

## Exhibit 9: Peer Reviewer Guidelines

**Conflict of Interest**—Do not review any ARS project plan if you have an institutional or consulting affiliation with the submitting institution, investigators, or collaborators, or will gain some benefit from the project, financial or otherwise. Also, please decline the review if, during the **past four years**, any of the following relationships are applicable with respect to the submitting applicants and collaborators: collaboration on research projects; co-authorship; thesis or postdoctoral advisorship; work as graduate students or postdoctoral associate. If you are uncertain about potential conflicts, please contact the OSQR for advice on your decision.

**Confidentiality**—ARS project plans may include detailed information about the underlying research and existing and anticipated research results that is considered by ARS to be proprietary or confidential information. For this reason, do not copy, quote, or otherwise use material gained during the Peer Review Process. If you believe that a colleague can make a substantial contribution to the review, consult with the OSQR before disclosing any information. When you complete the review, destroy the project plan and all associated materials from the OSQR.

**Mission**<sup>1</sup>—Our primary interest is in your evaluation of the technical and scientific quality of the research proposed for solving the problem or answering the hypothesis that is being addressed. If you are critical of the approach taken in a project plan or skeptical of the feasibility of a project, we would like your recommendations for improvement. Please see the attached “Example of a well written set of recommendations.”

**Review Criteria**—There are 3 categories of review criteria:

1) *Merit and Significance*. For this criterion, ARS is primarily interested in whether the problems to be solved or addressed fit within the National Program Action Plan to which the Project Plan is assigned. The National Program Action Plan has been developed with input from stakeholders, congressional mandates, customers, and ARS

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<sup>1</sup> Public Law 105-185, June 23, 1998. An Act To ensure that federally funded agricultural research, extension, and education address high-priority concerns with national or multistate significance, to reform, extend, and eliminate certain agricultural research programs, and for other purposes. Title I, Sec. 103(b) Advisory Board Review—On an annual basis, the Advisory Board shall review—(1) the relevance to the priorities established under Sec. 102(a) of the funding of all agricultural research, extension, or education activities conducted or funded by the Department; Sec. 103(d)(1) Peer Review Procedures—The Secretary shall establish procedures that ensure scientific peer review of all research activities conducted by the Department. Sec. 10 once every five years, that each research activity of the Department and research conducted under each research program of the Department has scientific merit and relevance. Sec. 104(d)(4) Composition of Review Panel—(A) In General—A review panel shall be composed of individuals with scientific expertise, a majority of whom are not employees of the agency whose research is being reviewed. Sec. 104(d)(4)(B) Scientists from Colleges and Universities—To the maximum extent practicable, the Secretary shall use scientists from colleges and universities to serve on the review panels. Sec. 104(d)(5) Submission of Results—The results of the panel reviews shall be submitted to the Advisory Board. 3(d)(2) Review Panel Required—As part of the procedures established under paragraph (1), a review panel shall verify, at least

and non-ARS scientists. Other aspects of these criteria that should be addressed are:

- Will the successful completion of the project enhance knowledge of a scientifically important problem?
- Will the project lead to the development of new knowledge and technology?
- Are you aware of any other data/studies relevant to this research effort?
- If applied research, peer reviewers comment on the value of the research to its customers.

2) *Adequacy of Approach and Procedures.* This evaluation criterion measures the scientific quality of the proposed research. Questions to be answered are:

- Are the hypotheses and/or plan of work well conceived?
- Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives?
- How could the approach or research procedures be improved?

3) *Probability of Successfully Accomplishing the Project's Objectives.* The feasibility of the project is evaluated by this criterion. The panel will determine:

- The probability of success in light of the investigator or project team's training, research experience, preliminary data if available, and past accomplishments;
- Whether the objectives are both feasible and realistic within the stated timeframe and with the resources proposed; and
- Whether the investigators have an adequate knowledge of the literature as it relates to the proposed research.

Satisfying each of these three criteria is essential to the implementation of research project plans.

**Action Classes**--After their discussion (panel reviewers) or completing the peer review form (ad hoc reviewers), each peer reviewer makes a judgement level of project modification needed to assure project quality. OSQR converts the action classification into a numerical score, averages the group of action classes submitted, and assigns a final action to the project plan.

1. *No revision required.* No revision is required, but minor changes to the project plan may be made.
2. *Minor revision required.* The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
3. *Moderate revision required.* The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
4. *Major revision required.* Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.

5. *Not feasible*. The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

**Panel Discussions**—Panel discussions are valuable to creating a single critique that reflects the most important, prominent points made by the reviewers. The primary reviewer is responsible for writing the recommendations and must use his or her best judgement in deciding on which points made in the discussion (also documented on the *Peer Review of ARS Research Project* forms) will be reported back to the researchers. No consensus of opinion is required.

**Nature of ARS's Research Projects** —Each project was created in response to a congressional mandate and/or to a workshop involving mostly non-ARS stakeholders. Input from these external groups is used to formulate National Program Action Plans for ARS's 22 national programs. You will review only those projects that are coded more than 50% to a particular national program.

ARS's Peer Review Process is dramatically different from an extramural competitive grants review. You'll review funded, intramural project plans. Some of the research is hypothesis driven. ARS projects usually contain long-term and/or high-risk research on national problems. These project plans cover the next five-years. Thus, we have asked the scientists to provide research contingencies when appropriate. Second, as mentioned above, some of the projects involve more than one national program. With a given project proposal assigned as a primary or secondary reviewer, you may not feel qualified to evaluate all of the project (e.g., part of the project deals with another national program). If so, please let the Panel Chair or OSQR Officer know as soon as possible.

**Documentation**—Use the provided *Peer Review of ARS Research Project* forms for your comments. (The forms will accompany the project plans.)

**Planning and Preparation**—We strongly encourage you to read the National Program's Action Plan prior to reviewing the project plans. In most cases, the Action Plan will be available from the ARS Web Page or via e-mail. We anticipate that it will take a few hours to read, interpret, and comment on each project plan. You may be given an overview of the National Program to aid your understanding of how the program is designed. Panel reviewers are given approximately 1 hour to discuss their individual comments on each project plan.

The size of these projects vary considerably, with some being limited in scope and personnel while others are wide ranging with several objectives. Nevertheless, the length and format of the project plans are uniform in order to limit your workload. The key information in project plans is limited to 15 to 25 pages, depending on the number

of scientists; which includes the objectives, a description of the need for the research, background, approach, milestones, and expected outcomes. However, you can expect the entire project plan to be an average of 40 pages; which includes bibliographies, information about the scientists, collaboration letters, and other material.

**The Final Recommendations**—Primary reviewers have the responsibility for preparing the final recommendations that summarize the key findings of the panel. Your Panel Chair will validate the recommendations before we except them

**Debriefing**—Panel reviewers will be asked to tell us about their experience as a peer reviewer. Your comments help to improve how we conduct peer review sessions. Your honesty and sincerity is appreciated.

**Obtaining Other Information**—If you have a question that is not answered by reading the project plan or other materials, please call the Office of Scientific Quality Review, (301) 504-3282. We will get the answer for you.

## **EXAMPLE OF A WELL WRITTEN SET OF RECOMMENDATIONS:**

**Project Title:** Development of Gentle Intervention Processes to Enhance the Safety of Heat Sensitive Foods

**Lead Scientist:** Dr. ARS Scientist

**National Program:** Food Safety

**Reviewer Number:** AAAA1120

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**Adequacy of Approach and Procedures:** Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?

Comments:

1. The hypothesis that... condensing steam will inactivate bacteria on the surface of solid foods without causing thermal damage if the interfering air and water layers on the surface are removed by vacuum and the condensed steam is removed to evaporatively cool the surface... is scientifically sound and workable. Indeed, the group has developed and tested the technology with a pilot plant prototype and chicken pieces, which indicated a 2 log reduction of LM in initial studies. Further refinement will involve retrofitting the prototype to treat the whole carcass (surface, visceral cavity) and development of a field VSV pasteurization system. Additional studies will focus on ready-to-eat meats, specifically hot dogs (and the known LM hazard) and catfish, with both aspects under appropriate CRADAs. The former is a high priority research need for food safety regulatory agencies, and the contingency inactivation studies “in-package” (within plastic) should probably be elevated to practice in the proposal. The portion of the proposal indicating the development of models and process simulations, towards determining the mechanism of VSV inactivation, is appropriate, but of lower priority in the overall project schema. Any modeling aspect should be focussed on process delivery and eventual development and validation of performance standards to support food safety.
2. The controversial theory that “pasteurization” of heat-sensitive foods is accomplished by applied voltage or magnetic field and, perhaps, can be demonstrated with the incumbents’ “uniquely modified RF heater” is the overall working hypothesis for this objective. This entire objective is very high risk, but the payoff is potentially high. The proposal articulates a clear, stepwise protocol. The modified RF “heater” appears to be designed to offset the often-stated criticism towards the non-thermal theories that precise measurements of the time-“temperature” history and its spatial variations are lacking.

Recommendations:

1. Objective 1 - The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?
2. Objective 1 – Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.
3. Objective 1 – The portion of the proposal on models and simulation of the bacterial “destruction” process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

**Comments  
for Section 21**

**The ARS Research Project Plan Instructions and Format**