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 III: 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 III: Focus Groups Exploring Consumer Reactions to Educational Materials." The objective of this study is to examine consumer reactions to draft educational materials providing information on biotechnology-derived foods and feed.

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 III focus groups follow the first and the second wave of focus groups that explored consumers' reactions to educational concepts on biotechnology leading to the development of draft educational materials to be tested in Wave III.

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.

In the previous phases of focus group research conducted by FDA in 2018 (Wave I and Wave II), we found out that participants are most familiar with the term "GMO" when referring to agricultural biotechnology; they use the term "GMO" when they talk about issues related to that topic. Additionally, the evidence from peer reviewed research in the literature review confirms that the term "GMO" is most familiar to consumers.

The educational materials to be tested in Wave III will be included in a context of a larger education initiative and will be primarily found as part of a website hosted by FDA. These materials are primarily intended to lead consumers to the Website and to introduce the topic. Once the Website is reached, consumers will be exposed to additional terminology including BE. As and example, the terms BE and GE are both introduced in the stimuli "GMO 101 web page content" in the second paragraph (please see Appendix V). 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.

Each tested piece will be placed in the context of a larger educational scope. The two social media visuals will play a role of drawing people's attention to the issue of agricultural biotechnology and make them visit a website; therefore, these social media visuals are not intended to answer all questions people may have about agricultural biotechnology but to encourage them to click on the link to the website.

A list of the materials to be tested follows (materials are available in the attachment):

- GMOs 101 web page content
- GMOs 201 web page content
- Timeline infographic
- Social media posts
- Video concept ("treatment")

3. **Description of respondents:**

The Wave III draft material testing research will consist of 20 focus groups with adult participants who do at least half of the grocery shopping for their households. All groups will include individuals ages 18 and over and will include a mix of participants of diverse ages and races/ethnicities. (See Appendix I)

These groups will be segmented by education levels of participants; half of the group discussions in each location will be conducted with lower education participants who hold an Associate's degree from a community college or lower; and the other half with higher educated participants who hold a Bachelor's degree or higher. Due to the high volume of test materials, participants in different groups will see varied examples of materials, so that in half of the focus groups in each location they will be shown 101 or 201 Web content and the infographic; and in the remaining groups they will see social media visuals and a video rendering. (See below.)

Focus Group Segmentation

Group Number	Location	Education	Test Materials
1	New York, NY	Lower education	101 Web and infographic
2		Lower education	Social media visuals and video
3		Higher education	201 Web content and infographic
4		Higher education	Social media visuals and video
5	Des Moines, IA	Lower education	201 Web and infographic
6		Lower education	Social media visuals and video
7		Higher education	101 Web content and infographic
8		Higher education	Social media visuals and video
9	Chicago, IL	Lower education	101 Web and infographic
10		Lower education	Social media visuals and video
11		Higher education	201 Web content and infographic
12		Higher education	Social media visuals and video
13	L.A., CA	Lower education	201 Web and infographic
14		Lower education	Social media visuals and video
15		Higher education	101 Web content and infographic
16		Higher education	Social media visuals and video
17	Dallas, TX	Lower education	101 Web and infographic
18		Lower education	Social media visuals and video
19		Higher education	201 Web content and infographic
20		Higher education	Social media visuals and video

Wave III focus groups will be conducted in one city of five different geographic regions: New York, NY; Des Moines, IA; Chicago, IL; Los Angeles, CA; and Dallas, TX.

Four groups will be conducted in each location, for a total of 20 focus groups. Focus groups will begin in May 2019, approximately six weeks from the date of OMB approval. Three urban locations were selected based on the demographic diversity of the local population; the presence of

a large population, which will contribute to recruitment success; and the availability of professional focus group facilities that have a proven track record of successful recruiting. Des Moines was selected because it is located near heavily agricultural areas in which the population may be more familiar with farming issues (e.g., understanding the value of biotechnology for large-scale food producers, but also having concerns about food or environmental safety). All 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 local professional focus group facility, 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.

In all five cities, facility staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. They will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

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 informed consent form (Appendix III) and have all participants sign and date one copy. The moderator will then use the attached moderator's guide (Appendix IV) to ensure that all relevant topic areas are addressed. The moderator's guide will be versioned. Version 1 will ask participants about their reactions to 101 or 201 Web content and infographic; and Version 2 will ask about social media visuals and a video rendering. As mentioned above, Version 1 will be used in half of the group discussions across different locations; and Version 2 will be used in the other half.

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 either from the observation rooms at the focus group facilities or remotely using streaming video technology. The streaming technology vendor will make 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 all contracted vendors (e.g., focus group facilities, streaming video vendor) 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.

5. **Number of focus groups:**

Twenty focus groups, each with 8 to 10 participants, will be conducted. We recruit 12 participants per group. We will only select 8-10 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 facilities that host focus groups 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 a reasonable cross section of participants who meet our screening requirements to participate in the focus groups.

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 have to 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. Incentives are based on (1) estimated costs related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately $48[1]; (2) estimated cost for an average driving commute to and from the facility of approximately $22[2] (including parking fees in locations selected for these focus groups); and (3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[3] 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.

[1] Assumes an hourly rate of $16 per hour for a professional babysitter

[2] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf, accessed 9/1/2018.

[3] 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.

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. The focus group facility in each location will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I).

Sufficient recruits will be screened in order to achieve a target of 8-10 participants per 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	800	5	67
Adult 18+	240	120	480
Total			547

REQUESTED APPROVAL DATE: May, 2019.

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Attachments:

Appendix I – Participant Screener
Appendix II – Recruitment Flyer
Appendix III – Informed Consent
Appendix IV – Moderator's Guide
Appendix V – Draft Materials