DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0021]


AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to collect information in the form of consumer research that will include a web-based experimental study and a behavior change study to help inform potential revisions to the current Safe Handling Instructions (SHI) label and assess whether a label revision would improve consumer food safety behaviors. FSIS also will collect information on consumer use and understanding of the labeling on ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products, in particular consumers’ ability to discern between the two types of products...
and to ensure that NRTE products that may appear to be ready to eat are thoroughly cooked.

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this Federal Register notice. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2018-0021. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.
Title: Consumer Research on the Safe Handling Instructions Label for Raw and Partially Cooked Meat and Poultry Products and Labeling Statements for Ready-to-Eat and Not-Ready-to-Eat Products

Type of Request: New information collection.

Abstract: Safe handling instructions are required on the labels of raw or partially-cooked (i.e., not considered RTE) meat and poultry products, if the product is destined for household consumers or institutional uses (9 CFR 317.2(l) and 9 CFR 381.125(b)). FSIS first required the SHI label for raw and partially cooked meat and poultry products in 1994 (54 FR 14528). Since that time, the required design of the SHI label has not been changed.

When the SHI label was developed in 1994, the minimal internal temperature requirements for determining whether a meat
or poultry product was cooked enough to be safe varied by product. Given this, as well as product and label size limitations, FSIS concluded that “Cook Thoroughly” was the only simple, single statement appropriate to use for all products (54 FR 14538). FSIS now recommends on its website four internal minimal temperatures: one for all poultry (165°F), one for ground meat (160°F), one for all whole-muscle meat (145°F and hold for 3 minutes), and one for fish (145°F). With only four temperature recommendations, the information could be more easily incorporated into the SHI requirements. Other possible changes to the SHI label include incorporating updated icons and providing a web link or phone number for more information.

In response to inquiries from consumer groups and other stakeholders 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. The NACMPI Subcommittee on Food Handling Labels recommended that FSIS pursue changes in the existing SHI label and conduct consumer research to determine the effectiveness of any revisions to the SHI label.

In 2015, FSIS conducted six consumer focus groups (OMB No. 0583-0166; 11/30/2017) to evaluate understanding of the current SHI label and responses to possible revisions. The focus groups
revealed that consumers would find certain revisions to the SHI label useful. Participants suggested changes to improve comprehension and adherence to recommended safe handling practices (e.g., add recommendations to use a food thermometer and endpoint temperatures for different cuts of meat and poultry). Based on the results of these focus groups, FSIS determined that additional research using more rigorous, quantitative approaches with a larger sample of consumers was needed to help inform potential revisions to the current SHI label and assess whether a label revision would improve consumer food safety behaviors.

In addition, during the March 2016 NACMPI meeting, the national advisory committee reviewed and discussed whether FSIS should pursue proposing mandatory features on the label of processed NRTE products that may appear to be fully cooked (e.g., are breaded or have grill marks). The committee recommended that FSIS require statements, such as “Raw,” “Uncooked,” or “Ready to Cook,” on the labels of raw products that may appear RTE, so it is clear that these products require cooking to a proper internal temperature before eating. The committee also recommended that FSIS conduct consumer research to understand the optimal messaging and design of packaging to ensure consumers properly understand that NRTE products that may appear to be fully cooked need to be cooked for lethality. The
committee stated that such labeling may help consumers properly distinguish between NRTE products, which require a lethality step, and RTE products, which do not require a lethality step; thus, the committee stated that this labeling may help consumers safely prepare NRTE products. Specifically, the committee suggested that FSIS conduct consumer research to evaluate the effectiveness of possible locations for point of purchase labeling information and various color options, font, and other display options. FSIS has not previously conducted research on this topic.

To assess whether revisions are needed to the SHI label required on all raw and partially cooked products and to evaluate the ability of consumers to properly discern between NRTE and RTE products and how labeling for these products can be improved, FSIS is requesting approval for a new information collection to conduct consumer behavior research. This research will include a web-based experimental study, as well as a behavior change study, which includes three components: an observational meal preparation experiment, an eye-tracking study, and in-depth interviews (IDIs). The research will help inform potential revisions to the current SHI label and assess whether a label revision would be likely to improve consumer behaviors related to safely preparing raw and partially cooked meat and poultry products. The study will also collect
information on consumer use and understanding of labeling for RTE and NRTE meat and poultry products.

FSIS has contracted with RTI International to conduct the web-based experimental study and the behavior change study. For the web-based experimental study, a selected sample of online consumer panel members will be invited to participate in the study via e-mail. Inbound sampling will be used to select a sample of respondents with demographic characteristics (e.g., age, education level, race, and ethnicity) similar to the U.S. population. The primary aim of the web-based experimental study is to test 25 mock SHI labels that vary by visual design elements (e.g., borders, white space, spatial arrangement) to determine which labels are most salient to consumers. Label salience (i.e., participants’ degree of attention to the label) will be assessed using a limited-time exposure approach with cued recall questions. Secondary aims of the study include assessing comprehension of safe handling instructions and safe handling icons and measuring the participants’ motivation to comply with safe handling messages. The data from the experimental study will be analyzed to identify the five SHI labels that best attract respondents’ attention, and from these, three labels will be selected for further testing in the behavior change study.
To assess and compare consumer behavior in response to the current SHI label (control) and the three alternative SHI labels, a behavior change study will be conducted in test kitchen facilities located in four different locations (one in each of four Census regions). Participants will be recruited using convenience sampling (e.g., by posting ads on social media). The study will ensure a diverse sample of participants with respect to race, ethnicity, age, education level, and presence of a child (0-17 years) in the household. The study will use a fully randomized experimental design with participants randomly assigned to one of three treatment groups (that will be used to assess three alternative SHIs) or a control group (that will be used to assess the current SHI). Participants will be given recipes and ingredients, including two raw meat products bearing the assigned SHI label and asked to prepare two meat dishes and a salad. To assess attention to the SHI label during meal preparation, participants will wear a mobile eye-tracking device. Research staff will video-record meal preparation and clean-up. Trained researchers will subsequently view the videos and use a coding rubric to assess adherence to the recommended safe handling instructions (e.g., washing hands before meal preparation and after touching raw meat). Statistical analysis comparing the differences in handling behavior scores between the control (current SHI label)
and treatment groups will be conducted to identify the label that may most effectively lead to participants’ following the safe handling practices on the label.

Following meal preparation, participants will be directed to examine each of six mock meat and poultry products (i.e., stimuli) while wearing the eye-tracking device: two RTE products, two NRTE products that appear ready to eat, and two raw products. Participants will be asked to complete a series of search tasks to determine which version of the SHI label (three treatment versions or the current label) is most often attended to on a meat and poultry package and to assess whether participants can properly distinguish between RTE and NRTE products that appear to be ready to eat. Eye-tracking metrics for each area of interest (AOI), including total time spent viewing each AOI, will be produced and used in statistical analyses to determine the label that best captures participants’ attention.

Lastly, participants will take part in an IDI and be asked debriefing questions regarding the meal preparation experiment and questions to understand how consumers determine whether a meat or poultry product needs to be cooked before eating it. The data will be analyzed by analysts using a thematic content analysis approach.
Estimate of Burden: For the pretest for the web-based experimental study, it is expected that 1,700 individuals will receive email invitations to complete the study and that 100 will be eligible and subsequently complete the study. For the web-based experimental study, it is expected that 70,000 individuals will receive email invitations to complete the study and that 3,600 will be eligible and subsequently complete the study. The invitation email for the pretest and the full-scale study is expected to take 2 minutes to read (0.033 hour). The survey is expected to take 20 minutes to complete. The total estimated burden of the web-based experimental study is 3,623.3 hours.

For the behavior change study, it is expected that 1,695 individuals will complete the screener and that 565 will be eligible and subsequently be contacted by phone to schedule an appointment. Of these, it is assumed that 480 will take part in the study. Each screening is expected to take 8 minutes (0.133 hour). It is expected to take 7 minutes (0.117 hour) to read or listen to each appointment call/confirmation email/reminder call. It is expected to take 10 minutes (0.167 hour) to read the informed consent form and watch the instructional video. Taking part in the behavior change study will take a total of 140 minutes (2.333 hours), which includes an observational meal preparation experiment (80 minutes), an eye-tracking component
(30 minutes), and IDIs (30 minutes). The estimated annual reporting burden for the behavior change study is 1,491.9 hours, which is the sum of the burden estimates for each component of the study (including the burden for individuals who initially complete the screener but are not eligible or do not agree to participate).

For all components of the information collection, the estimated total number of individuals to be screened is 73,395, and the estimated total number of individuals to complete the web-based experimental study, including pretest, and the behavior change study is 4,180. The estimated total burden for the information collection is 5,115.2 hours.

Estimated Annual Reporting Burden for the Web-Based Experimental Study and the Behavior Change Study

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<tr>
<th>Study Component</th>
<th>Estimated No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
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<td>Pretest invitation</td>
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<td></td>
<td># of Subjects</td>
<td># Responses</td>
<td># of Submissions</td>
<td>Average Time (min.)</td>
<td>Total Time</td>
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<td></td>
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<td>Total</td>
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Estimated Annual Reporting Burden for the Web-Based Experimental Study and the Behavior Change Study (continued)

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<th>Behavior Change Study</th>
<th># of Subjects</th>
<th># Responses</th>
<th># of Submissions</th>
<th>Average Time (min.)</th>
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<td>reminder phone script</td>
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<td>Consent form</td>
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and video (10 min.)

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<th>Meal Preparation, eye-tracking &amp; in-depth interviews</th>
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**Total**

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**Total**

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<th>5,115.2</th>
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**Respondents:** Consumers.

**Estimated No. of Respondents:** 73,395

**Estimated No. of Annual Responses per Respondent:** 1.

**Estimated Total Burden on Respondents:** 5,115.2 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of
information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

**Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this *Federal Register* publication on-line through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, *Federal Register* notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the
FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Fax: (202) 690-7442
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Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Paul Kiecker,
Acting Administrator.

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