

**Supporting Statement for
Experimental Study of *Trans* Fat Claims on Foods
OMB No. 0910-0533**

B. COLLECTION OF INFORMATION USING STATISTICAL METHODS

1. Universe and Sampling

The study uses an Internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will be implemented using a convenience sample drawn from a large national consumer Internet panel with one million households. The consumer panel includes consumers who span the full range of education, age, race and income characteristics in the population. By implementing the study in such a sample frame the generalizability of the findings to a large fraction of the general population is ensured.

Participants will be adults, aged 18 and older, who agree to participate in a study about foods and food labels. Each participant will be randomly assigned to one of 144 experimental conditions.

2. Procedures for Collecting Information

Participants will be asked to review the package labeling of one product presented to them and then answer questions about the product's perceived health benefits and nutritional characteristics and other questions (see Attachment F: Draft Questionnaire).

Participants will view a two-dimensional color mock-up of a food label. For each product, the front panel will be presented first, followed by some questions about the product. Then the participant will look at the back panel of the product label that contains a Nutrition Facts Panel (NFP) for the food product. Participants then answer a series of product perception questions related to expected health benefits and perceived nutritional characteristics of the product.

Key Product Perception Questions

1. How likely is it that eating this food as a regular part of your diet would raise the risk of [disease/health condition]? 7-point rating scale from 1 ("Very Likely" 1) to 7 ("Very Unlikely")

Will be asked for three health conditions (heart disease, high blood cholesterol, overweight and high blood pressure).

2. Do you consider this product to be high, medium or low in... [list of nutrients-calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, carbohydrates]?
3. Overall, how important would [this margarine/pound cake]/[these crackers] be as part of a healthy diet? On a scale from 1 to 7 where 1 means "Very Important" and 7 means "Not at all Important."

Background questions will include standard demographics, current food label use, and health status.

In the Full Information condition, participants will read a one-page summary of the current state of scientific evidence for the health effects of *trans* fat in the diet. Nutrition scientists at FDA will review the summary for accuracy. The Full Information summary will be presented prior to viewing any labels.

Analysis Plan

This study can be viewed as an evaluation of the impact of *trans* fat content claims on judgment accuracy. Judgment accuracy will be bounded by the performance of participants in several comparison conditions: those who see no *trans* fat content claims, those who are "fully informed" about *trans* fat, and those who see the same product with varying fatty acid profiles. The impact of *trans* fat content claims and accompanying information statements will be assessed by estimating the discrepancy between participants' judgments made under these conditions compared to participants' judgments made under the respective comparison conditions. It will be possible to estimate the experimental effects of content claims and accompanying statements compared to no claims, depending on whether participants are fully informed or not, and depending on the product's fatty acid profile. Analysis of variance with specific contrasts and multivariate regression techniques will be used.

3. Methods to Increase or Maximize Response Rates

Participants are sent multiple reminders asking them to complete the interview instrument. Because participants are practiced at accessing and completing such instruments, no additional measures are necessary.

4. Tests of Procedures or Methods

The contractor will conduct three waves of Internet pretests. The first wave will include up to 15 participants. Any procedural problems identified in the first wave will be addressed and the revised procedures tested on a second wave of up to 15 participants. If additional modifications are needed, the revised procedures

will be tested on up to 10 participants. Prior experience shows that this number of pretests will be sufficient to identify and correct any procedural problems in the study.

5. Identification of Consultation

The contact individuals are Alan S. Levy, Ph.D., Consumer Studies Staff, Office of Regulations and Policy , HFS-727, telephone (301) 436-1762 (Project Officer), and Brenda M. Derby, Ph.D., Consumer Studies Staff, Office of Regulations and Policy HFS-727, telephone (301) 436-1832 (Statistician), and David B. Lambert, Ph.D., Senior Vice President, TNS Intersearch, (215) 442-9638.

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