EXCEL®

A Cargill Foods Company

April 8, 2003

00-011N
00-011N-3
Daniel L. Schaefer
William H. Sperber

FSIS Docket Room
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

(3)

Re: Docket No. 00-011N, FSIS Procedures for Notification of New Technology

Dear Sir or Madam:

Cargill, Incorporated and its subsidiary companies, including Excel Corporation, Cargill Turkeys, and Sunny Fresh Foods, appreciate the opportunity to comment on this particular notice. Cargill is major producer of beef, pork, turkey, processed meats, and eggs under FSIS inspection. We, too, have noticed that since the Agency "shifted away from a command and control approach to one that gives industry greater flexibility to innovate in order to meet food safety requirements" in 1996, that the incidence of meatborne pathogens and foodborne illnesses has decreased significantly. The Agency is to be commended for its intentions to better protect the public health.

We are proud to be a continuing part of industry efforts to develop novel pathogen reduction technologies. We have already contributed significant innovations, including steam pasteurization (patent numbers 5,711,981, 5,976,005, and 6,019,033), steam vacuuming, chemical washing of hog mouths (patent number 5,928,074), application of peroxyacetic acid on carcasses, and at least three additional confidential projects. Our experience has shown that innovation can be applied to improve the products we produce.

Our thorough review of the proposed regulatory changes in this notice has resulted in the following comments:

1) The definition of "new technology" is too vague and unclear. **We believe that new technology defined for the purposes of this proposal should be limited to processes that directly affect product safety, inspector safety/ability to conduct inspection, or require a variance to an existing regulation**. All other process changes should be applicable through HACCP or SSOP modifications. Ideally the agency would provide decision tree guidance to aid in determining when a "new technology" is applicable.

2) Confidentiality is always an issue with new technology. Neither the current methods nor the proposal contain any reference to maintenance of project confidentiality. If both the protocol and test results must be reviewed by FSIS, it creates several issues with disclosure of confidential information and infringement of patentability rights. **We believe the regulation should specifically address the topic of confidentiality and provide specific provisions for protecting confidentiality.**

3) While we appreciate the shortening of the timelines from the current process, the proposed period of 60 days to provide a letter of no objection seems unreasonable to us. Extended interruptions in the development process tend to cause loss of focus and intensity. In addition, if the requestor failed to receive a letter of no objection after 60 days, they would be forced into a protracted approval process that could drag on

indefinitely. To a significant extent, this notice simply defines current practice. It will accomplish little to speed up the review and approval processes, thereby streamlining the adoption of new technologies. Given the outstanding resources and expertise within FSIS, **we believe the requestor should be granted approval in 14 days or less.**

4) The proposed changes set forth a standard of practice for approval of the new technology at the highest levels of FSIS, however they fail to recognize any method of communicating the approval to the district and local levels. From our experience with previous projects the burden of communication typically falls on the requestor. This burden creates delays and frustrations about the implementation of the technology. **We believe that if this level of regulatory oversight is required for new technology, the burden of communication should be the responsibility of FSIS. To this end, when approval or letter of no objection is granted, district and local inspection personnel should be copied on the letter.**

5) The proposed changes fails to address third party research. As written, the proposed changes imply the requestor is a processor. In addition to industry driven research, we rely on innovations from academia, government agencies (e.g., ARS), and our supplier/vendor community. **We believe the proposed changes should be more amenable to third party research**, otherwise the proposed changes will stifle these valuable technology contributors.

6) The proposed changes should more clearly address approvals that are plant specific versus company or industry specific. In many cases, new technology will have application across multiple plants (e.g. steam pasteurization) and if properly validated, general approval should be granted rather than seeking approval by plant or by district.

7) Our experience with the current process has shown that product labeling can be a stumbling block to new technology. **We believe the proposed changes should address new technology that effects product labeling standards and allows for temporary labeling variances.**

We appreciate the agency's recognition and support of new technology and the opportunity to provide our comments. We hope that the proposed changes foster innovation and in no way inhibit innovation. We support the agencies continued move toward science-based inspection. This directive should be another step towards allowing the processor the freedom to trial new ideas without additional bureaucracy.

If we knew what we were doing it wouldn't be called research, would it?
----Albert Einstein

Respectfully submitted,

Daniel L. Schaefer
Director, Beef Research and Development

William H. Sperber, Ph. D.
Director, Meat Technology Development Center