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:

Consumer Knowledge and Behavior Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed – Wave IV: Focus Groups Exploring Consumer Reactions to Educational Materials

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, "Consumer Knowledge and Behavior Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed – Wave IV: Focus Groups Exploring Consumer Reactions to Educational Materials." Similar focus group studies were previously approved by OMB for Wave I focus groups (approved 01/23/2018), Wave II focus groups (approved 08/06/2018), and Wave III focus groups (approved 05/02/2019). The objective of this study is to examine consumer reactions to draft educational materials providing information on environmental and humanitarian impact of biotechnology-derived foods and feed as well as consumer-tailored information of genome editing.

Some evidence suggests consumers' limited knowledge and understanding of agricultural biotechnology poses a significant barrier to their being able to make well-informed decisions about the purchase and use of these products (Wunderlich and Gatto, 2015; Wunderlich, et al, 2017; McFadden and Lusk, 2017). FDA proposes a targeted public information and education initiative to advance knowledge and understanding about biotechnology and FDA's role in regulating human and animal biotech foods and feed prior to such products reaching the market.

FDA, in coordination with the Secretary of Agriculture, was commissioned to "provide consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products and animal feed," henceforth referred to as "biotech foods and feed." The education and outreach are intended to be implemented "through publication and distribution of science based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology, food products, and feed" (Consolidated Appropriations Act, 2017).

Representatives from the USDA's Agricultural Marketing Service, the USDA's Foreign Agricultural Service, and the USDA's Animal and Plant Health Inspection Service; and the EPA's Office of Pesticide Programs are included in the biotech foods and feed consumer research project as well as the biotech education initiative. These representatives are active members of the Consumer Research Workgroup and the Steering Committee, both established specifically for this initiative. The Consumer Research Workgroup oversees the consumer research process and the

Steering Committee oversees the entire education initiative. FDA shares all study instruments and reports with these representatives from USDA and EPA; the representatives will also receive an opportunity to provide input and observe all focus groups in real time.

Findings from the consumer research component of this initiative is being utilized to provide input into the development of educational messages and the outreach strategy for informing and educating the American public about biotechnology-derived foods and feed.

The Wave IV focus groups follow the three prior waves of focus groups that explored consumers' reactions to educational concepts and initial informational pieces on biotechnology. Prior waves of testing lead to the development of draft educational materials to be tested in Wave IV. The Wave IV materials are a thematic expansion of the FDA informational initiative; they cover environmental and humanitarian impact of biotechnology derived foods and animal feed as well as provide consumer-tailored information on genome editing.

Participants in the focus groups for this study will be notified that the study is being conducted on behalf of the U.S. Food and Drug Administration when they participate in the study.

2. **Intended use of information:**

The consumer research component of this initiative provides valuable input for both the development of educational materials/messages and the outreach strategy for informing and educating the American public about biotech-derived foods and feed.

The educational materials to be tested in Wave IV will be a continuation and an expansion of the existing FDA education initiative and will be primarily found as part of a website hosted by FDA. Moreover, FDA will dedicate a section of the Website to the new USDA labeling requirements and will link to the USDA's Website for obtaining more information.

A list of the materials to be tested follows (materials are available in the attached Appendix V):

- GMOs 101 Fact Sheet
- Environmental Impacts Infographic
- Humanitarian Impacts Infographic
- Genome Editing Fact Sheet

3. **Description of respondents:**

The Wave IV draft material testing research will consist of 16 focus groups with adult participants who do most of the grocery shopping for their households. All groups will include individuals ages 18 and over and will include participants of diverse ages and races/ethnicities. (See Appendix I)

The focus groups will be segmented to align with the key target audiences identified for the initiative, which include:

- African American adults who are primary food shoppers and/or cook at least three meals per week for their households (we recommend two to four groups with this audience)
- Hispanic adults who are primary food shoppers and/or cook at least three meals per week for their households (we recommend two to four groups with this audience)

- Young adults (i.e., ages 18–24) who are primary food shoppers and/or cook at least three meals per week for their households (we recommend two to four groups with this audience)
- General adults, segmented as in previous focus group waves — two groups with lower education level and two groups with higher education level.

Participants will be recruited from different locations throughout the United States. Eligibility criteria (see Population column in Table 1) have been established to ensure minimal overlap across participant segments.
Table 1.

Group #	Population	Location/Segmentation	Time
1	African Americans 25 years and up	NYC	7p EDT
2		Chicago	8p EDT
3		Dallas/Houston	8p EDT
4		LA/SD	9p EDT
5	Hispanics 25 years and up	NYC	7p EDT
6		Miami	7p EDT
7		Dallas/Houston	8p EDT
8		LA/SD	9p EDT
9	Young Adults 18-24 years old, all races/ethnicities	NYC	7p EDT
10		Chicago	8p EDT
11		Dallas/Houston	8p EDT
12		LA/SD	9p EDT
13	General Adults 25 and up, NOT AA and NOT Hispanic	Lower Ed (NYC)	7p EDT
14		Higher Ed (Chicago)	8p EDT
15		Lower Ed (Dallas/Houston)	8p EDT
16		Higher Ed (LA/SD)	9p EDT

Focus Group Segmentation

Focus groups will begin in June 2022, approximately four weeks from the date of OMB approval. All focus groups will be conducted online via Zoom Webinar. Selected cities have professional focus group facilities and a large enough population to ensure recruitment success.

4. **How the information is being collected:**

Recruitment Information

All recruitment will be conducted by a professional focus group facility, PRC, which will enable us to meet the criteria described in section 3, above. Recruitment strategies for these facilities include outreach to their proprietary databases; placement of ads in local media outlets, such as in newspapers and the local Craigslist site, and in venues where consumers who are particularly interested in biotechnology-derived foods and feed may be found (e.g., bulletin boards at local restaurants, grocery stores, and farmers' markets). Content for these advertisements can be found in Appendix II.

For all online focus groups participants will provided all necessary information and instructions to ensure successful login into Zoom Webinar platform on the agreed upon date and time. Westat, the contractor selected for Wave IV, will oversee recruitment. PRC recruiters will ensure that eligible participants show up for their scheduled time slot by sending confirmation and reminder correspondences to recruited participants. Participants will also receive a copy of the informed consent form (Appendix III) in one or more of these correspondences from PRC and will be instructed to review the form prior to their scheduled focus group.

Focus Group Discussions

A Westat senior social science researcher will serve as a moderator for all focus groups. Prior to beginning each discussion, the moderator will review the key elements of the informed consent form (Appendix III) and answer any questions participants may have about their rights as research participants. The moderator will then use the attached moderator's guide (Appendix IV) to ensure that all relevant topic areas are addressed.

Prior to beginning the discussion, the moderator will ensure that the FDA project director and other members of this initiative may observe all the sessions via Zoom Webinar platform. The streaming technology will allow to produce both audio and video recordings of each group, as well as provide a near-verbatim transcript of each discussion, to ensure that participants' views and opinions are accurately captured. These transcripts will form the basis of the data analysis.

Westat and the contracted vendors (PRC) 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 materials shared with FDA (e.g., recruitment updates) and will be removed from participant screen names upon entry into the Zoom platform. Verbatim quotes included in the final report will not be attributed to any individual.

5. **Number of focus groups:**

Sixteen focus groups will be conducted. We will recruit 8 participants per group, however, we will only select 5-6 to participate in the discussion and the remaining participants will be dismissed.

6. Amount and justification for any proposed incentive:

To prepare for these focus groups, we consulted with recruitment facilities that provide focus group participants to determine incentive rates. Based on these consultations, we propose offering $75 to show a token of our appreciation to participants. The incentives will ensure that we are able to attract desired participants who meet our screening requirements to participate in the focus groups. In the previous waves I through III conducted in 2018 and 2019, OMB approved a $75 token of appreciation.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment;

- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants); and
- Increased probability that a focus group may need to be cancelled or postponed because of insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs but also puts additional burden on the recruited participants who must reschedule their participation in the focus group.

Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the focus groups. The proposed amounts are comparable to what has been the level of reimbursement for the target audiences in similar government-funded activities. As noted above, we expect that lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

The proposed incentive amount is considered to be 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 (90 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)[1]. 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 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)[2]. This national average, however, might not fully capture the variability in price and availability of childcare in a given 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 child care desert'.[3] 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.

[1]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).
[2]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).
[3] 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).

- 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 all the more restrictive when considering the unique challenges of this particular study population of women 45 years of age and older. 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.[4] On top of that, nearly 30% of family caregivers also have dependent children in their household.[5] 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.).[6]

This study also recruits U.S. women 65 years and older, which itself poses additional challenges to the recruitment. Pew links not using internet to older age, lower education, and lower income, which reflects a key segment of this study.[7] Pew also finds that 34% of older internet users (65+) say they have little to no confidence in their ability to use electronic devices to perform online tasks, suggesting the need for a higher incentive to encourage older adults to overcome their discomfort to join a virtual group.[8]

In Westat and their vendors' experiences, 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.[9] The consequences of offering an insufficient incentive include the following:

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[4] 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).

[5] 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

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

[7] Perrin A and Atske S. 7% of Americans don't use the internet. Who are they? | Pew Research Center (visited September 28, 2021).

[8] Anderson M and Perrin A. Tech Adoption Climbs Among Older Americans | Pew Research Center (visited September 28, 2021).

[9]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.

- 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).
- Skewed participant demographics, with increased representation of participants with lower incomes and lower education levels.
- 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.

7. Questions of a Sensitive Nature:

There will be no questions of a sensitive nature asked of participants.

8. Description of Statistical Methods (i.e., Sample Size and Method of Selection):

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. PRC will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I).

For each focus group we will recruit eight in order to have five to six participants in each group. . To maximize participation rates, recruiters will make at least five attempts to contact each potential participant to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	384 (3 x 128)	5	32
Adult 18+	96 (6 x 16)	120	192
Total			224

REQUESTED APPROVAL DATE: July 7, 2022.

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FDA CENTER: Center for Safety and Applied Nutrition

Attachments:

Appendix I – Participant Screener
Appendix II – Recruitment Flyer
Appendix III – Informed Consent
Appendix IV – Moderator's Guide
Appendix V – Draft Materials (GMOs 101 Fact Sheet; Environmental Impacts Infographic; Humanitarian Impacts Infographic; and Genome Editing Fact Sheet.