

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 I: Focus Groups Exploring Consumer Reactions to Educational Concepts

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 I: Focus Groups Exploring Consumer Reactions to Educational Concepts.” The objective of this study is to collect qualitative information from consumers regarding their attitudes, beliefs, and understanding of agricultural biotechnology, as well as examining their reactions to preliminary educational concepts providing information on biotechnology-derived foods and feed.

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 is 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 the purpose of this initiative. The Consumer Research Workgroup oversees the consumer research process and the Steering Committee oversees the entire education initiative. FDA will share 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.

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.

Findings from the consumer research component of this initiative will 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 I focus groups will be followed by a second wave of focus groups that will explore consumers’ reactions to close-to-final educational materials on biotechnology. We will seek a separate OMB review for the Wave II of this study.

2. Intended use of information:

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

Based on information from the literature review and additional input from educators and subject matter experts, the FDA’s creative team will develop preliminary message concepts and educational materials. These focus groups will examine adult participants’ reactions to the concepts, with a focus toward understanding how they respond, both cognitively and affectively, to different educational stimuli. The focus group findings will be used to further refine the concepts and develop educational materials.

3. Description of respondents:

The Concept Testing/Message Development research will consist of 20 focus groups with adult participants who do at least half of the grocery shopping for their households and who are at least somewhat knowledgeable and interested in issues of food and nutrition. All groups will include individuals ages 18 and over and will include participants of diverse ages and races/ethnicities. (See Appendix I)

These groups will be segmented by education level, gender and age 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; at the same time, half of all groups in each location will be conducted with female and the other half with male participants, as well as half of the groups in each location will be conducted with younger participants (18 to 34 years old) and half with older participants (35 to 65 years old). (See below.)

Focus Group Segmentation

Group No.	Location	Level of Education	Gender	Age
Group 1 & 2	Bethesda, MD (Metropolitan DC)	Higher	Female	Younger (18-34 year old)
			Male	Older (35-65 year old)
Lower		Female	Older (35-65 year old)	
		Male	Younger (18-34 year old)	
Group 5 & 6	Portland, ME (Northeast Coast)	Higher	Female	Older (35-65 year old)
			Male	Younger (18-34 year old)
Lower		Female	Younger (18-34 year old)	
		Male	Older (35-65 year old)	
Group 7 & 8			Female	Younger (18-34 year old)

			Male	Older (35-65 year old)
Group 9 & 10	Des Moines, IA (Midwest)	Higher	Female	Younger (18-34 year old)
			Male	Older (35-65 year old)
Group 11 & 12		Lower	Female	Older (35-65 year old)
			Male	Younger (18-34 year old)
Group 13 & 14	Atlanta, GA (South)	Higher	Female	Older (35-65 year old)
			Male	Younger (18-34 year old)
Group 15 & 16		Lower	Female	Younger (18-34 year old)
			Male	Older (35-65 year old)
Group 17 & 18	Spokane, WA (West Coast)	Higher	Female	Younger (18-34 year old)
			Male	Older (35-65 year old)
Group 19 & 20		Lower	Female	Older (35-65 year old)
			Male	Younger (18-34 year old)

4. **Date(s) to be conducted and location(s):**

Wave I focus groups will be conducted in one city in each of five different geographic regions: Bethesda, MD (Metropolitan DC); Portland, ME (Northern East Coast); Des Moines, IA (Midwest); Atlanta, GA (South); and Spokane, WA (West Coast). Four groups will be conducted in each location, for a total of 20 focus groups. Focus groups will begin in February 2018, 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. Both Des Moines and Spokane were selected because they are 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.

5. **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 questions related to knowledge and attitudes before showing informational concepts to participants; Version 2 will show concepts first and then ask questions related to knowledge and attitudes. Version 1 will be used in half of the group discussions across different locations, education levels, and genders; 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 private 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:

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.

7. 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 \$54¹; (2) estimated cost for an average driving commute to and from the facility of approximately \$20²; 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.

8. Questions of a Sensitive Nature:

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

9. 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 contractor 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: December 22, 2017

Ila S. Mizrachi (PRA Analyst)
Ila.Mizrachi@fda.hhs.gov
 301-796-7726

¹ Assumes an hourly rate of \$18 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/JSMProceedingspaper.pdf>, accessed 7/1/2016.
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.

Ewa Carlton (Program Contact)

ewa.carlton@fda.hhs.gov

240-402-2948

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 – Concept Mock-ups