products, Chinese poultry, and "hot" speciality items usually for Moslem, Chinese, Hispanic, and Hawaiian markets.

Comments related to kosher products identified two specific areas of concern. First, antimicrobial treatments would cause a serious problem under kosher dietary laws if applied before the salting process and would cause practical problems if applied after the salting process. Second, the time and temperature requirements for carcass cooling might significantly shorten the available time for ritual salting, particularly for religious holidays, which might limit the availability of kosher meat. For these reasons, commenters requested exemptions from using antimicrobial treatments and from following proposed time and temperature requirements for meat and poultry products that are certified and sold as kosher.

The Chinese-American community expressed concern about the added cost of whole birds prepared for religious purposes. Commenters requested an exemption for such products.

Other commenters noted that proposed time and temperature requirements for carcass cooling conflict with "hot pork," a process during which hogs are slaughtered and delivered to customers in some ethnic markets with little or no chilling. A similar process is used with lamb, goat, and beef for Moslem customers. An exemption was also requested for these products.

III. FSIS' Current Thinking on Issues Raised by Comments

FSIS is examining how it can provide the regulatory flexibility needed to adequately address the concerns noted above while still achieve its food safety and public health objectives.

FSIS expects the final rule to contain changes that will as a general matter increase industry's flexibility to use alternative technologies and procedures which reduce and control pathogens to meet the microbial performance standards. This approach may help address some of the concerns expressed by religious and cultural groups. If any individual group's unique problems are not adequately addressed by this approach, the agency would consider other alternatives that respect well established religious, ethnic, and cultural practices as much as possible while assuring fundamental public health and food safety objectives are achieved.