

**Professional Services to Support Requirements Gathering Sessions
for Safe Food Handling Instructions (SHI)**

OMB No. 0583-NEW

Supporting Statement

A. Justification

A.1. Circumstances Making Collection of Information Necessary

The U.S. Department of Agriculture’s Food Safety and Inspection Service’s Office of Public Affairs and Consumer Education (USDA, FSIS, OPACE) ensures that all segments of the farm-to-table chain receive valuable food safety information. Through its consumer education programs developed by OPACE’s Food Safety Education Staff, the public is educated on how to safely handle, prepare, and store meat, poultry, and egg products to minimize incidence of foodborne illness.

Safe Handling Instructions (SHI) are required if the meat or poultry component of a product is raw or partially cooked (i.e., not considered ready-to-eat) and if the product is destined for household consumers or institutional uses (9 C.F.R. § 317.2[1] [meat]; 9 C.F.R. § 381.125[b] [poultry]). FSIS established the SHI for raw and partially cooked meat and poultry products in 1994. Consumer focus groups were conducted to inform the design of the SHI (Teague & Anderson, 1995; Teague & Anderson, 1993). Since that time, the SHI have not been revised.

In response to inquiries from consumer groups and other stakeholders for more information about potential changes to SHI requirements, FSIS gathered input from members of academia, industry, and consumer stakeholders in November 2013. FSIS presented these suggestions to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) in

January 2014. When the SHI were developed in 1994, minimal internal temperature requirements for determining doneness varied by product. Given product and label size limitations and varying endpoint temperatures, FSIS concluded that “Cook Thoroughly” was the only simple, single statement appropriate to use for all products. FSIS now recommends only three internal minimal temperatures: one for all poultry (165°F), one for ground red meat (160°F), and one for all whole-muscle red meat (145°F and hold for 3 minutes). With only three temperature recommendations, the information could be more easily incorporated into the SHI requirements through rulemaking. Other possible changes to the SHI include incorporating new icons developed and branded under USDA’s Food Safe Families campaign and providing a Web link/phone number for more information (NACMPI, 2014; Murphy-Jenkins, 2014).

The NACMPI Subcommittee on Food Handling Labels recommended that FSIS pursue changes in the existing SHI and to conduct consumer research to determine the effectiveness of any revisions to the SHI (NACMPI, 2014). In November 2014, FSIS conducted a strategic planning session (facilitated by a third-party) to elicit input from FSIS senior leadership on potential revisions to the SHI, the impact any revisions may have on consumers and industry, and pitfalls to consider. The findings from this session underscored the need to conduct consumer research to determine consumers’ requirements for potential revisions to the SHI.

To inform decisions about possible modifications to the SHI, OPACE is requesting approval for a new information collection to conduct consumer focus groups. The purpose of the focus groups is to understand what information on the SHI is or could be useful to consumers in order to safely handle and prepare raw and partially cooked meat and poultry at home and if revisions are needed to improve consumers’ handling and preparation of these products. In addition to this exploratory consumer research, FSIS plans to conduct a preliminary break-even

analysis to examine the costs and benefits of revisions to the SHI that may affect consumer practices (e.g., thermometer use).¹ FSIS will use the focus group findings and the results of the preliminary break-even analysis to decide if revisions to the SHI are needed to improve consumers' food handling and preparation practices when cooking raw and partially cooked meat and poultry products at home and thus help to reduce foodborne illness. Section A.16 describes the approach FSIS will use to analyze the focus group data to determine if revisions to the current SHI are needed.

If FSIS decides that revisions to the current SHI are needed, the Agency will develop alternative formats for a revised SHI based on consumers' requirements for potential revisions to the SHI as identified in the initial focus groups). The Agency would then conduct additional consumer research (e.g., focus groups or an experimental study) to test the alternative versions and to determine a format for the revised label that would be most effective at encouraging consumers to follow recommended safe handling practices for raw and partially cooked meat and poultry products. The results of the second round of consumer research along with a final cost-benefit analysis would help inform regulatory impact analysis for potential future rule making on mandated revisions to the SHI.

A.2. How, by Whom, and Purpose Information Is to Be Used

FSIS has contracted with RTI International to conduct six consumer focus groups to gather information on consumers' understanding and use of the current SHI and responses to possible revisions to the SHI. The groups will be segmented by at-risk population (i.e., older adults, parents of young children, and immunocompromised individuals or their caregivers) and the general population. To provide geographic diversity, we will conduct two focus groups in

¹ Break-even analysis examines the question of how large the benefits of a program or policy need to be in order to exceed its cost to society. Interventions with ratios of greater than one would be expected to have health benefits that exceed the costs of the changes; higher ratios indicate greater benefits.

three different locations (for a total of six groups): Sacramento, CA; Oklahoma City, OK; and Raleigh, NC. In each location, we will conduct one focus group with English-speaking adults and one focus group with Spanish-speaking adults.

A moderator's guide (see Appendix A.1) will provide structure for the focus group discussions and ensure that the following topics of interest are addressed:

- Handling of raw and partially cooked meat/poultry products at home
- Use of labeling information when preparing raw and partially cooked meat/poultry products
- Current awareness of the SHI
- Use of the current SHI when preparing raw and partially cooked meat/poultry
- Reactions to possible modifications to the SHI (e.g., addition of recommendation to use food thermometer and/or endpoint temperatures, replace current icons with Food Safe Families icons, include USDA Web site address for more information).
- Preferred methods for communicating information about revisions to the SHI

Additionally, participants will be asked to complete short pre- and post-discussion questionnaires (see Appendices B and C). The purpose of each questionnaire is to collect information on participants' current awareness and use of the SHI and the likelihood they would change their behaviors if the SHI is revised. The Agency will use the findings of the initial, exploratory focus groups to understand consumers' knowledge and use of the current SHI for raw and partially cooked meat and poultry products and consumers' responses to possible revisions to the SHI. As previously mentioned, the focus group findings coupled with results of a break-even analysis, will be used by FSIS to guide decision making regarding whether the Agency should proceed with conducting a second round of consumer research to revise the

current SHI (i.e., make a go/no go decision). If the focus group findings and break-even analysis suggest that the costs of revising the SHI exceeds the benefits, then FSIS will not move forward with additional research or rulemaking. If FSIS decides to move forward with conducting a second round of consumer research, then the Agency will submit a separate information collection for this research.

A.3. Use of Improved Information Technology

To interpret the study findings, the focus groups will be digitally recorded, and the audio-recordings will be transcribed. No electronic copies of the questions will be provided to the participants before the focus group meeting.

A.4. Efforts to Identify and Avoid Duplication

The Agency concluded that the proposed data collection will not duplicate any similar study and the existing knowledge base and literature do not meet the Agency's informational need.

A.5. Methods to Minimize Burden on Small Business Entities

No small businesses will be involved in this collection.

A.6. Consequences of Less Frequent Data Collection

This is a one-time data collection. Without this study, FSIS will not have the needed information to understand consumer interpretation of, use of, and response to the SHI and possible revisions to the SHI. The lack of understanding would impede the Agency's ability to provide more useful information to consumers to help reduce foodborne illness in the United States.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 that Would Cause the Information Collection to be Conducted in a Manner:

- requiring respondents to report information to the agency more often than quarterly;

- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

This information collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection that would be inconsistent with the regulation.

A.8. Consultations with Persons Outside the Agency

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice requesting comments regarding this information collection request (80 FR 1242; 3/6/15). The

Agency received one comment from the Center for Foodborne Illness Research & Prevention and Consumer Federation of America that fully supported the information collection. The National Agricultural Statistics Service also reviewed the collection and made supportive comments.

A.9. Payments to Respondents

We understand that the OMB guidance about incentives for participation in research is based on the principles of the 2006 memo: Guidance on Agency Survey and Statistical Information Collections. We propose providing each focus group participant a \$75 cash incentive so that we can effectively recruit hard-to-find populations, such as immunocompromised individuals; to ensure a high-show rate for the focus groups; and to improve data quality. Additionally, participation in focus groups requires substantial commitment and investment of time on the part of the participant, in that they must make a commitment to attend the discussion at a certain time on a specific date. Participation also requires participants to travel to a designated location, with the average commute in the United States metropolitan areas estimated at about 25.1 minutes (McKenzie and Rapino, 2011), and may also require that the participant obtain child care for a fee (especially for the focus groups with parents of young children and other participants who may have children). Thus, incentives have long been considered a standard practice in conducting qualitative research such as focus groups.

Table A-1 provides a breakdown of the cost to participate in the focus group discussion by subpopulation. Although the cost to participation varies by group depending on whether child care is needed (from \$28.87 to \$73.87), we propose to offer all participants the same incentive amount (\$75) to avoid introducing selection bias that might occur by offering different incentive

amounts to different subpopulations.

The proposed \$75 incentive amount is in line with the industry standard. These industry-standard stipends help ensure that respondents can be recruited efficiently and ensure their arrival and participation in the groups. These standards also exist to provide fair compensation for costs incurred by participants while attending groups (i.e., travel and child care expenses). In addition to covering reasonable costs of participation, payment to participants is necessary to ensure that a sufficient number of respondents from the target populations, especially hard-to-reach populations such as those proposed for this study, participate in the study. Payment to participants must encourage potential participants to agree to allocate their time to the focus group discussion and maintain that commitment on the day of the research.

Offering no incentive or a smaller incentive could potentially exclude sections of the population who cannot attend the groups, either due to the cost of child care and/or travel or the cost of missing work. Excluding sections of the population would limit the qualitative information that would be gained through the focus group discussion and potentially bias the information needed to address the research questions of interest, thus negatively impacting data quality.

Moreover, the \$75 incentive payment proposed is consistent with what OMB has approved for other 90-minute focus group studies, for example, OMB No. 0583-0141: *Consumer Research, Assessing the Effectiveness and Application of Public Health Messages Affecting Consumer Behavior Regarding Food Safety*; OMB No. 0920-0910: *Perceptions of Health Risk from Smokeless Tobacco Products and Nicotine Replacement Therapy among Pregnant Women and Women Planning a Pregnancy*; and OMB No. 0584-0561: *Healthy Incentives Pilot Evaluation*.

To encourage recruited individuals to not only attend but to arrive on time for the focus group discussions, we will include all those who sign in 15 minutes prior in each group to a drawing for a chance to win an extra \$50 (cash). We anticipate that without the cash incentive and drawing, we would need to screen more people to achieve the desired cooperation rate. The current estimated annualized burden for the participant screening is 64 hours. Without the incentive, we expect the burden to be approximately 88 hours, an increase of approximately 40%. The cost to respondents and the federal government would increase accordingly.

Table A-1. Estimated Cost to Participants of Taking Part in the Focus Group Discussion by Subpopulation

Parents of Young Children			
Cost Component	Estimated Number of Units	Unit Cost	Total Cost
Cost to travel to/from facility	50.2 miles ^a	\$0.575/mile ^b	\$28.87
Cost of child care during travel time (1 hour round trip) and attending focus group (15 minutes before group to park and check-in, 90 minute discussion, 15 minutes after group to check-out and receive incentive)	3 hours	\$15/hour ^c	\$45.00
Total			\$73.87
Older Adults			
Cost Component	Estimated Number of Units	Unit Cost	Total Cost
Cost to travel to/from facility	50.2 miles ^a	\$0.575/mile ^b	\$28.87
Total			\$28.87
General Population and Immunocompromised (with children)^d			
Cost Component	Estimated Number of Units	Unit Cost	Total Cost

Cost to travel to/from facility	50.2 miles ^a	\$0.575/mile ^b	\$28.87
Cost of child care during travel time (1 hour round trip) and attending focus group (15 minutes before group to park and check-in, 90 minute discussion, 15 minutes after group to check-out and receive incentive)	3 hours	\$15/hour ^c	\$45.00
Total			\$73.87
General Population and Immunocompromised (without children)^d			
Cost Component	Estimated Number of Units	Unit Cost	Total Cost
Cost to travel to/from facility	50.2 miles ^a	\$0.575/mile ^b	\$28.87
Total			\$28.87

^a The average commute in a U.S. metropolitan areas is an estimated 25.1 minutes to the designated location (McKenzie and Rapino, 2011) for a total of 50.2 minutes. Assuming participants travel 60 miles an hour the total number of miles is 50.2 miles.

^b Source: <http://www.gsa.gov/portal/content/100715>

^c Source: <http://www.care.com>

^d Assume 50 percent of adults in the general population and immunocompromised groups will require child care and 50 percent will not require child care.

A.10. Assurance of Confidentiality

The privacy of the focus group participants will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants.

The only Information in Identifiable Form (IIF) that will be obtained are the participants' name, phone numbers, and email or mailing addresses for setting up interview appointments and mailing confirmation letters. This IIF will be maintained at each of the local market research firms in their own proprietary files. These personal identifiers will not be linked to data and will not be shared with FSIS or RTI.

Participation in the focus groups is voluntary and participants will be advised that their responses will be treated in a secure manner and will not be linked to their names. During the focus groups, only first names will be used. Focus groups will be transcribed for use by the RTI research team in developing a report but participants' first names will be replaced with the word "participant." The digital audio tapes will be stored on a password protected share drive, accessible only to RTI project staff.

Assurances of data privacy and security are documented in the informed consent form (see Appendix F). The study protocol and instruments were reviewed and approved by RTI's Institutional Review Board (see Appendix D).

A.11. Justification for Questions of Sensitive Nature

During the focus group discussions, participants will not be asked any questions that are personal or sensitive in nature. However, during the recruitment of potential participants for the focus group with immunocompromised individuals, we will ask potential participants if they or household members have been diagnosed with cancer, diabetes, or other conditions that weaken the immune system. Individuals will not be asked for a specific diagnosis. Immunocompromised individuals are considered at risk for foodborne illness; thus, it is important to collect information on their or their caregivers' understanding and use of the SHI.

A.12. Estimates of Respondent Burden

The total estimated burden is 157 hours (see Table A-2). A local market research company in each location will recruit individuals from their databases and other sources, if necessary, using the screening questionnaires developed for study recruitment (see Appendix E). We estimate screening 480 individuals to obtain no more than 60 focus group participants (10 participants per group). Each screening is expected to take 8 minutes (0.133 hour), and each

focus group discussion is expected to last 1.45 hours. Before and after each group, participants will be asked to complete a short survey that will take about 3 minutes (0.05 hour) to complete.

Table A-2. Estimated Annual Reporting Burden

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening questionnaire	480	1	480	0.113 (8 min.)	64
Pre-discussion questionnaire	60	1	60	0.083 (3 min.)	3
Focus group discussion	60	1	60	1.45	87
Post-discussion questionnaire	60	1	60	0.083 (3 min.)	3
Total					157

The annualized cost to all respondents for the collection of information is \$2,648.59 (157 x \$16.87) at \$16.87 per hour (the 2013 U. S. median hourly wage rate). See http://www.bls.gov/oes/current/oes_nat.htm.

A.13. Capital and Start-Up Cost and Subsequent Maintenance

There are no capital, start-up, operating or maintenance costs associated with this information collection.

A.14. Annual Cost to Federal Government

The estimated total cost to the Federal Government for this information collection is \$100,053. The costs arise from the time spent by the contractor to develop and conduct the study, analyze the data, and prepare and deliver a final report.

A.15. Reasons for Changes in Burden

This is a new information collection.

A.16. Tabulation, Analysis, and Publication

The planned schedule for this information collection is shown in Table A-3. Once OMB approval is received, it will take up to 60 days to recruit individuals and conduct the six focus groups. The contractor will provide FSIS a summary report of the focus group discussions within 30 days of the last focus group. No statistical analyses will be conducted, and there are no plans to publish the data for statistical use. Dissemination of the study results may include internal briefings, presentations, and reports and posting on FSIS's Web site.

Table A-3. Project Schedule

Date	Activity
Within 60 days following OMB approval	Conduct six focus groups
Within 30 days following last focus group	Completion of focus group summary report

As mentioned previously, FSIS we will use the findings from the initial exploratory focus groups in conjunction with the break-even analysis to make a go/no go decision about whether to move forward with conducting a second round of consumer research to test proposed revisions to the SHI. The primary consideration for revising the current SHI is that most focus group participants think it would be useful to add the recommendation to use a food thermometer (and possibly information on endpoint temperatures) to the label. Since the development of the original SHI, FSIS now places greater emphasis on the recommendation for consumers to use a food thermometer. Additionally, only three endpoint temperatures are now recommended; thus, this information could be more easily incorporated on the label if consumers think that it would be useful. Secondary considerations for revising the current SHI are many participants believe the current label is hard understand, the current label is not useful because it is missing important information, or the current label does not encourage consumers

to follow the recommended practices. Although the decision making process on whether to move forward with additional consumer research to support revisions to the SHI will be somewhat subjective, the approach outlined in Table A.4 will help guide the Agency’s decision making process.

Table A-4. Analysis of Focus Group Data: Go/No Go Decision for Conducting Second Round of Consumer Research

<i>The Agency will consider moving forward with conducting a second round of consumer research to test alternative formats for the SHI if two or more of the following conditions are met:</i>	
Section of Moderator Guide and Item Number ^a	Condition
Section IV, Responses to Possible Modifications to SHI, Item 2 – Recommendation to Use a Food Thermometer	Majority (i.e., more than half) of participants in at least 4 of the 6 groups believed the recommendation for consumers to use a food thermometer is important for consumers to know and should be added to the label
Section IV, Responses to Possible Modifications to SHI, Item 3 – Recommendation to Add Endpoint Temperatures for Different Cuts of Meat/Poultry	Majority of participants in at least 4 of the 6 groups believed the information on different endpoints is important for consumers to know and should be added to the label
Section III, Awareness and Use of Current SHI, Item 3 – Comprehension	Majority of participants in at least 4 of the 6 groups found the current label confusing or hard to understand
Section III, Awareness and Use of Current SHI, Item 4 – Usefulness	Majority of participants in at least 4 of the 6 groups believed information was missing from the label (in particular, instructions to use a food thermometer)
Section III, Awareness and Use of Current SHI, Item 8 – Persuasiveness/Behavior Change	Majority of participants in at least 4 of the 6 groups believed changes were necessary to the current label to encourage people to follow the recommended practices

Section IV, Responses to Possible Modifications to SHI, Item 4 – Recommendation to Add Source for More Information	Majority of participants in at least 4 of the 6 groups believed it would be useful to add source for consumers to get more information (e.g., Web site or phone number)
Section V, Food Safe Families Logo, Item 3 – Replace icons on current SHI with Food Safe Families (FSF) icons	Majority of participants in at least 4 of the 6 groups believed that replacing the current icons with the FSF icons would encourage consumers to follow the recommended practices

^a Appendix A.1 provides a copy of the moderator guide.

A.17. OMB Approval Number Display

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

A.18. Exceptions to the Certification

There are no exceptions to the certification.

References

McKenzie, B., & Rapino, M. (2011). *Commuting in the United States: 2009*. Supplemental Table C. Mean travel time to work by means of transportation and selected characteristics: 2009. Washington, DC: U.S. Census Bureau.

Murphy-Jenkins, R. (2014, January). *Food safety handling labels*. Washington, DC: USDA, FSIS. Retrieved from <http://www.fsis.usda.gov/wps/wcm/connect/9adeea60-4d52-4eb6-a15a-8e15b6873192/NACMPI-Food-Safety-Handling-Labels-010714.pdf?MOD=AJPERES>

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Food-Safe-Handling-Labels-NACMPI.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/70d59a26-32bb-4d25-9050-462b0b0cacb5/Food-Safe-Handling-Labels-NACMPI.pdf?MOD=AJPERES)

Teague, J. L., & Anderson, D. W. (1993). *Consumer focus groups on safe-handling labels for the pathogen reduction effort*. Final report prepared for USDA, Food Safety and Inspection Service. Research Triangle Park, NC: RTI International.

Teague, J. L., & Anderson, D. W. (1995). Consumer preferences for safe handling labels on meat and poultry. *The Journal of Consumer Affairs*, 29(1), 108–127.