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April 3, 2003

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00-011N
00-011N-1
David Meeker

FSIS Docket Room
Docket #00-011N
Room 102 Cotton Annex
300 12th Street, S.W.
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, D.C. 20250-3700

Re: Procedures for Notification of New Technologies

The National Turkey Federation (NTF) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Federal Register Notice entitled "Procedures for Notification of New Technology." 68 *Fed. Reg.* 6,873 (February 11, 2003). NTF strongly supports the expeditious implementation of new technologies by streamlining FSIS review. To further this goal, we would recommend certain clarifications and modifications to the Procedures discussed below.

NTF is the only national trade association representing the turkey industry exclusively. NTF represents more than 98 percent of the United States turkey industry, including processors, growers, breeders, hatchery owners, and allied industry. Since our members are inspected by FSIS, we have an interest in working cooperatively with the agency in implementing new technologies that can further enhance the safety of our products.

Our principal concern is that the Procedures are essentially the same as the current FSIS Directive 10,700.1. To be sure, there are changes: principally specifying an initial sixty day review period to permit a rapid decision as to whether a pre-use review is necessary. However, we do not believe the changes made will have an appreciable effect on streamlining implementation of new technologies; more is needed.

In this regard, we would recommend FSIS implement several changes in the Procedures: (1) specify in greater detail when a pre-use review is unnecessary; (2) expressly provide for passive approval if the agency does not respond within the sixty day period: (3) clarify when an in-plant trial would be required; and (4) include resolution of labeling in the streamlined procedures. We submit that these changes will greatly improve the agency's review process by providing greater specificity of the decision making criteria and streamlining all issues posed by new technologies.

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Specify When No Submission is Required

As currently drafted, the Procedures do not articulate precisely when a submission would even be required. Moreover, we believe there are a variety of situations where such submission would not be necessary. Since the Federal Register Notice indicates that if the establishment uses a intervention before the end of the sixty day review period, the product manufactured using the technology may be subject to regulatory action, the Notice guarantees that no establishment will make a change, no matter how minor, until clearance has been obtained. This adds an automatic, and often unnecessary, sixty delay.

Accordingly, we suggest the Procedures be modified to provide:

- When use of a particular piece of equipment has been previously permitted, no submission would be required if the equipment has been modernized, but still operates in the same basic manner. For example, if an establishment wishes to purchase a newer model of a spray cabinet, it should not have to submit a request for pre-use review before using the new model.

- When use of a particular substance has been previously permitted, no submission would be required if the establishment wishes to modify the use level, provided, of course, the use level is still within the regulatory range (or consistent with the GRAS status).

- When the establishment wishes to use a GRAS substance in a manner consistent with its GRAS status, no request for pre-use review should be required.

On the latter, we respectfully submit that this is a prime example of when no pre-use review is necessary. A GRAS product, by definition, cannot adversely affect product safety. Likewise, any question as to worker safety will be covered, if necessary, by existing OSHA requirements, so its use cannot jeopardize the safety of FSIS inspection personnel. Moreover, an establishment, in consultation with FSIS in-plant personnel, can readily determine if the use of the substance will interfere with inspection procedures. Finally, absent an express prohibition on the use of the substance (or controls on the use of substances in standard of identity products), there would be no need for a waiver of any agency regulation. In this situation it is clear in advance that no review would be required. That being so, there is no reason to submit any request to the agency.

Provide for Passive Approval

As currently drafted, the Procedures provide that FSIS will have sixty days to review a submission to determine whether a full submission is required. However, there is no guarantee that the agency will complete this review within the time period. Moreover, it is unclear whether at the end of the sixty days the establishment can implement the technology. We recommend that the agency expressly recognize a "passive approval;" that if the agency has not responded to the establishment at the end of the sixty days, the agency will be deemed to have no objection to the use of the technology. This will

ensure that a submission does not get delayed needlessly, and will be consistent with the Agency's use of passive approval under the final *Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements* rule.

Clarify When an In-Plant Trial is Required

The Procedures do not provide any clear standard for when an in-plant trial would or would not be required. We respectfully submit that an objective criteria be established. In this regard we would suggest that the requirement for an in-plant trial be based on the nature of the agency's concern. For questions as to whether the new technology would adversely affect product safety, it would seem that such a concern would not be dependent on whether a technology is employed in a plant setting or in a laboratory/research plant. Likewise, the issue of whether a regulatory waiver is required does not seem to be dependent on operation of the technology in a plant environment. Hence, we recommend that when the agency's concern involves these two issue, no in-plant trial be required. For the other two issues identified by FSIS – safety of inspectors and impact on inspection procedures – we recognize that an in-plant trial may be needed to resolve these matters.

Use and Labeling

In many situations, generally involving the use of substances as an intervention, the delay in approval has not centered on any of the four factors identified by the agency as requiring pre-use review; rather the delay has centered around whether the substance is "safe and suitable" and/or whether any labeling would be required. In these areas, delays have been frequent, bordering on excessive. Unless FSIS streamlines the entire process of implementing new technologies, there will continue to be long and unnecessary delays.

To avoid this morass, we recommend the Procedures include provisions on use and labeling of substances – the general rules are well established:

- The use of a food additive or GRAS substance will be permitted to the extent consistent with the food additive regulation, the GRAS regulation or GRAS affirmation, as appropriate. GRAS self-affirmations would be permitted if supported by the findings of a GRAS panel.

- A substance which qualifies as a processing aid need not be declared on the label.

- If the technology involves use of moisture, the product labeling must be consistent with 9 C.F.R. § 441.10.

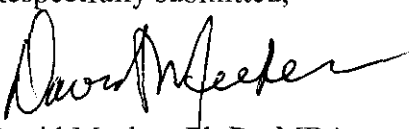
We believe that if an establishment need only follow these well-established rules and not be required to submit to pre-use review, this will eliminate the vast majority of delays attributed to use/labeling review.

Conclusion

We applaud the FSIS initiative to streamline the review and subsequent implementation of new technologies. We respectfully submit that including the clarifications and modifications suggested above will further improve the effectiveness of the Procedures.

As always, we appreciate the opportunity to comment on this matter and look forward to working with the agency to enhance food safety.

Respectfully submitted,



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