FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Front-of-Pack Focus Groups

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Front-of-Pack Focus Groups."

   The U.S. is continuing to face an epidemic of diet-related chronic diseases, many of which are experienced disproportionately by racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas. To help address this problem, FDA has continued to prioritize its nutrition activities[1] by leveraging its authority to help empower consumers with nutrition information and facilitating industry innovation for healthier foods. FDA is focused on 1) creating a healthier food supply for all; 2) establishing a healthy start to set the foundation for a long, healthy life; and 3) empowering consumers through informative labeling and targeted education.

   As part of its labeling efforts, FDA is exploring the establishment of a standardized, science-based front-of-pack (FOP) scheme that helps consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern.

   Scientific Literature on FOP

   In Spring of 2018 FDA conducted a systematic review of the scientific literature on FOP symbols, noting that there had been several such reviews conducted in the recent past. FDA is also monitoring the scientific literature on FOP as it is published. A seminal 2005 literature review published by Cowburn and Stockley on consumer understanding and use of nutrition labeling summarized more than 100 studies[2]. That 2005 review concluded that FOP interpretational aids could contribute to consumers making healthy point-of-purchase choices and, moreover, that these aids could help consumers interpret the contribution of the food to the overall diet.

[1] https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives

[2] Cowburn and Stockley. 2005 Consumer understanding and use of nutrition labeling: a systematic review. Public health Nutrition 8(1):21-28.

The first large systematic review of FOP nutrition indicators was conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM)[3], with its findings published in 2010. This report, requested by Congress, evaluated the international landscape on FOP nutrition symbol created by manufacturers, supermarkets, organizations, and governments. The report discusses three types of FOP symbols: 1) Nutrient-Specific Systems; 2) Summary Indicator Systems; and 3) Food Group Information Systems. The key takeaways were that a FOP rating system or symbol could help consumers identify and select healthy foods; that calories and serving size would be helpful to include in the symbol; and that further testing of consumer use and understanding of "nutrient-specific information" or a "summary indicator" would be necessary. The NASEM report also concluded that a FOP symbol should be geared toward the general population.

NASEM produced a Phase II report[4] in 2012, focused on consumers' use of FOP symbols. The Phase II report concluded that, for a FOP symbol to encourage healthier food choices, a simple summary symbol "…that serves as a signal or cue…" would be better than detailed information about nutrient content; the Phase II report recommended "…shifting from an informational approach to an interpretive one…," and asserted that a successful symbol system would encourage product reformulation or development of products that meet the criteria.

Meanwhile, FDA commissioned a literature review to update the Cowburn and Stockley (2005) literature review. The 2011 FDA literature review (published by Hersey, et al, 2013)[5] looked at scientific studies on FOP and Shelf Label Nutrition Systems - to learn which types of FOP systems are most effective for influencing healthy food choices. This literature review found that summary systems incorporating text and color worked better than those using only numeric information in attracting consumer attention and getting them to make healthier food choices.

In 2016, FDA commissioned an update to the 2011 literature review. This update (published by Research Triangle Institute, 2016) captured the scientific literature on FOP from 2010 to August 2016[6]. Similar to previous reviews, the addendum reported that 1) the literature suggests that graphic elements help consumers with food purchase decisions; 2) consumers, no matter the nutrition literacy, prefer visually simple labels that are quick and easy to read over those that have more complex numerical information; 3) color coding with some text leads to better understanding of the nutrition information; 4) there is not enough evidence to indicate exactly which type of FOP label most influences consumers' behavior; and 5) there is some evidence that FOP labels influence sales but no evidence on whether they lead to decreasing consumption of nutrients to limit or increasing consumption of nutrients to get enough of.

[3] IOMa (Institute of Medicine). 2010 Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report. Washington, DC: The National Academies Press.

[4] IOMb (Institute of Medicine). 2012. Front-of-Package Nutrition Ratings Systems and Symbols: Promoting Healthier Choices. Washington, DC: The National Academies Press.

[5] Hersey, JC, KC Wohlgenant, JE Arsenault, KM Kosa, MK Muth. 2013. Effects of front-of-package and shelf nutrition labeling systems on consumers. Nutrition Reviews. 71(1):1-14.

[6] Research Triangle Institute (RTI). 2016. Addendum to Policy Research for Front of Package Nutrition Labeling: Environmental Scan and Literature Review. Report prepared for U.S. Food and Drug Administration.

In 2018, FDA reviewed the scientific literature from August 2016 to present, using the same targeted database search algorithm and the analytical categories used in earlier reviews. Forty-four scientific articles on FOP were included in this 2018 literature summary. In short, the updated FDA 2018 review did not yield results different from what the literature over the years has already revealed.

Although the scientific literature on FOP is nuanced because of variation in research focus, there are global take-aways from the literature on FOP:

- A FOP rating system or symbol can help consumers identify and select healthy foods.
- Consumers generally prefer visually simple labels (such as the ones using a summary system).
- There is limited research on 1) which type of summary system works best (and no agreement on defining "works best"); and 2) whether consumers' use of summary systems result in healthier diets.
- Some manufacturers have reformulated products following the implementation of FOP nutrition symbols; there is some evidence of increased sales of products bearing a FOP symbol.
- Institutional endorsement of logos may be related to greater confidence in the label.

As noted above, the initial NASEM report in 2010 categorized FOP schemes as 1) Nutrient-Specific Systems; 2) Summary Indicator Systems; and 3) Food Group Information Systems. More recently, Roberto[7] displayed the major types of FOP schemes in a grid that captures important FOP dimensions, many of which overlap between various symbols. Roberto summarized the five main FOP symbol types adopted by countries throughout the world.

Dimension	**Guideline Daily Amount (US firms)**	**Traffic Light (United Kingdom)**	**Nutri-Score (France)**	**Health Star Rating (Australia/New Zealand)**	**"High-in" (Chile)**
Symbol	No symbol	Traffic lights	Letters/colors	Star system	Stop sign displaying "high-in" statement(s)
Summary vs. Nutrient Specific	Nutrient-specific	Nutrient-specific	Summary	Summary	Nutrient-specific
Interpretive vs. Noninterpretive	Noninterpretive	Interpretive	Interpretive	Interpretive	Interpretive
Nutrient Threshold(s) for label display	No threshold	No threshold	No threshold	No threshold	Threshold

Prototype FOP Schemes for Eliciting Information from Consumers

[7] Roberto, Christina A. "The Influence of Front-of-Package Nutrition Labeling on Consumer Behavior and Product Reformulation." Annual review of nutrition. 41.1 (2021): 529–550. Web.

FDA first explored testing FOP schemes in 2009 by conducting focus groups and two experimental studies. That research tested a subset of the FOP schemes that this present focus group project is intending to explore, and the 2009 research goals were different from the focus of this current project. In summary, the conclusions of the 2009 FOP research were:

- At that time, no FOP system inspired consumers to focus on nutrition when making product decisions; only the Nutrition Facts label was able to do this.
- The Nutrition Facts label effect may have been due to the relative prominence of Nutrition Facts compared with FOP information on the front label, or the "brand identity" of Nutrition Facts label as a symbol of thinking about health.
- Consumer education and positive marketplace experience would enhance the prominence and "brand identity" of a widely adopted FOP system that would have a similar effect of the Nutrition Facts label.

Following the 2009 FDA label testing, Congress directed the Institute of Medicine (now NASEM) to create expert panels to examine FOP schemes and make recommendations on standardized schemes that food manufacturers could implement. During this time, food manufacturers offered that voluntary FOP systems of their own design could meet the nutrition information needs of consumers. In the intervening years, many nations around the world have adopted FOP schemes, of varying types, and numerous consumer studies have been carried out that support the value of FOP. In the United States, consumer and public health groups have urged FDA to revisit the issue, given the steady growth of diet-related disease, especially among populations that have lower nutrition literacy.

In 2018, FDA embarked on an exploration of a graphic representation of the nutrient content claim "healthy." Manufacturers can voluntarily use "healthy" on the product label when the product meets the FDA definition for using the claim. FDA conducted three sets of focus groups on the "healthy" symbol (ICR Reference Number for Phase III groups, 201911-0910-015) and are intending to conduct a consumer survey and experimental study after receiving OMB clearance for the research (Docket No. FDA 2021-N-0336). The "healthy" symbol and the FOP nutrition schemes are complementary, while also conveying different information and having different purposes. For example, both are intended to help consumers identify foods that are part of a healthy eating pattern, but the tested "healthy" symbol is a depiction of the nutrient content claim and an FOP scheme would aim at providing additional, complementary information. As the more recent literature demonstrates, the FOP schemes help consumers with lower nutrition literacy identify more quickly and easily foods that are part of a healthy eating pattern.

For the purposes of initial consumer testing in this current set of focus groups, FDA graphic designers developed a set of FOP prototypes largely based on schemes currently found in the marketplace. (See schemes to be tested in Appendix A). These schemes will be used to elicit information from consumers about the various elements in each scheme (e.g., use of numbers, color, summary words). The information may be used to develop a refined set of schemes for additional consumer testing. The schemes to be tested fall into three themes, each with variations and subtypes:

1. Guideline Daily Amounts (GDA) - lists calories and nutrients and the adult proportion recommended for daily consumption represented by a serving of the food.
2. Nutrition Tips – mimics the iconic design of the Nutrition Facts Label. Will include interpretive versions (High/Medium/Low, traffic light colors).
3. High-in – indicator showing the nutrient(s) and the daily values in the product that, per serving, are considered high and have recommended daily limits.

FDA is not planning to test any versions of the "summary" schemes (sometimes represented in the marketplace using stars or a letter grade to indicate the summarized overall nutrient profile). FDA is relying on the Nutrition Facts label and implementing regulations to provide the foundation for FOP schemes.

The focus group results will help FDA gain a better understanding of consumer reactions to FOP schemes and help determine which types are most useful to consumers, especially those of lower literacy. The focus groups will also help FDA understand which type of scheme works best for gaining consumers' attention and which may inform consumers which foods are part of a healthy eating pattern.

2. **Intended use of information:**
The information gathered from the FOP focus group research will help FDA assess the potential for establishing a FOP scheme that helps inform consumers, particularly those with lower nutrition literacy, quickly and easily which foods are part of a healthy eating pattern.

3. **Description of respondents:**
Groups will include only adults (18+) and will be segmented by level of nutrition motivation/literacy/knowledge (high/low), assessed using a brief set of questions garnered from validated measures for each dimension (see Appendix B for the participant screener). Segmenting by nutrition motivation/literacy/knowledge will help FDA understand how the schemes being tested perform with different audiences.

Groups will also be segmented by education level with a quarter of the groups being comprised of individuals with some university level courses and higher and three quarters with a community college degree and lower. The groups will have a mix of ages, race/ethnicities, and genders. No more than 6 participants will participate in a group (see Appendix B, Participant Screener).

4. **Date(s) to be conducted and location(s):**
Focus groups will be conducted approximately one month from the date of OMB approval. The study will enroll participants who reside in various regions of the United States. The focus groups will be conducted online.

5. **How the Information is being collected:**
<u>Recruitment Information</u>
The contractor will recruit participants using the participant screener (Appendix B). The recruiter will provide all necessary information and instructions to ensure participants

access the Zoom link on the agreed upon date and time. The contractor will ensure that the needed number of participants show up for their scheduled time slot. The contractor will send confirmation and reminder correspondences to recruited participants to help ensure participation.

Focus Group Discussions

The moderator will use the attached moderator's guide (Appendix C) to ensure that all relevant topic areas are addressed. The contractor will audio and video record the groups to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. **Number of focus groups:**
   A total of 12 online focus groups of 6 participants will be conducted.

7. **Amount and justification for any proposed incentive:**
   Based on our considerable experience conducting government focus groups with contractors, we propose an incentive of $75 as a token of our appreciation to participants. All focus group participants will receive their tokens of appreciation after all focus groups have been completed. This ensures that we can attract participants who meet our screening requirements to participate in the online focus groups and improve the likelihood that they will log on and participate in the discussion.

   The proposed incentive amount is below market rate for focus groups, whether online or in-person. Recruiting firms and researchers determine market rates for research participation based on what other comparable studies in the field are offering and what rate will incentivize the required population to participate in the research. Vendors estimate that studies conducted with similar populations and levels of effort in this market in 2020-2021 provide incentives of $100-$150. Our proposed incentive is based on participants spending approximately two hours of their time on this effort, which includes time spent for online and phone screening (5 minutes), time for testing the platform (10 minutes), time to participate in the focus group (75 minutes), and the request to log in 15 minutes early to confirm technical operation. The Bureau of Labor Statistics (BLS) calculated that the average hourly wage of employees on private nonfarm payrolls in July 2021 is $ $30.54 (Bureau of Labor Statistics, 2020)[8]. At that hourly rate, compensation for two hours is approximately $61. Additional factors contributing to the cost of our proposed incentive include:

   - Participants are required to join the group from a quiet location where there are no distractions, which may require childcare or special accommodations during that time. Participants cannot log into the focus groups from a public space, as that would violate the privacy of all participants and discussion topics of the focus

[8]Bureau of Labor Statistics, U.S. Department of Labor, Economic News Release, on the Internet at https://www.bls.gov/news.release/realer.htm#re_table1.f.p (visited August 18, 2021).

group. BLS calculated in May 2020 that the average hourly wage of childcare workers is $12.88, making the average cost of two hours of childcare $26 (Bureau of Labor Statistics, 2020)[9]. This national average, however, might not fully capture the variability in price and availability of childcare in each region. In fact, the Center for American Progress notes that over 80% of the counties they studied could be considered as an 'infant and toddler childcare desert'.[10] This need for childcare is likely vastly increased when considering that there might be even more limited supply of ad-hoc childcare at a participant's home during this COVID-19 pandemic.

- The focus groups will be conducted online, and participants must have a computer or tablet and broadband Internet to participate in the groups; participating will consume approximately two hours of data usage on their Internet plans, as well as utility fees. Computer or tablet usage could also be a factor if participants were to rent this equipment for 2 hours.

These factors become more restrictive when considering the unique challenges of this study population, which includes primary household food shoppers, most of whom are women[11]. Women are generally the primary caregivers both to children in the family and older relatives[12]. For example, nearly 25% of adults 45-64 years old are caregivers of adults 65 and older, and just over 25% of all U.S. women are caregivers.[13] On top of that, nearly 30% of family caregivers also have dependent children in their household.[14] This means that, prior to the COVID-19 pandemic, this population was already a challenge to recruit for focus groups, which necessitated a higher incentive. Unfortunately, the COVID-19 pandemic has not only further compounded the challenges for this already taxed population—but has also added new ones. For parents, this has meant serving as part-time teacher (for schools that still do partially or fully remote education), lab technician (in the case of administering at-home COVID tests), atop their other day-to-day obligations (work, home life, caregiving, etc.).[15]

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[9] Bureau of Labor Statistics, U.S. Department of Labor, Occupation Employment Statistics, on the Internet at https://www.bls.gov/oes/current/oes399011.htm. (visited August 18, 2021).

[10] Jessen-Howard S, Malik R, and Falgout MK. (2020). Costly and Unavailable: America Lacks Sufficient Child Care Supply for Infants and Toddlers. https://www.americanprogress.org/issues/early-childhood/reports/2020/08/04/488642/costly-unavailable-america-lacks-sufficient-child-care-supply-infants-toddlers/ (visited September 27, 2021).

[11] Flagg, LA, B. Sen, M. Kilgore, and J. Locher. 2014. The Influence of Gender, Age, Education, and Household Size on Meal preparation and Food Shopping Responsibilities. Public Health Nutrition. 17(9): 2061-2070.

[12] Hess, C. T. Ahmen, M. Phil, and J. Hayes. 2020 Providing Unpaid Household and Care Work in the United States: Uncovering Inequality. Institute for Women's Policy Research. Briefing Paper #C487. https://iwpr.org/wp-content/uploads/2020/01/IWPR-Providing-Unpaid-Household-and-Care-Work-in-the-United-States-Uncovering-Inequality.pdf

[13] Centers for Disease Control and Prevention. Caregiving for Family and Friends — A Public Health Issue. https://www.cdc.gov/aging/caregiving/caregiver-brief.html#:~:text=22.3%25%20of%20adults%20reported%20providing,in%20five%20(18.9%25)%20men. (visited September 27, 2021).

[14] AARP Public Policy Institute & National Alliance for Caregiving. (2015). *Caregiving in the US.* https://www.aarp.org/content/dam/aarp/ppi/2015/caregiving-in-the-united-states-2015-report-revised.pdf

[15] Yin T., Zhou Q., Bashford C. (2002). Burden on Family Members. *Nursing Research*, 51(3), 199–208. 10.1097/00006199-200205000-00009.

In FDA's and our contractor's experience, offering lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and may result in longer recruiting time as well as higher overall project costs to the government (for which additional funding is not available). Lower or nonmonetary incentives generally produce participation rates no better than the complete absence of any incentives.[16] The consequences of offering an insufficient incentive include the following:

- Increased time and cost of recruitment due to lower response and enrollment levels, and/or the need to schedule additional groups to achieve the overall number of participants.
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants).
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and places additional burden on the recruited participants who have to reschedule their participation in the focus group.

8. **Questions of a Sensitive Nature:**
None.

9. **Description of statistical methods (i.e., sample size & method of selection):**
The Contractor will contact prospective participants and screen them for eligibility to participate (Appendix B). he contractor will provide all necessary information and instructions to ensure participants can access the Zoom link at the agreed upon date and time. The contractor will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

Table 1 shows the estimated annual reporting burden for the groups, assuming 6 participants per group.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	120	5	10
Focus group discussion	72	90	108
Total			118

[16]See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. Public Opinion Quarterly, 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. Maternal and Child Health Journal, 16(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: Studies of welfare populations: Data collection and research issues, 105-128.

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