

public health-driven targets, guidelines, or standards that establishments will be held accountable for meeting. This should have its greatest impact in slaughter establishments, where such targets, guidelines, or standards do not generally exist today.

FSIS will focus its own limited technology development efforts on tools that can assist the Agency in detecting and evaluating food safety hazards or addressing other issues within its statutory responsibility, such as economic adulteration. These efforts have traditionally included, and will continue to include, the development of sensitive and reliable analytical methods and diagnostics that can assist the Agency in verifying the safety of meat and poultry products and detecting product characteristics of regulatory interest. FSIS will also continue its efforts to develop tools that it can use to advance its food safety mission but that require long-term commitment to develop, such as various computer models on pathogen behavior. In these cases, the Agency has (1) carried out its own technology development efforts, as it did in developing quick tests for antibiotics and species identification; (2) secured the assistance of the Agricultural Research Service and Cooperative State Research Service, as it has done with computer modeling of pathogen growth under various times and temperatures; and (3) occasionally, supported specific work by academic institutions or other private entities through use of competitive bidding processes, as it did recently by awarding more than \$700,000 in contracts for development of methods to detect pathogenic microorganisms.

The resources available to FSIS for such technology development activities are very limited. Moreover, FSIS has found that there is often considerable interest within the regulated industry in using technologies that were originally developed by FSIS. FSIS intends to explore mechanisms for stimulating private sector investment in analytical methods and other technologies that can assist the Agency in its regulatory role but that also can assist the industry in carrying out its food safety responsibilities.

FSIS believes that its primary role with respect to new in-plant technologies developed by industry should be to ensure that the technologies do not interfere with inspection, threaten the safety of the product, or violate other statutory standards, such as those concerning economic adulteration.

In some circumstances, the FSIS evaluation of a new technology may need to consider the efficacy of the technology, that is, its success in accomplishing its intended objective. For example, if FSIS has a regulatory requirement for the use of an antibacterial treatment, as is proposed elsewhere in this document, the Agency will take an evaluative interest in whether a specific treatment in fact has the intended and required effect. In addition, if a company intends to make a marketing claim for a process or technology used in an establishment—such as a claim that its product is “pathogen free”—FSIS will require a demonstration that the claim is valid.

On the other hand, in circumstances where industry interest in the technology is not based on required or claimed health and safety effects, but on a productivity concern, FSIS interest will be limited to ensuring that relevant safety questions have been addressed.

When FSIS makes significant decisions about the safety or effectiveness of an in-plant technology, it must ensure that its decisions are scientifically sound and open to appropriate public scrutiny and participation. An example of how this can be achieved is the approach taken in an earlier section of this document to inviting public comment on the possible antimicrobial treatments that might satisfy the proposed requirement that all meat and poultry establishments adopt at least one antimicrobial treatment. FSIS invites comment on this approach and other means for ensuring that its scientific decisions are sound and open to public scrutiny.

During the past several years, staffs in the Agency have begun efforts that would permit technological change to proceed more readily from the development to the implementation stage. The Facilities, Equipment and Sanitation Division has explained many of the principles and criteria that it uses to make decisions in publicly available documents so that they can be readily understood and used by companies as they plan changes in their physical plants. The Microbiology Division has provided public notice about the circumstances under which it will formally evaluate analytical methods that may be useful in the FSIS program, and it has negotiated a Memorandum of Understanding with the AOAC Research Institute that will permit manufacturers of test kits designed for use by the industry to have their technologies evaluated for that purpose. The Processed Products Inspection Division has developed guidelines to be used in preparing various required QC

programs. The Slaughter Inspection Standards and Procedures Division has developed and made available protocol guidelines so that companies that want to conduct in-plant demonstrations of antimicrobial treatments will know what is necessary to secure Agency approval.

Providing clear guidance of this kind assists companies in meeting the Agency's requirements and will continue to be an important part of FSIS's effort to improve its technology review function. As outlined below, however, FSIS intends to take a number of additional steps to help foster development, appropriate review, and prompt implementation of beneficial new technologies, especially those that can help improve the safety of meat and poultry products.

Future Agency Activities

As already noted, FSIS is reviewing all of its existing systems of prior approval or other procedural requirements that are now in place regarding the development and implementation of technologies in meat and poultry establishments. The Agency intends to eliminate, streamline, or otherwise modify its systems and procedures, as appropriate, to ensure that its legitimate oversight obligations are met without unduly delaying the introduction of beneficial new technologies or imposing unnecessary burdens on establishments seeking to adopt such technologies.

One approach FSIS is considering is a simplified single-stop approval mechanism for industry-wide application of proven pathogen reduction technologies, once necessary laboratory and in-plant trials have been completed and the data have been evaluated. The generic approvals FSIS recently granted for use of hot water and organic acids in conjunction with the final carcass wash in beef slaughter establishments could provide a workable model for expediting the adoption of pathogen-reducing technological developments. The Agency's scientific evaluation would be for the purpose of ensuring that efficacy is demonstrated, that conditions of use are specified so the technology can be widely replicated, and that verification techniques are available. Once this scientific evaluation has been completed on a generic basis, approval for industry-wide use without further constraints, such as plant-by-plant review, could be granted by the Administrator or his/her designee. FSIS invites comment on this approach, including what public process would be appropriate in making such decisions.