# CREATIVE COMMUNICATIONS NETWORK, INC.

**PUBLIC RELATIONS ● ADVERTISING ● MARKETING**

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## Market Research Outline and Plan
## Cell Culture Food Industry
## January 26, 2021 (revised)

This research is being conducted for the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling (ONFL). The research is in support of the FDA Nutrition Innovation Strategy (NIS), which includes both modernization of labeling claims and modernization of food Standards of Identity (SOI) to achieve three primary goals: (1) protect consumer against economic adulteration; (2) maintain the basic nature, essential characteristics, and positive nutritional attributes of food; and (3) promote industry innovation and provide flexibility to encourage manufacturers to product more healthful foods.

Modernization of labeling claims and SOI, including any potential related regulations, requires that FDA know what changes are occurring in food production, manufacturing and marketing – specifically in the emerging cell culture food products industry. The cell culture meat industry presents a potential food revolution and major disruption of global and U.S. meat production as developed and practiced for more than a century. As noted in the blog Global AgInvesting.com in an October 30, 2020 analysis: "Now a global trend, 80 startups work on lab-grown meat worldwide in one way or another. Four years ago there were two." A look at the forces driving Cellular Agriculture indicates "lab-grown meat will be a part of everyday life in a surprisingly short time." The blog notes that between 2013 and the summer of 2020, the price for a serving of lab-grown meat has decreased at a faster rate than some of the most powerful technologies, including the transistor over a period of 12 years. The price drops of those technologies revolutionized societies. The same may be expected in meat production as cost per serving continues to sharply decrease.

This research will detail the current landscape of the cell culture food industry so as to inform policy decisions regarding labeling these foods produced using cell culture and related technology. The research will provide understanding of the potential market for these foods in the United States, the economic, environmental, and societal concerns driving the development of these food products, the companies developing these products, and the major, often multinational, companies investing in or partnering with those companies.

The research will detail the types of products each company is developing, the current and projected stages of development and scale-up for each product, the timeline for each product's test marketing and launch, the parameters of that launch, the names of the products and their

intended labeling and features/benefits claims. Some details may not be known or may be proprietary at the time of this research. The research will examine the multinational aspects of these companies and products – whether these companies intend to export, and what cell cultured foods and related products may seek to entry to the United States import market, and thus also require SOI and labeling regulation.

The foods that are the subject of this research are cell culture meat (beef, pork, lamb, etc.), poultry (chicken, turkey, etc.) and seafood (ocean and inland species). These are all encompassed in the term "animal." There are at a minimum 12 categories of inquiry for eliciting information and understanding, as incorporated in this research plan and the stages outlined:

1. What companies are developing cell culture technologies.
2. Which specific animal species are currently in development to have cell culture alternatives.
3. The physical forms of food that is anticipated to come into the marketplace.
4. Terms which might be used to describe the physical forms (for example, burgers, chunks, fillets, structured meat with added fat, etc.)
5. Potential marketing claims on products which are derived from cell culture production.
6. Estimates of when food products produced using cell culture technology will come to market.
7. The number and type of products currently on the market which contain cell culture animal products and plant-based proteins combined into one food.
8. An examination and forecasting of the market for "hybrid" non-animal-based products: a combination of cultured material and plant-based proteins.
9 An examination of statements of identity and claims that may be used for cell culture meat.
10. When foods produced from cell culture technology could first appear on the international market.
11. The availability and/or development of other foods produced using technologies similar to cell culture technology, but which do not use the cells of whole animals (for example, milk or egg proteins produced using yeast or bacterial cultures).

The research does not need to include plant-based foods unless they include cell culture meat, in which case labeling claims planned for these products should be identified. The research also does not need to include the specific types of cells (stem, satellite, etc.) each company uses in cell culture technical processes, nor the cell proliferation method (skeletal muscle explants, scaffold-based system) used by each company. The study does include the types of proteins being used in combination with traditional animal products that may be included in the cell culture food products (item 8), but the study does not need to include all the chemicals and ingredients that may be added or part of the meat production process. This information may be so proprietary companies will be hesitant to share the information. Again, primary focus is the marketable products in development, their launch horizon and any potential labeling statements or labeling claims firms may consider making.

Foreign companies usually will not be included in the research unless U.S. companies will be importing products or ingredients from cell culture meat producers in another country. How foreign governments regulate cell culture meats and related products will not be included unless their regulations could somehow interfere with or contradict U.S. regulations. The research should attempt to identify *when* cell culture foods from other countries can be expected to appear in the U.S. domestic market.

The research will include reviewing agribusiness press and information from meat and seafood trade organizations. These sources will provide insight as to attitudes, concerns, and defensive postures of the "status quo" producers, their trade organizations, market intermediaries, and processors.

The research phase of this study will take several months to complete because of the diversity of those 12 areas of inquiry and because of the ever-expanding universe of available documents and data, which will need to be reviewed by CCN for pertinence to the study and content. Throughout the data collection, analysis and reporting phases of this program CCN will work (in coordination by the Contracting Officer's Representative) with FDA expert economists and food technologists, PAG members, stakeholders, SMEs, and FDA staff working with CCN on this requirement. CCN will rely on them for advice, background information, insights and guidance as the research unfolds and questions arise. We will not be a pest, but do believe that partnership and dialog with these experts will help assure the proper focus is maintained and research/analysis stays on track to deliver the final report FDA needs.

## RESEARCH CONCEPT AND METHODOLOGY

This will be a Descriptive study with Observational/Conceptional research featuring extensive document/data collection and analysis, followed by select discussions via phone and/or email with stakeholders in the industry and science. These follow-up phone calls will be "informal" discussions, not surveys, and therefore will be exempt from the Paperwork Reduction Act. The purpose will be clarification or help interpreting information in documents, or industry trends. If sources are to be named and quoted directly, their portion of the report would need to be cleared with them (after FDA staff review and approval).

The most effective approach to eliciting the information required will be this hybrid combination of extensive qualitative research supplemented with quantitative data charts and graphics. The qualitative aspects will include gathering, analysis and cataloging of perhaps more than 100 documents, such as academic and industry papers, prior research, company and industry information and filings. FDA experts will occasionally be consulted to clarify or interpret issues identified during data collection. CCN will index documents collected and highlight key portions that would be cited. FDA and the PAG may be asked to review some of these outlines and provide comment/approval within set timeframe as requested so CCN can proceed with the analysis/reports.

The industry landscape data and interview documentation will enable summation and analysis, and creation of the study's final report. The quantitative data will summarize in text and charts many of the qualitative findings and also could include any consumer data CCN finds. While eliciting information regarding consumer demographics and expectations is not a major emphasis of this study, research findings may identify other sources of information on consumer attitudes toward cell culture meat. For example, Consumer Reports conducted a nationally representative phone survey in June 2018 that found the vast majority of Americans think that food produced from cultured animal cells should be differentiated in some way on the label. Also, data from a survey by a food and agriculture marketing firm found only 3% of consumers expressed "no reservations" about eating such products, while 57% responded, "No, absolutely not." A third survey, by a food trends research firm found that 68% said they were "not interested" in cultured meats. Consumer demographics and attitude data should help determine which segment of the U.S. population will be most likely to buy these products, and where. The industry data developed by this study, combined with how consumers perceive the products (i.e., dangerous, safe, misleading, etc.), will help FDA determine the urgency of defining these products and determining the needed level of compliance and enforcement or neither depending on consumer expectation.

The research contract deliverables table includes a guideline of 90 days for collection and analysis of the data beginning almost two months after contract award (actually, some data collection began weeks ago as part of proposal and plan development). This seems reasonable but this plan anticipates there will need to be flexibility in that schedule since it will overlap with holidays. CCN suggests 120 days for data collection because of the ever-expanding dynamics of the industry and information about it.

CCN will have 30 days after data collection and analysis to prepare a summary of preliminary findings, followed by another 30 days to prepare the draft of the final report, followed by another 21 days to complete the final report with outcomes, findings, results and recommendations, and which will be written at a level suitable for public understanding. The draft report containing the review, analysis, and evaluation of the data will describe the findings of this study so as to assist, improve, and otherwise enhance an understanding of the foods produced using cell culture and related technology.

The final report summarizing findings will include an executive summary covering key points and other significant information that needs the immediate attention of FDA. The latter may include impending launch of products or unexpected developments in the industry that point to a need for accelerated regulatory and/or labeling deliberation and decisions. Of course, should CCN come across anything of this nature we would notify FDA immediately, not wait until the final report.

The final report will include a summation of the work performed and will be in sufficient detail to describe comprehensively the results achieved for the entire contract period of performance. The final report will include all deliverables that will fully document the final report and project

outcomes, finding and results. The final report will be submitted not later than 21 calendar days (September 7, 2021) prior to the last day (September 28, 2021) of the period of performance.

CCN's art director will create tables, graphs, charts, and infographics as needed to help readers visualize relevant statistics and findings, including the processes used in cell cultured food production. Design, typefaces and labeling of graphics will be uniform for a consistent look.

We appreciate FDA's invitation to offer additional line items or additional proposals containing alternative line items, and our outline incorporates a couple of our ideas into the research on the 12 areas of greatest concern. There are several companies using cell culture for non-meat food products such as fragrances, sweeteners, proteins, gelatins, flavors, etc. that already come under FDA regulations. These products will not be included in this research. Pet food that includes cell culture meat also will not be included in the research.

## PLAN STAGES OUTLINE

I. Determine what ONFL already knows.
   - A. Obtain, review and catalog policy papers, documents, meeting presentations (July 12, 2018, for example), transcripts or video that is publicly available.
   - B. Discussion of this information with ONFL staff, Project Advisory Group (PAG) members and other Subject Matter Experts (SMEs) as needed.

II. Develop possible data sources in coordination with ONFL and PAG.
   - A. Academic papers on cell culture that reveal companies and food technologists actively developing products. Obtain, review, catalog.
   - B. Industry organizations (Alliance for Meat, Poultry and Seafood Innovation, Cell Based Tech, etc.) papers, policy statements, news releases, member company and investor lists, etc. Obtain, review, catalog.
   - C. Non-profit organizations that support and promote cellular agriculture (New Harvest, etc.)

III. Create summaries of <u>each</u> of the United States companies and the overseas companies actively involved in developing cell cultured foods, and also companies investing in development programs (ADM, Cargill, Tyson, GE), and identify whether they are actually planning to participate in the cell culture meat industry or merely hedging against what their competitors may be planning. Collect and sort data according to species. Identify companies that have expressed interest in cell cultured foods, but are not now active.
   - A. Company history, governance, financing (publically traded, private equity),

management.

B. Company technological expertise, animal species specialization, facilities, technical staff.
   1. Identify companies working on beef products.
   2. Identify companies working on pork products.
   3. Identify companies working on poultry products.
   4. Identify companies working on seafood products.
   5. Identify companies working on meat other than the above.
   6. Identify companies working on ingredients for these species products.

C. Each company's products in development, stage of development, testing, launch horizon. The physical forms these products will take (patties, "nuggets," cuts/parts, fillets, chops).

D. Identify how the pandemic has impacted research and development of cell cultured meat. Have product roll-out schedules been changed? How are companies planning for a future scale-up that might still include COVID-19 risks?

E. Company marketing strategy, features/benefits claims, marketing channel (direct to consumer, wholesale distribution, direct to major retailers, private labeling for chain stores).

F. The company's corporate public documents (investor relations news, prospectus, SEC filings). Obtain, review, catalog.

G. Identify companies partnering with other companies, whether through investment, sharing of technology, market reach, etc.

H. Determine if/how deep-pocket investments by major multinational companies will accelerate research, scale-up and marketing.

IV. Develop an overview of the current scope of innovative technology-enabled food products coming to the market or already available.

A. Food products that will combine cell culture meat and traditionally produced animal proteins.

B. The types of proteins being used in these combination products.

C. How these combination products are being identified to other food companies or to consumers, and what features/benefits claims are being made about them.

V. Develop an overview of the international cell culture food technology market, regulatory landscape and how/when products may enter the U.S. domestic food market. Interviews are not planned.

A. Identify which nations have companies active in developing cell culture food products. Develop short profiles of each company.
B. Identify countries where regulations may conflict with potential U.S. regulatory approaches or policies.
C. Identity the likely timeline for when each of those companies would expect to launch cell culture food products into the U.S. domestic food market.

VI. Develop an overview of ancillary foods, proteins, and ingredients using technologies similar to cell culture technology, but without the use of cells from whole animals.
A. Identify companies producing milk proteins, egg proteins and other ingredients using yeast or bacterial cultures.
B. Identify what products or ingredients are *already* being marketed and the technology used to produce them. Identify what food products include them, or are likely to include them in the *near future*.
C. Identify what products or ingredients are in development, the technology used to produce them, the timeline for launch, and what food products would include them.
D. Identify how products from these companies and technologies are regulated and their marketing strategies and customers.

VII. Identify data on United States consumer attitudes, expectations, and demographics related to cell culture meat to better understand what FDA needs to include in a labeling and regulatory system for cell culture meat.
A. Sources and studies of consumer attitudes expectations.
1. Consumer Reports.
2. Marketing firms.
3. Food Trends analysis firms.
4. Any Government agency consumer research that may be available.

VIII. Identify the types of labeling statements or claims companies may be considering to align their products more closely with any of several environmental, economic and social factors driving alternative meat sources. Such product positioning may relate to one or more of the following concerns.
A. Demand for meat protein due to population increases.
B. Environmental issues related to climate change, greenhouse gasses, desertification of former agricultural land, extensive land required for current livestock and feed production. The livestock sector already consumes about 70% of global

agricultural land, according to a report by a Maastricht University report published in the Annals of the New York Academy of Sciences.

C. Demand for meat protein due to economic factors, such as fewer people living in poverty and thus improving their diets. A 2011 Food and Agriculture Organization of the United Nations (FAO) report predicts worldwide meat consumption to increase by 73% by 2050.

D. Social factors such as animal welfare opposition to confined animal feeding operations, routine use of antimicrobials in animal feed, and other concerns about current meat processing practices that could be eliminated, such as animal shipping stresses and slaughter. Also, concerns about the health and welfare of workers in processing plants.

E. Organic meat considerations. What cell culture meat products might fit the concerns or consumer who prefer organic meats. Certified organic beef is free of artificial pesticides, fertilizers, antibiotics, hormones, GMOs, or other synthetic contaminants.

IX. Identify and explain the potential impacts of any gaps or constraints in the data.

A. Critically review data gathered to determine where data and documents may fall short. Describe the gaps and potential impact on labeling and regulation of certain cell culture products.

B. Recommend remedial steps to address areas of inquiry that need further research.

X. Verify all footnotes and citations collected to facilitate incorporation into the final report.

## TIMELINE OF TASK PLAN AND ACTION REGISTER

CCN will abide by the timetable FDA needs. We do understand that the cell culture food industry is moving ahead rapidly in product development and scale-up, and FDA needs to have this research completed and findings reported to help back up Agency regulatory decision making and justification. The following timeline for the research program and final report correlate with and expand the deliverables schedule in the contract by adding calendar dates, though there should be some flexibility to accommodate holidays and unforeseen events. The timeline assumes the deliverables schedule refers to calendar days, not business days (Monday through Friday).

Contract award: September 29, 2020

Kick-Off meeting: October 28, 2020

Conference report on kick-off meeting: Nov. 2, 2020

Development of this project plan outline: December 7, 2020

Data Collection (already in progress) resumes: December 8, 2020

FDA comments on plan: December 23, 2020

Finalizing of plan: December 29, 2020

First bi-monthly status report and follow-up teleconference: January 8, 2021

Conference report on status report discussion: January 12, 2021

Second bi-monthly status report: March 1, 2021

Conference report on status report discussion: March 5, 2021

Third bi-monthly status report: May 3, 2021

Conference report on status report discussion: May 7, 2021

Collection and analysis of data completed: April 30, 2021*

**Note: CCN plan will be to complete outline items I through III by Jan. 29, items IV through VI by February 26, and the remaining sections by April 30. There could be some slippage depending on the volume of data, the availability of source material, and the timely availability of individuals to be contacted for clarifications. CCN may recommend moving the preliminary results summary and draft of report down the calendar a week if it would result in a more complete assessment.*

Preliminary research findings summary: May 28, 2021

FDA comments/changes to results summary: June 18, 2021

Fourth bi-monthly status report: June 1, 2020

Conference report on status report discussion: June 3, 2021

Draft of final report: July 12, 2021

FDA comments/changes to draft final report: July 30, 2021

Fifth bi-monthly status report: August 2, 2021

Conference report on status report discussion: August 4, 2021

Submission of final report: August 20, 2021

(This schedule allows time for further revisions, if necessary, of the Final Report and completion no later than the contracted 21 days prior to contract end: September 7, 2021)