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An Overview of the Cell Culture Food Industry in the United States

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Cell Culture Food Industry Research Report

September 27, 2021

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Executive Summary

In the United States the cell culture food industry saw a new "first" when in 2015 a start-up company named Memphis Meats began work on cell culture chicken. In 2017 Finless Foods announced plans to produce cell culture Bluefin tuna. That same year the Hampton Creek Foods (now Eat Just, Inc., with the GOOD Meat brand) announced it would develop cell culture chicken products as well as its line of plant-based egg substitutes. New cell culture companies have been launched in the U.S., Israel, Singapore, the United Kingdom, Australia, Japan, Germany, and many other nations. As of mid-2021, the Good Food Institute, a non-profit organization promoting alternative protein sources, listed more than 70 publicly disclosed companies working primarily to develop cell culture seafood, meats, fats and ingredients.[1]

The Diverse Spectrum of U.S. Cell Culture Food Companies
In the U.S. the cell culture food industry now has at least 17 companies (Figure 1) in various stages of technological and product development. All are dedicated to providing consumers with cell culture meat and seafood products, a category that includes beef, pork, poultry, and lamb. Some companies are hoping for sales in the U.S. as soon as late 2021 or early 2022. The time frame will depend on when companies can receive regulatory inspection, approval and oversight by Federal agencies. More cell culture food companies than those announced could still be in "stealth" mode or about to emerge. Typically a company is being stealthy while working through early research and development (R&D) problems and validating its science and business models that later will allow commercial scale. These companies also will be establishing protection for trade secrets, filing patent applications, and seeking initial investors during the stealth phase.

The 17 U.S.-based companies are planning to launch food products across a full spectrum of meats and seafood. The products announced or already being taste tested – and in one instance sold in Singapore – include beef in the form of burgers, brisket, jerky; pork sausage and cutlets; chicken tenders and whole cuts; and minced or whole cuts of turkey duck, lamb, American bison and elk. The seafood products in development are Bluefin tuna, sushi-grade salmon, yellowtail (Japanese amberjack), mahi mahi, red snapper, Chilean sea bass, lobster, shrimp, scallops, and crab.

This research report is in support of FDA's overall mission that includes ensuring that these innovative food products are appropriately labeled. The research is part of FDA's initiative to better understand the status and issues presented by the nascent cell culture food industry. Most, if not all, of the 17 new cell culture food companies have participated in pre-market discussions with regulatory staff at FDA. These talks are confidential and help the companies avoid missteps while better understanding food production and labeling laws and rules. The information in this report was gleaned from public sources, news articles, statements and postings by the companies, and not from any of the pre-market consultations.

Information provided by the companies indicates salmon, tuna, mahi mahi and chicken could soon begin to turn up on menus at high-end U.S. restaurants, perhaps in 2022. Most of the U.S. companies are making steady progress in technological and product development. In Appendix A to this report there are very detailed profiles of each company, including location, founders, planned products, claims likely to be made for the product, the company's technology and investor funding. Some companies are still holding back details of technology and products. Most of the companies have at least a website, often with social media links.

Figure 1 shows the 17 U.S. companies, their announced products, the form of those meat and seafood products, claims they are likely to make about those products and a timeframe they suggest for product launch. Figure 1 also includes information about three overseas companies moving quickly to commercialization. At some point in the near term they are likely to seek approval to export their cell culture food products into the U.S. market. Some Israeli companies have stated plans to manufacture in the U.S. Further details on each of the 17 U.S. Companies can be found in Appendix A of this report.

International and U.S. Production Ramping Up

Some of the 17 U.S. companies and others overseas are gaining considerable momentum toward scaling up and commercializing their products.

The San Francisco company Eat Just had its own "world's first" in late 2020 when the Singapore Food Agency (SFA) gave regulatory approval for sale of Eat Just's GOOD Meat brand cell culture chicken in restaurants, home delivery, and eventually supermarkets. On July 28, 2021, the SFA provided another "world's first" when it granted a license and approval to the Singapore contract manufacturing company Esco Aster to begin production of cell culture chicken, including Eat Just's products, at a facility in Singapore.[59] SFA will conduct safety assessment reviews during production. In May 2021, Eat Just had announced plans to build two pilot production plants, one in the U.S. and another in Singapore.[3] It is unclear whether the production agreement with Esco Aster fulfills that Singapore objective or Eat Just eventually will build its own plant. More recently Eat Just announced it also will build a production facility in Doha, Qatar as a hub for markets in the Middle East and North Africa (MENA) region.

In a "world's first" announced on June 21, 2021, cell culture seafood company Wildtype publicized the opening and operation of its pilot production plant in San Francisco to produce sushi-grade salmon.[2] With 7,700 square feet, the plant's near-term output is expected to be 50,000 pounds of seafood per year. At maximum capacity the plant is may produce upwards of 200,000 pounds per year. Wildtype executives say this plant helps make the company "market ready" by the end of 2021. While Wildtype's facility may have beat Esco Aster by a few weeks in starting production, the difference is that Esco Aster has government approval in Singapore for commercial sales and the U.S. regulatory process for cell culture food products is yet to be announced.

The U.S. cell culture seafood company BlueNalu has established a pilot-scale food production plant in San Diego. At 38,000 square feet, it is large enough for full scale-up to commercial output.[5] BlueNalu announced on September 13, 2021 a partnership with Nomad Foods, Europe's leading frozen food company, to explore the eventual introduction of cell-cultured seafood in Europe, the largest regional importer of seafood in the world.[60]

Also in the U.S., a pilot production plant is being built by Memphis Meats, the early pioneer of the U.S. cell culture food industry. Based in Berkeley, California, Memphis Meats is now doing business under

the UPSIDE Foods brand and will initially produce chicken, although the company first gained attention by producing a cell culture beef meatball.[4]

Among overseas companies, Mosa Meat is building its pilot production plant in The Netherlands for its burgers, and Future Meat Technologies has announced the start of operations in its pilot plant in Israel to produce chicken. Other companies have or will soon be moving into new plants financed by millions of dollars from venture capitalists.

Transition from Laboratory to Manufacturing Faces Hurdles

The transition from laboratory to food-grade pilot plants is a major step in scaling production toward commercialization. Companies will have to resolve new problems and a few old, very complex technological challenges involved in turning cells into meat and seafood. Elsewhere in this report is discussion of the technological scale-up challenges the companies must address if they are to offer products on a commercial scale, and how some companies are addressing those challenges.

So far Singapore is the only nation that has approved the production and sale of cell culture meat, and so far only for the GOOD Meat chicken nugget, which is 70 percent cell culture chicken and 30 percent plant-based mung bean protein.[3] The content of the UPSIDE Foods chicken has not been announced, though it is described as "real meat, and the company plans beef and seafood products later."[4] Several other U.S. and overseas companies have said their products will be "hybrids" either of cell culture meat and plant-based proteins or hybrids of culture meat and conventional meat.

Market analysts caution that the industry must:

- Increase metabolic efficiency to speed the output of the culturing process.
- Decrease growth media cost and improve its efficiency by switching from costly pharmaceutical-grade media ingredients, including growth factors, to less costly food-grade ingredients.
- Replicate the fibrous quality of conventional meats by adding nonmeat ingredients to induce the cells to form fibers and meat-like fat, which will provide savory qualities to please consumers.

Implied and Expressed Claims

The new cell culture food industry is indeed innovative and typically will be claiming a more healthful product or at least something preferable for consumers concerned about the environmental and ethical issues involved in conventional meat production. Some companies promote their upcoming products as "real meat" or "the same as" conventional meat, even though they are hybrids. These ingredient combinations and other aspects of cell culture food technology present regulatory authorities in the U.S. and elsewhere with various issues as they work through product naming, labeling and food category guidance and regulations.

Claims about the benefits and features of the products have been expressed by company executives in news releases and online content. So far the claims convey four sorts of information, often colored by marketing strategies. (1) What *is* in the product – meat or seafood with essential vitamins, minerals, omega-3 fatty acids, for example; (2) What *is not* in the product – genetically modified organisms, contaminants, antibiotics, growth hormones, etc.; (3) How the product *is* made – with pathogen-free sterile stainless steel equipment, and with inspection by FDA and/or USDA, for example; and, (4) how the product *is not* made – no animals were slaughtered, no fisheries were depleted. The claims must be substantiated by science and the facts of product production and content.

Since no company has yet attempted to launch a packaged cell culture meat or seafood product in the U.S., no labels or specific label claims have been formally evaluated by FDA or USDA. Still, the companies have been articulating and publishing what could be construed as claims for their proposed products, their technology, and their mission. Further details on the implied claims and messaging trends are included elsewhere in this report.

Consumers Willing but Wary

Recent consumer acceptance research indicates a sizable portion of the public is willing to try cell culture foods if the price is right. However, cell culture meat and seafood products are not projected to decrease in cost to reach price parity with conventional meat products until the early 2030s, assuming technological advancements and reductions of production input costs continue downward at the present pace.[6]

The keys to consumer acceptance identified by research are taste, texture, mouthfeel, and assurances on the label that this product is regulated, such as a U.S. Department of Agriculture (USDA) inspection. Eat Just commissioned a study reported in early 2021 finding 72 percent of U.S. consumers are open to substituting cell culture chicken for animal-based chicken after being shown photos of the cell culture chicken product and reading a description of how it was made.[27] Another study from 2019 in the journal Frontiers in Nutrition found nearly 65 percent of U.S. consumers would probably or definitely try cell culture meat products.[28] Further detail on these and other studies is included elsewhere in this report, including consumer motivators and barriers to trying cell culture meat and seafood.

Consumer research has included terminology that would provide consumers with clear understanding and more comfort in purchasing cell culture meat and seafood. A 2021 study with U.S. and U.K. consumers found they had equal preference for "cultivated" and "cultured" as descriptor terms, which they preferred over "cell-based" and "cell-cultured" in both a social and a labeling context.[24] A number of studies have found that nomenclature has a significant impact on cell culture food acceptance. These studies have largely demonstrated that consumers have a more positive reaction to neutral and benefit-focused terms, in comparison to less appealing terms such as "lab grown meat," which tend to invoke concerns about naturalness. [31, 32, 33]

Terminology and labeling requirements could make consumers ask questions, doubt answers, and shy away from cell culture foods. Consumer response also could be impacted by another significant unknown – misinformation. U.S. companies are hopeful that transparency in their operations and how the meat is made will create a consumer comfort level with products. Further findings of consumer research on nomenclature are detailed elsewhere in this report.

An important aspect of consumer acceptance will be how production is inspected for product safety. Influential consumers organizations may ask how inspectors are being trained, how they do inspections, what they look for, how departures from acceptable practices are handled, and what are the standards and practices the agencies will apply to cell culture food production. The FDA has decades of experience inspecting and overseeing production using bioreactors for producing pharmaceuticals and other regulated biological systems. Knowing that experienced and knowledgeable inspectors are part of the production system should add to the acceptance of cell culture foods from a production perspective.

Searching for Solutions and Partners

Intellectual property concerns have caused cell culture meat companies to "silo" and try to solve problems on their own while they work out patents and trade secret protections for their solutions. A few

companies claim to have solved issues with cell lines, growth media and scaffolding for aligning cells. Other companies are urging the cell culture food industry to increase collaboration and transparency to help solve technical problems sooner. Several are exploring supplier relationships to help them outsource solutions, such as buying their scaffolding or growth media from a supplier, or leasing "off-the-shelf" bioreactors instead of re-inventing them.

The boom in fermentation technologies for alternative proteins of meat, eggs and dairy has resulted in fresh approaches to enhancing non-animal based production of proteins from plants, algae, fungi, and microbes. Several companies are developing or already producing new or improved technologies and products in fermentation science. They see a path toward spill-over to cell culture meat and seafood production. Some cell culture meat and seafood companies see potential in fermentation as a problem solver for production inputs, and also for improving their own products' functional nutrition, texture, taste and "mouthfeel." Fermentation also is often a key production aspect of the plant-based proteins that are and will be going into hybrid food products combining plant-based and cell culture sources of protein.

GFI and others supporting the cell culture meat industry have urged additional government investment in research and development of this food sector. Public investment in cell culture food production could accelerate the industry's progress while forcing it to be more open sourced and transparent. It's a funding process that has recently started in the U.S. and overseas. The National Science Foundation (NSF) grant to the University of California at Davis for research on cell culture meat is a modest start. The Federal government, through its agencies and commissions, and perhaps land-grant universities, has many routes to support the industry. This could demonstrate that cell culture meat and seafood have strategic value within the nation's food supply and can contribute to economic growth.

Commercialization Challenges

Cell culture meat is not expected to completely replace conventional meat production, but encroachment is foreseeable. If projections hold true, cell culture meat and seafood will attain cost parity with its conventional counterparts by about 2032. This would set the table for substantial year-over-year sales. At that point, cell culture meat and seafood may well be an option at some of the world's biggest fast food companies, just as Burger King and McDonalds have added plant-based burgers to menus.

Even without cost parity over the next 10 years, more cell culture food companies are nearing commercialization on at least a pilot scale. The acceleration of investment is expected to continue. While U.S. regulatory requirements remain uncertain, most company executives don't seem too worried in their public statements. Perhaps that is because they are encouraged by pre-market discussions with FDA and USDA.

The response of the vested conventional meat industry stakeholders is not fully known, though organizations of cattle and pork producers may seek influence in how cell culture products are labeled. The U.S. Cattlemen's Association refers to cell culture meat as "lab-grown fake meat," which suggests the meat turf blowback could be strong from some producer and allied organizations.[61]

On the other hand, giant meat companies such as Tyson and JBS have shown their interest in participating in any consumer switch from conventional to alternative meats, wherever in the world that may happen. Cell culture meat and seafood can be produced virtually anywhere, without the need for pastures, feedlots and long-haul transportation to cities. Singapore, Qatar, Israel and other nations that must import much of their food are looking to cell culture meat to reduce that dependency. Qatar and

Just Food announced on August 31, 2021 that Just Food will build a manufacturing plant there to produce and market the company's GOOD Meat cell culture chicken. Some cell culture food companies say they can help the U.S. localize food production to mitigate some of the supply chain disruptions and shortages caused by events such as pandemics.

Currently virtually all of the 17 U.S. cell culture meat and seafood companies are competing to recruit highly skilled technicians and production engineers, who may be in short supply as demand steadily increases. Managing or working in a slaughterhouse requires one skill set, but producing cell culture meat requires something quite different. In its recent report on cell culture meat commercialization issues and outlook, "Cultivated Meat: Out of the Lab, into the Frying Pan,"[51] McKinsey & Company noted the possibility that after scale-up the same number of jobs will be available as in conventional meat production. The big difference is that up to 20 percent will be for bio-processing engineers and other highly skilled professionals. The talent search is global as well, so highly skilled workers need not immigrate for one of those good jobs. U.S. companies that lack the resources to attract these professionals may fall behind in commercialization objectives.

Venture capitalists specializing in start-up companies and new technologies have been pouring record amounts of funding year-over-year into the alternative protein category. The cell culture meat and seafood sector has yet to achieve the funding levels of the plant-based and fermentation sectors, but is catching up quickly and may accelerate once regulatory uncertainties are resolved in the U.S. and elsewhere.

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Overview of the Current Cell Culture Food Industry

In 2013 in front of a London studio audience scientist Dr. Mark Post and food technologist Peter Verstrate unveiled a cell culture hamburger, created in a laboratory and without harming an animal. A new food industry was born. Three years later the company Mosa Meat was founded in The Netherlands by Post, Verstrate and their team. Mosa Meat estimates the cost of that first hamburger at $300,000. Their hamburger now has more fat (the good kind, they note), has no animal components in production, and has vastly lower cost of $100 per serving. Still a pricey burger, but the cost is steadily coming down. Price parity with today's ground beef is expected within a very few years.

In a Mosa Meat photo Dr. Mark Post reveals the first cell culture burger, 2013.

BlueNalu photo of cell culture fish, 2021.

Eat Just's GOOD Meat Singapore chicken bite 2021, soon available in Qatar as well.

In the United States this new cell culture food industry began in 2015 with the launch of a start-up company named Memphis Meats (now UPSIDE Foods) that began work on cell culture chicken. Then in 2017 Finless Foods announced plans to produce cell culture Bluefin tuna. That same year the Hampton Creek Foods company (now Eat Just, Inc., with the GOOD Meat brand) announced it would add cell culture chicken to its line of plant-based egg substitutes. New cell culture meat companies have been launched around the world – in the United States, Israel, Singapore, the United Kingdom, Australia, Japan, Germany, Argentina, Italy, Canada, South Korea, Chile, China and South Africa. As of mid-2021, the Good Food Institute, a non-profit organization promoting alternative protein sources, listed more than 70 publicly disclosed companies working primarily to develop cell culture seafood, meats, fats and ingredients.[1]

In the U.S. the cell culture food industry now has at least 17 companies (Figure 1) in various stages of technological and product development. All are dedicated to providing consumers with cell culture meat and seafood products, a category that includes beef, pork, poultry and lamb. Some companies are hoping for sales in the U.S. as soon as late 2021 or early 2022. The time frame will depend in part on when companies can receive regulatory inspection, approval and oversight by Federal agencies. The regulatory framework is still being developed by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). More cell culture food companies than those announced could still be in "stealth" mode or about to emerge. Those quiet companies are a few years from launching products or scaling up for commercialization. Typically a start-up company is being stealthy while working through early research and development (R&D) problems and validating the science and business models that will allow scaling up to commercial success. These companies also will be establishing protection for trade secrets, filing patent applications, and seeking initial investors during the stealth phase.

The 17 U.S.-based companies are planning to launch food products across a wide range of meats and seafood. The products announced or already being taste tested – and in one instance sold in Singapore – include beef in the form of burgers, brisket, and jerky; pork sausage and cutlets; chicken tenders and whole cuts; and minced or whole cuts of turkey duck, lamb, American bison, and elk. The seafood products in development are Bluefin tuna, sushi-grade salmon, yellowtail (Japanese amberjack), mahi mahi, red snapper, Chilean sea bass, lobster, shrimp, scallops, and crab.

Information provided by the 17 companies indicates salmon, tuna, mahi mahi and chicken could soon begin to turn up on menus at high-end U.S. restaurants, perhaps in 2022. Most of the U.S. companies are making steady progress in technological and product development. In Appendix A to this report there are very detailed profiles of each company, including location, founders, planned products, claims likely to be made for the products, the company's technology and investor funding. Some companies are holding back details of technology and products. Each of the 17 companies has set up a website, often with social media links.

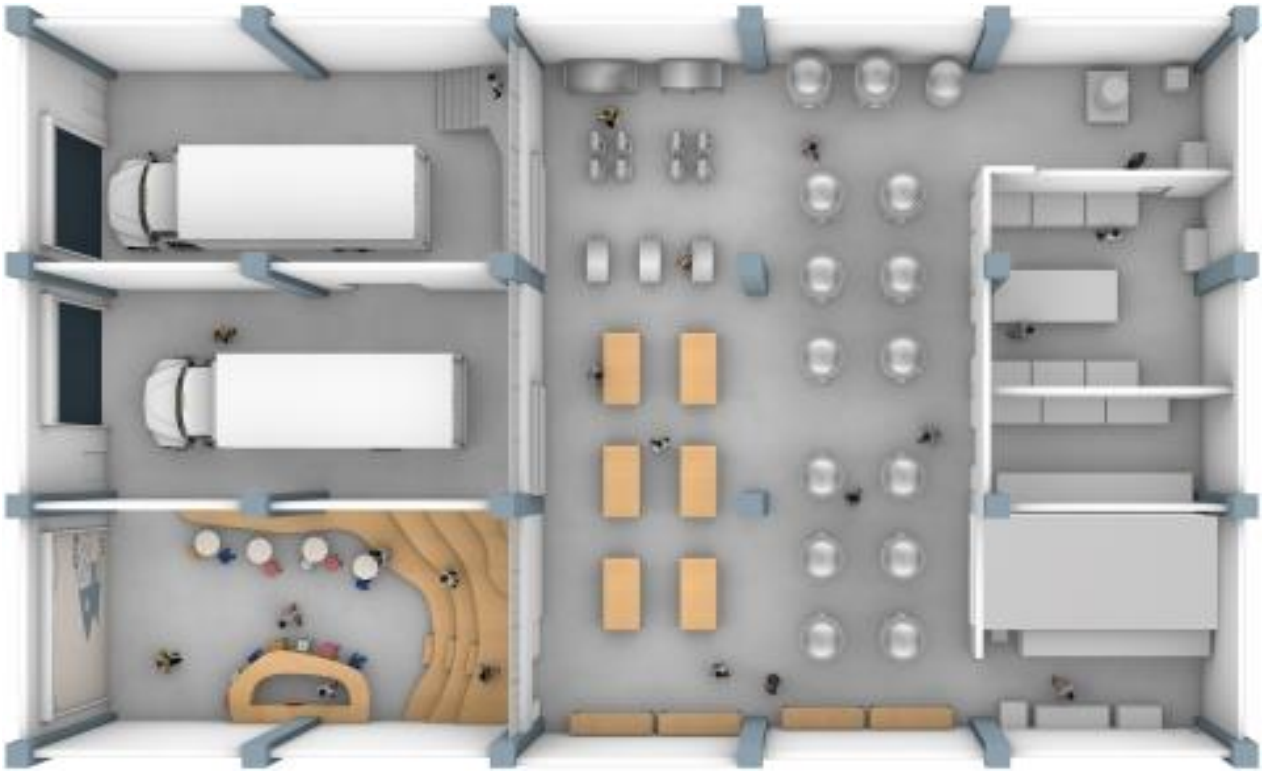
Some of the companies are gaining considerable momentum toward scaling up and commercializing their products.

The San Francisco company Eat Just had its own "world's first" in late 2020 when the Singapore Food Agency gave regulatory approval for sale of Eat Just's GOOD Meat brand cell culture chicken in restaurants, home delivery, and eventually supermarkets. The GOOD Meat chicken nugget being sold in Singapore is 70 percent cell culture chicken and 30 percent plant-based mung bean protein.

On July 28, 2021, the SFA provided another "world's first" when it granted a license and approval to the Singapore contract manufacturing company Esco Aster to begin production of cell culture chicken, including Eat Just's products, at a facility in Singapore.[59] SFA will conduct safety assessment reviews during production. In May 2021, Eat Just had announced plans to build two pilot production plants, one in the U.S. and another in Singapore.[3] It is unclear whether the production agreement with Esco Aster fulfills that Singapore objective or Eat Just eventually will build its own plant.

Eat Just announced on August 31, 2021 that it has partnered with Doha Venture Capital and the Qatar Free Zones Authority (QFZA) to build the first cell culture meat facility in the Middle East and Northern Africa (MENA) region.[53] This will provide Eat Just a regional hub with direct access to Hamad Port. The hub will include R&D space, large-scale manufacturing for East Just's GOOD Meat division and a processing facility for the company's plant-based egg division. The company is identifying restaurants in Qatar that would be partners for the Middle East launch of the chicken product, much as Eat Just did in Singapore. The company said the QFZA and the Qatar Ministry of Public Health have "indicated their intention" to grant regulatory approval for the chicken product "very soon" and have already approved an export license.[54]

In another "world's first" announced on June 21, 2021, the U.S. cell culture seafood company Wildtype publicized the opening and operation of its pilot production plant in San Francisco to produce sushi-grade salmon.[2] With 7,700 square feet, the plant's near-term output is expected to be 50,000 pounds of seafood per year. At maximum capacity the plant is may produce upwards of 200,000 pounds per year. Wildtype executives say this plant helps make the company "market ready" by the end of 2021. While Wildtype's facility may have beat Esco Aster by a few weeks in starting production , the difference is that Esco Aster has government approval in Singapore for commercial sales and the U.S. regulatory process for cell culture food products is yet to be announced.



Wildtype provided a schematic of its new production plant.

Further details about the plant are found in the company's website blog. In an effort toward consumer education and manufacturing transparency, the facility is set up so that the public can learn about the science of cell culture meat production and how Wildtype's food is made. There is a sushi bar named The Dock, bleacher seating in an education center, and a window looking onto the production floor. The company says the most important aspect of the operation will be how it helps Wildtype shorten "innovation cycles" in product development, and how it enables steady improvements in quality, volume and frequency of "harvested" batches of the seafood, its taste, texture and "mouthfeel."

A U.S. pilot production plant is being built by Memphis Meats (now UPSIDE Foods), the early pioneer of the U.S. cell culture meat industry. Based in Berkeley, California, the company will initially produce chicken, although the company first gained attention by producing a cell culture beef meatball. The content of the UPSIDE Foods chicken has not been announced, though it is described as "real meat." The company plans beef and seafood products later.[4]

Memphis Meats first introduced a cell culture meatball such as shown in the company's photo.

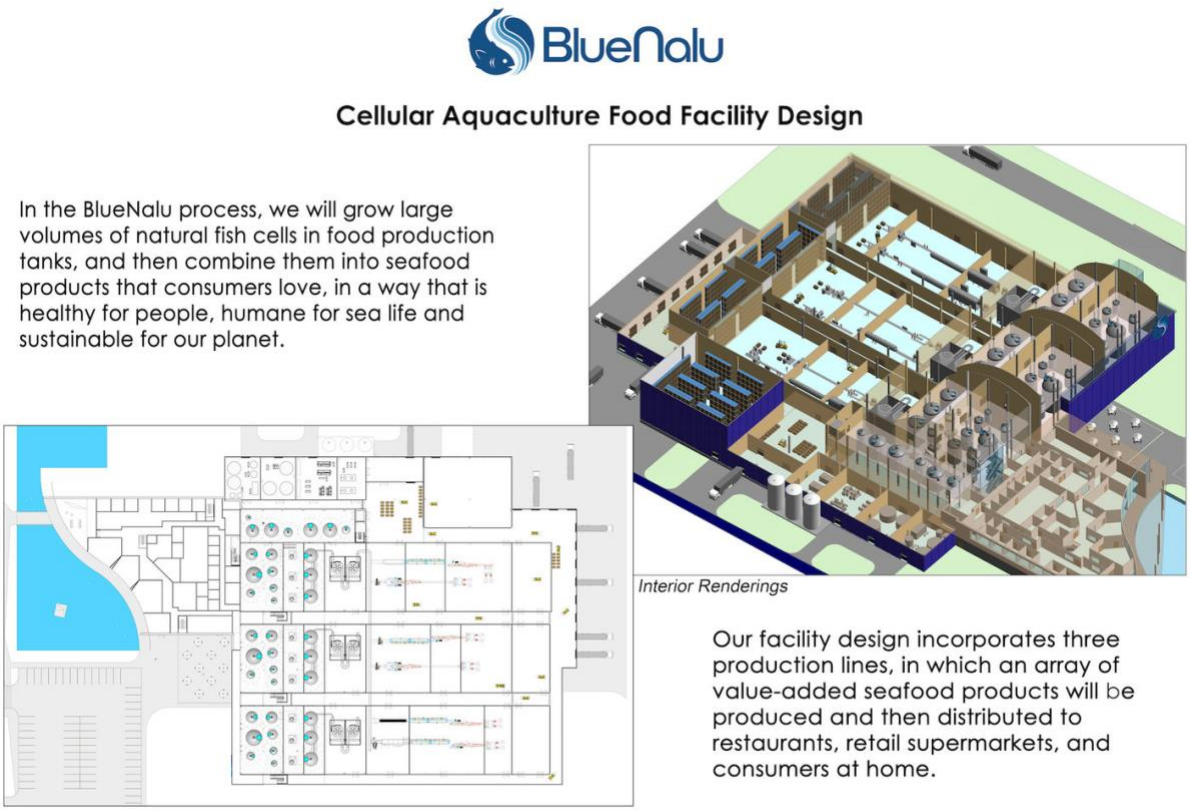
But now Memphis Meats plans to first commercialize its cell culture chicken as shown on its plate photo.

The U.S. cell culture seafood company BlueNalu has established a Good Manufacturing Practices (GMP) pilot-scale food production plant in San Diego. At 38,000 square feet, it is large enough for full scale-up to commercial output.[5] BlueNalu announced on September 13, 2021 a partnership with Nomad Foods, Europe's leading frozen food company, to explore the eventual introduction of cell-cultured seafood in Europe, the largest regional importer of seafood in the world.[60] The agreement includes the U.K., which is Nomad Foods' largest market. The agreement is the first of its kind in Europe between a consumer packaged goods company and a cell culture seafood company.

BlueNalu's business strategy is to "partner with leading multinational companies" on market research, regulatory affairs, product design and development, manufacturing, marketing, sales and distribution, with to increase the efficiency and effectiveness of consumer sales worldwide.[60] BlueNalu also has collaborations with Pulmuone Col, Ltd. in South Korea, Sumitomo Corporation and Mitsubishi Corporation in Japan, and Thai Union in Thailand.

Among overseas cell culture food companies Mosa Meat is building its pilot production plant in The Netherlands for its burgers, Future Meat Technologies has announced the start of operations in its pilot plant in Israel to produce chicken, and other companies have or will soon be moving into new plants financed by venture capitalists who foresee economic promise in the cell culture meat industry.

BlueNalu posted exterior and interior (next page) schematics of its commercial production plant.



The transition from laboratory to food-grade pilot production plant is a major step toward scaling production toward commercialization. Companies will have to resolve new problems and a few old, very complex technological challenges involved in turning cells into meat. An unknown is when other companies will be able to make that transition to pilot plant production.

Figure 1 (following pages) shows the 17 U.S. companies, their announced products, the form of those meat products, claims they are likely to make about those products, and a timeframe they suggest for commercialization. Figure 1 also includes information about three overseas companies moving quickly toward commercialization and likely to seek approval to export their cell culture food products into the U.S. market. Some Israeli companies have announced plans to have manufacturing facilities in the U.S. Further details on each of the 17 U.S. Companies can be found in Appendix A of this report.

U.S.-Based Cell Culture Meat Companies

And Announced Product Plans as of Mid-2021

COMPANY	MEAT SPECIES	FOOD FORM	DESCRIPTIVE	CLAIMS LIKELY	MARKET TIMING
Air Protein Pleasanton, CA	Chicken first. Then other meats	Powdered protein	Texturized and extruded into meat	High protein and minerals; environmental benefits; free of pesticides, herbicides, hormones, antibiotics	Not specified, five-year R&D horizon
Artemys Foods San Leandro, CA; San Francisco	Beef and fat	Hybrid of cell culture meat and plant protein	Burgers	Great meat, same or better nutrition	Not specified; Covid-19 delay from fall 2020
Balletic Foods Davis, CA	Not specified	Not specified	Not specified	Sustainable cultivated meat; recombinant protein	Not specified
BioBQ Austin, TX	Beef	Brisket and beef jerky	Whole cuts	Real beef, no slaughter	Prototype in 2023
Blue Ridge Bantam (Vitro Foods, Inc.) Durham, NC	Turkey	Various forms	Whole cuts, ground, rendered fat and flavoring	Healthy, tasty and sustainable meat	Not specified
BlueNalu San Diego, CA	Seafood	Mahi Mahi, red snapper, sea bass, tuna, yellowtail	Fillets	Great tasting, healthy, safe, trusted and sustainable; third party certification of food safety & traceability	Early 2022
Boston Meats Boston, MA	Beef, pork, poultry	Fiber spun from pig gelatin, ethanol, water	Whole cuts	Same quality, structure, taste, texture as current meat	Not specified
Cultured Decadence Madison, WI	Seafood	Lobster, shrimp, scallops, crab	Whole cuts	Nutritious, sustainable, authentic; no shell, organs, or waste	Early 2022
Finless Foods Emeryville, CA	Seafood	Bluefin tuna first, and later salmon, shrimp	Raw Sushi grade tuna	Safe, healthy, great tasting; no mercury, plastics, antibiotics, or growth hormones	Early 2022

U.S.-Based Cell Culture Meat Companies

And Announced Product Plans as of Mid-2021

COMPANY	MEAT SPECIES	FOOD FORM	DESCRIPTIVE	CLAIMS LIKELY	MARKET TIMING
Fork & Goode Nutley, NJ	Pork	3D printed meat from cell cultures	Not disclosed but whole cuts most likely	Same real meat nutrition; no hormones, harmful bacteria; less harm to animals and environment	Not disclosed
GOOD Meat (aka Eat Just) San Francisco	Chicken	Minced meat hybrid, 70% culture meat, 30% mung bean protein	Nuggets	Safe, high protein and amino acids, no GMOs or saturated fat	Safe, high protein and amino acids, no GMOs or saturated fat
Lab Farm Foods New York, NY	Pork, chicken	Bacon, pork belly, chicken, hybrid of cell culture meat and plant-based protein	Nugget 50-50 cell chicken-plant; also 50-50 cell chicken and farm chicken; pork liver pate 100% cell pork	Genuine, sustainable meat	Not disclosed, but plan is to license technology to other companies for their products
Memphis Meats, DBA UPSIDE Foods Berkeley, CA	Chicken first, poultry, beef, seafood later	Not disclosed if chicken is 100% cell meat or hybrid with plant protein	Premium whole cuts of chicken	Real meat, delicious, sustainable, humane; no harmful bacteria	Late 2021 or early 2022
Mission Barns Berkeley, CA	Pork, chicken, beef, duck, fats	Mission Fat as ingredient; hybrid cell cultured meat and/or fat with plant-based proteins	Bacon, sausage, burgers, nuggets, dumplings, hot dogs, meatballs	Animal fat without the animal; better taste, texture with less carbon, water and land than conventional meat	Not specified, but 2022 likely for the fats as ingredients in products of other cell cultivated meat companies
New Age Meats Berkeley, CA	Pork	Minced cell meat with plant-based ingredients for taste, texture, nutrition	Sausage and dumplings	Real meat, delicious, safe, healthy	Late 2021
Orbillion Bio San Francisco	"Heritage" beef, elk, bison, lamb	Ground cell culture Wagyu beef meat, steak shaped	"Steak" shapes now, whole cuts later	Healthy, flavorful, ethical, low fat and cholesterol, higher protein, unsaturated fats, no antibiotics or hormones	Pilot samples 2023

U.S.-Based Cell Culture Meat Companies

And Announced Product Plans as of Mid-2021

COMPANY	MEAT SPECIES	FOOD FORM	DESCRIPTIVE	CLAIMS LIKELY	MARKET TIMING
Wildtype San Francisco	Seafood	Sushi-grade coho salmon	Raw whole cuts for rolls, nigari, sashimi, baked or smoked	Clean, sustainable seafood; salmon has same flavor, aroma, texture and fat as wild caught	Late 2021

International Cell Culture Meat Companies Planning or Likely to Export Products to U.S.

COMPANY	MEAT SPECIES	FOOD FORM	DESCRIPTIVE	CLAIMS LIKELY	MARKET TIMING
Aleph Farms Israel	Beef	3D printed steaks	Whole Cuts	Mirrors the sensory quality, texture, flavor and fatty marbling of traditional steaks; certified zero pathogens	Second half of 2022
Future Meat Israel	Chicken first, beef, lamb and pork later	Hybrid of cell culture meat and plant protein for flavor, aroma	Chicken breast	Clean meat with the look, texture, smell, taste of farm chicken, and no GMOs	2022
Mosa Meat Netherlands	Beef	Fully formed muscle and fat that then can be ground	Burgers, meat balls, steak tartar	Full of flavor, looks, smells, tastes just as good as current beef; no animals harmed, no GMOs	Not specified, but company has global objectives

How Companies Produce Food from Cell Culture

The microbiology, genetics, chemistry, engineering and other sciences involved in turning animal cells into meat, seafood and other foods can be seen as a logical evolution from human tissue engineering. Many of the founders of cell culture food companies and their leading scientists have come from biomedical backgrounds. Using stem cells as the starting point to build heart muscle or repair other organs took many years to evolve into today's regenerative medicine, and continues to progress with increasingly ingenious applications that change and save lives. It's not surprising that this field of biomedicine inspired academics and businesses to recognize the possibility of generating meat and seafood from cultures of food animal cells.

At its simplest, the art and science of cell culture meat begins with a biopsy. A tiny sample that may contain tens to thousands of cells is taken from a very healthy and high quality meat-producing animal such as a cow or pig, or perhaps an ideal specimen of tuna or salmon. The animal isn't harmed and can rejoin the herd or water to live out its life or perhaps provide more cells in the future. Certain cells may be selected for characteristics that make them better candidates for the food they will become. Most of the cell culture food companies would like to develop their own "immortalized" cell lines. These are a population of cells which normally would not proliferate indefinitely but, due to mutation, have evaded normal cellular decay as they age and instead can keep undergoing division. The cells can therefore replicate for prolonged periods without needing to be replaced, which saves cost. Another option is to obtain the needed cells from other companies that specialize in collecting and developing cell lines. Some companies may use genetic engineering (GE or GM) techniques to make the cells immortalized, though this can raise issues where GE foods are not allowed or cause objections from segments of the public. Regardless of source or mutation, the cells are handled carefully and fed "growth media" or "growth factors" so they rapidly multiply and accumulate mass. The cell proliferation process normally takes place in a sterile stainless steel tank called a bioreactor or cultivator. It may look like the equipment in a small brewery, but it's far more sophisticated.

The cells may differentiate to produce muscle, fat, collagen or other components of meat. The cells are kept at an optimum temperature and continuously bathed in growth media that contains formulations of sugars, salts, amino acids, minerals, vitamins, etc. The media needs to closely replicate the environment that would nourish the cells within the animal. Different cells from different species need different combinations of the nutrients. Ideally this growth media would be inexpensive and could be "recycled" for nearly continual use as additional batches of food are produced. Growth media and the process of cultivation will produce some "waste" material that has to be filtered out for disposal or for use in some other process. R&D to optimize formulations, use animal-free components, and create recycle technologies will be needed to make cell culture media significantly more affordable.

Scaffolding provides structural support for cells to adhere, differentiate, replicate and mature, making it crucial for the creation of structured meat products like steak.[41] The composition of the food-grade scaffolding that the cells grow along will depend on the food species and form of it (minced or whole cuts) being produced. The most likely materials to be used as scaffold for cell culture food will be abundant, affordable, and food-safe. Some examples include polysaccharides such as chitosan, alginate, or cellulose; proteins such as zein; or complex composites such as lignin or textured vegetable protein. The materials can be assembled by existing techniques including 3D printing, polymer spinning technologies such as electrospinning, decellularization, tunable hydrogels, or even by nature itself (e.g., fungal mycelium). Several business-to-businesses (B2B) companies using various materials or methods of assembly aim to supply the industry with scaffolds. Many other companies are likely to start up.

The selection of a scaffold and its properties will be highly dependent on the final product, with the scaffold having an increasingly important role in more structured products. Scaffolds may be intentionally designed to be biodegradable such that they are replaced with native extracellular matrix by the time a product is harvested. Alternatively, scaffolds can make up a significant portion of the final food, creating a hybrid product. Scaffold materials that end up in a final product must meet requirements for how that product may be cooked and prepared, as well as how the material influences the product's safety, digestibility, taste, and nutrition.[41]

The cell proliferation is just one event happening in a bioreactor, a very technically sophisticated piece of equipment connected to several other devices. This equipment system controls what goes into and comes out of the bioreactor, the temperatures, pressure, and other parameters that optimize food production. The bioreactor is sealed so that pathogens and pollutants cannot enter the food stream.

Future Meat Technologies has provided photos of its bioreactors.

Companies will usually be using different designs and functionality of their bioreactors, perhaps having them custom built for their process. When sufficient mass of meat has been produced, it can be harvested either by stopping the process or by removing most of the food and letting the production process continue. Once the food has been harvested the company can further process it to add the desired flavors, textures, colors and shapes. The meat may be blended with plant-based proteins to create a hybrid form that still maintains its identity based on the species of the donor animal. Some equipment suppliers are developing cell culture food bioreactors that can be an "off the shelf" option for companies that prefer not to custom-build their own systems. Esco Aster's cell culture seafood manufacturing

platform now approved in Singapore may illustrate this approach. The company, a subsidiary of the Esco Lifescience Group, has been manufacturing and distributing bioreactors, tools and technology commercially for the past decade to clients in various sectors, including cell culture foods and alternative proteins, bioprocessing, stem cell and life sciences companies.[59]

The Evolving U.S. Regulatory Framework for Cell Culture Food

As more U.S. cell culture food companies begin pilot production and stage more tasting events with volunteers, public awareness of their progress is being elevated. The focus increasingly turns to the regulatory platforms that will enable food products to move into U.S. restaurants, food service and eventually grocery stores. While USDA and FDA have yet to approve a cell culture meat and seafood product for human consumption, the preliminary steps have been underway for a few years. Most of the companies have been taking part in early talks with FDA and USDA regulatory authorities in a process of pre-market consultation. These discussions are confidential to enable and encourage frank discussion of company plans and concerns while protecting company intellectual property and offering guidance to help prevent missteps that could delay or complicate their eventual regulatory compliance.

Federal regulators have maintained the confidentiality of those pre-market consultations. The information in this report does not include any information from those private discussions or documents provided to the agencies. Rather, this report has been compiled from public sources that included cell culture food company websites, social media postings, news releases, and presentations at industry conferences. Data also was gathered from articles in major news broadcast and print media and the food industry trade press. Public documents from FDA, USDA, and the U.S. Securities and Exchange Commission (SEC) provided information, as did documents from organizations such as GFI, New Horizon, Dun and Bradstreet, and the Cellular Agriculture Society.

This research provides an overview of the current status of the cell culture food industry for FDA's 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 produce more healthful foods.

The most recent public steps FDA and USDA have taken to inform the process of regulatory questions was to request that stakeholders submit their suggestions regarding the naming and labeling of cell culture food products. On September 2, 2021, USDA's Food Safety and Inspection Service (FSIS) published an advance notice of proposed rulemaking (ANPR) to solicit comments and information regarding the labeling of meat and poultry products made using cultured cells derived from animals under FSIS jurisdiction.[55] FSIS will use these comments to inform future regulatory requirements for the labeling of these food products.

In 2020, FDA issued Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information regarding stakeholder suggestions for labeling of foods comprised of or containing cultured seafood cells.[10] FDA received 35 comments from organizations, academicians, companies and individuals with a variety of preferences for labeling nomenclature and regulatory process. Some organizations and companies favor "cultivated meat" while others prefer "cell-cultivated meat." Consumer research detailed later in this report may point toward terms that can be readily understood by

the public. USDA is expected to receive similar industry and stakeholder nomenclature ideas for beef, pork, poultry and other cell culture meat. [9, 10] USDA's comment period concludes after 60 days.

The comments submitted to FSIS and FDA, along with extensive information from other sources, plus current laws, regulations and practices, will help the agencies establishes the principles by which the two agencies will evaluate the labeling of cell culture foods. The product label has to be clear and not misleading about what is in that package. Numerous questions have arisen, some quite fundamental. For example, should a food be considered seafood if no fish was wild-caught or farmed to make it? Is a product "beef" if no cattle were slaughtered to make it? Does DNA have a role in determining what constitutes a specific food? There are many questions and there are different, often conflicting answers from stakeholders.

While moving expeditiously but cautiously toward regulatory guidance and decisions, FDA and FSIS have been coordinating their approaches to how this new cell culture meat industry would be brought into a reasonable regulatory regime. On November 16, 2018 USDA and FDA announced their intent to implement a joint regulatory framework for cell culture food in keeping with each agency's statutory authority and customary regulatory responsibilities. FDA will oversee cell collection, cell banks, and all cultivation inputs and processes including cell growth and differentiation, up through the moment of "harvest" from the bioreactors. USDA will then oversee the further processing and labeling of food products derived from the cells of livestock and poultry. FDA will retain jurisdiction over cell culture seafood, excepting catfish, all the way through processing and labeling. This regulatory framework is intended to leverage both FDA's experience regulating cell-culture technology and living biosystems and USDA's expertise in regulating livestock and poultry products for human consumption.[6, 7]

On March 7, 2019, FDA and USDA released a formal agreement regarding their roles under the framework and their collaboration to regulate production of cell culture meat and its entry into commerce. The agreement helps assure a predictable regulatory path for cell-based food and that it will be safe and accurately labeled.[8] In June 2019 USDA and FDA formed three interagency working groups on cell culture meat, and have confirmed the framework of the formal agreement in a joint webinar titled "Roles and Responsibilities for Cultured Animal Cell Human and Animal Food Products." The agencies continue to work to refine the technical details of this framework, to include robust collaboration and information sharing between the agencies, and to permit each to carry out its role.[6] The three working groups are focused on pre-market assessment, labeling, and transfer of jurisdiction when the cell culture meat (other than seafood) is harvested and goes from FDA oversight to USDA oversight. The pre-market conversations with companies have been helpful in understanding how the strategies and technologies of the companies differ from one another (as can be seen in the company profiles in Appendix A).

Companies Focus Messaging as Commercialization Approaches

FDA and FSIS ultimately will provide the policies and labeling that will govern cell culture food, but claims about the benefits and features of the products originate with the companies producing them. Companies tend to want to convey four sorts of information, often colored by marketing strategies that may include some exaggeration. (1) What *is* in the product – essential vitamins and minerals, for example; (2) What *is not* in the product – genetically modified organisms, contaminants, antibiotics, growth hormones, etc.; (3) How the product *is* made – with pathogen-free sterile stainless steel equipment, or with inspection by FDA and/or USDA, for example; and, (4) how the product *is not* made – no animals were slaughtered, no fisheries were depleted. FDA and USDA will insist the claims be substantiated by science and the facts of product production and content.

See Appendix B for a more detailed summary of the types of claims FDA allows and the categories of claims the cell culture food companies have been making over the past few years in their presentations, websites and interviews with the media.

Several companies across various food categories are drawing near to commercialization of products as they bring production capabilities up to scale. The following are some of the claims, statements, and strategies the companies are using as of mid-2021. Many of these positioning and marketing claims may not be added to the final food product packaging, or may be changed if necessary to meet regulatory constraints, or may be modified if not factually supported by actual production procedures.

Seafood

Key words in BlueNalu's more recent promotional statements include "great tasting, healthy, safe and trusted products that support the sustainability and diversity of our ocean." The company calls its production process "cellular aquaculture" and has trademarked the term "Eat Blue" to suggest consumer seafood choices that are similar to "going green" in other environmentally positive decisions. Also, the company is pursuing internationally recognized third-party certification of safety and traceability in its supply chain.[11]

Cultured Decadence describes its lobster, shrimp, scallops and crab as nutritious, sustainable, and authentic, without shells, organs or waste; free of mercury and micro-plastics. Identical to the real seafood, but more sustainable, "animal-friendly," and indistinguishable in form and function from wild caught.[12]

Finless Foods says its cell culture tuna is "comparable to raw sushi grade tuna," and features all of the delicious traits of wild-caught tuna without the potential for environmental contaminants like mercury. The tuna is "safe, healthy, great tasting seafood with no mercury, plastics, antibiotics or growth hormones."[13]

Wildtype describes its seafood as clean and sustainable. Its salmon "has the same flavor aroma, texture and fat as wild caught." "Loaded with omega-3 and omega-6 fats, our salmon has all the nutritional benefits of wild fish, without any of the microplastics, mercury, parasites, and other toxins commonly found in seafood today."[14]

Poultry, Chicken

Air Protein says its powder and extruded chicken will have 80 percent protein content and all nine essential amino acids, along with minerals and vitamins including B-12. "Superior protein levels and unparalleled benefits to the planet."[15]

GOOD Meat chicken and mung bean nuggets are described as safe, high in protein and essential amino acids, with no Genetically Modified Organisms or antibiotics, and low in saturated fat, high in healthy monounsaturated fat. Extremely low and significantly cleaner microbiological content than conventional chicken.[16]

Memphis Meats/UPSIDE Foods chicken is "Real. Delicious. Meat." It is described as real meat, delicious, sustainable, and humane, with no harmful bacteria. "Looks, cooks, and tastes like chicken because it is real chicken." Free from the risk of animal infectious diseases. Follows the highest standards of production and quality in the world.[17]

Beef
Artemys beef burgers will be "A really great piece of meat with the same or better nutrition."[18]

Orbillion Bio "Heritage" beef, elk, bison and lamb will be "healthy, flavorful, ethical, low fat and cholesterol, high in protein and monounsaturated fats, with no antibiotics or hormones.[19]

Pork
Fork & Goode pork is described as having the same real meat nutrition, with no hormones or harmful bacteria, and produced with less harm to animals and the environment.[20]

New Age Meats says its pork will be "the purest, most delicious, nutritionally dense meat possible," "intensely flavorful meat that's better for you, the planet and animals." It "can reduce risk of heart attack and cancer while being much more sustainable for the planet and animals."[21]

Consumer Acceptance is Crucial
Those claims all sound wonderful, but will consumers bite? The cell culture meat industry presents a potential food revolution decades from now and eventually a major disruption of global and U.S. meat production as practiced for more than a century. None of that will happen if consumers considering cell culture food will not try it, buy it, and keep going back for more.

A key aspect of consumer acceptance on a scale large enough to satisfy investors and change purchasing practices is simply product price. Cell culture meat is projected to decrease in cost to reach price parity with conventional meat products as early as 2030 if technological advancements and reductions of production input costs for growth media and scaffolding continue downward at the present pace.[6] In the years between 2013 and the summer of 2020, the price for a serving of cell culture meat decreased at a faster rate than some of the most powerful technologies did in their early years, including the transistor over a longer period, 12 years.[7]

And yet, even if lower cost brings cell culture food down from the pedestals of elite restaurants to the meat counters at Walmart, will consumers trust this novel meat and seafood enough to try it? Research suggests a sizable number of consumers will give it a go – if those key characteristics of taste, texture, and mouthfeel are acceptable, and if it is being appropriately regulated. Eat Just commissioned a study reported in early 2021 finding 72 percent of U.S. consumers are open to substituting cell culture chicken for the animal-based meat after being shown photos of the cell culture chicken product and reading a description on how it was made.[27] Another study from 2019 in the journal Frontiers in Nutrition found nearly 65 percent of U.S. consumers would probably or definitely try cell culture meat.[28]

The following research is current, concerns cell culture in general (thus, beef and pork as well as chicken), is focused on U.S. consumers, and largely aligns with other consumer studies in recent years.

Titled *U.S. and U.K. Consumer Adoption of Cultivated Meat: A Segmentation Study,* this recent consumer research was commissioned by the Israeli cell culture beef company Aleph Farms. Aleph has used 3D printing to produce ribeye steaks, and its investors include Cargill, the global food corporation headquartered in Minnetonka, MN. The research[24] published May 11, 2021 in the MDPI journal *Foods* surveyed large representative samples of consumers in the U.S. and the United Kingdom. The inclusion of U.S. consumers suggests Aleph has plans to either manufacture products in the U.S. or, perhaps with Cargill's help, import them. Regardless, current insights into consumer sentiments will help guide

product positioning, marketing, claims and communications. The study was conducted by researchers from Arizona State University, Glendale; the University of Bath in the U.K., and Crafton Hills College, Yucaipa, CA. Aleph participated in the study design, but not other aspects of the project.

Willingness to try cell cultured meat was at a high level of openness, 80 percent, in both the U.S. and U.K. populations, with 40 percent somewhat or moderately likely to try and 40 percent highly likely to try. Younger generations had the greatest openness: 88 percent of Gen Z, 85 percent of Millennials, and 77 percent of Gen X. Even 72 percent of Baby Boomers were at least somewhat open to trying cell culture meat. All segments envisioned this meat to become nearly half of their total meat intake.

U.S. participants said the most important on-package label was one indicating government assurances by FDA and USDA, followed by the claim that the product is made without antibiotics. This reflects previous study findings that consumers desire that cell culture meat products be effectively regulated.[25] Participants preferred non-GM products over GM products. U.S. consumers prefer nutritionally superior meat over nutritionally equivalent meat. For U.S. consumers being free from pathogens was of high importance. The study research team notes that consumer acceptance studies over recent years have identified a consistent set of motivators to buy cell culture meat and a set of barriers. Although consumers generally recognize the benefits of cell culture meat for animals and the environment, many raise taste, price, and safety concerns. Some consumers perceive cell culture meat as unnatural, though this depends on how the technology is explained. Disgust and persistent fear of any new food are barriers for some consumers.

Initial population-level support for cell culture meat production was fairly high for an unfamiliar technology (only 5–7 percent were highly familiar) and this support further increased after reading an expanded description of how the meat is made. After reading a detailed description of cell culture meat technology the overall majority were open to supporting the technology, to trying cell culture meat, and purchasing it regularly, and to replacing conventional meat. About half were open to paying more. This underscores the importance of increasing public familiarity with the technology through transparent communication and evidence-based message design.

This research used a tool called the Diffusion of Innovation framework to help understand how new inventions are adopted in the market, based on population segments. Figure 2 shows the model, with its five segments based on an individual's openness to new ideas and products.

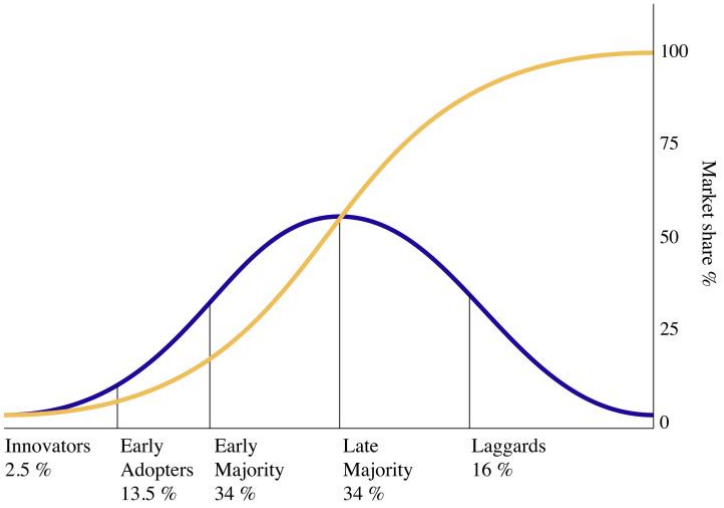


Figure 2.
The 'Diffusion of Innovations' Model.

Adopter categorization on the basis of innovativeness.
Source: Wikipedia, Creative Commons Attribution

Innovators, who typically make up just 2.5 percent of the market, are the first people to adopt an innovation. They are eager to use new products and are likely to be willing to pay a premium for the privilege. The next group, Early Adopters, makes up 13.5 percent of the market and is the second group to adopt an innovation. They are comfortable with change, need little persuasion to adopt a new product, and are more likely than Innovators to provide reliable social proof to adopter groups that come along later. The Early Majority and Late Majority groups each make up 34 percent of total consumers. These groups are not particularly open to innovations, but are not particularly conservative either. Social proof is important to them. They want to see others using a product and know that it is safe, functional, and beneficial before they adopt it. They may also wait for later iterations of an innovation in which initial problems have been addressed. Finally, the Laggards, 16 percent of the market, are the last to adopt new innovations, and may only do so with significant social coercion.

The Diffusion of Innovation framework suggests that adoption of a new innovation typically follows a normal curve over time. The results of this study suggest that cell culture meat could quickly become adopted within the general population based on more than 10 percent of the population indicating a high willingness to pay more, 25-30 percent highly interested in purchasing regularly, as well as 40 percent expressing high interest in trying the new meat.

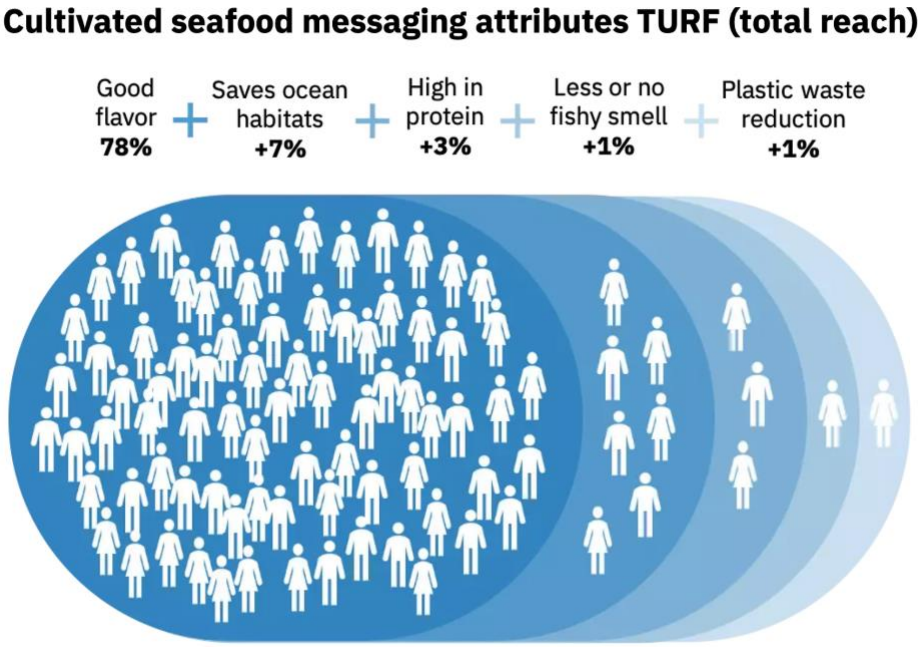
For stakeholders wishing to accelerate adoption, learning about and appealing to the models' earlier adoption segments (the innovators, early adopters, and early majority) will be most effective. Consumer segmentation is helpful to identify characteristics of these groups, as well as product and messaging strategies which will be most appealing to them. Meanwhile, companies and organizations need not put much weight on the preferences of laggards, who are unlikely to quickly adopt the new innovation. Therefore, segmenting a market in this way and catering to earlier groups can help to speed up the early stages of an innovation's acceptance and diffusion through society.

The authors note there are some limitations to their study. First, data collection via self-reported online survey is subject to known issues, including data inaccuracies due to imperfect recollection or judgement.[29] Moreover, respondents in the survey would likely be subject to considerable uncertainty about cell culture meat, as many were learning about it for the first time. Data quality measures were taken to ensure respondent quality, and some level of knowledge was ensured by requiring respondents to spend a minimum amount of time reading the descriptions of the cell culture meat technology. That said, the conditions in this survey were quite different from those that consumers will experience while shopping.

Future research could use the Diffusion of Innovations framework to examine in more detail the preferences and objections of laggards. While it is most advantageous from a sales perspective to examine earlier adopter segment, it is also useful to understand the perceptions and preferences of more skeptical consumers.

The study concludes there are solid consumer markets for cell culture meat in the U.S., despite an overall lack of familiarity with the product. Younger generations are the most open to trying cell culture meat, and government seals of inspection and/or approval are considered important. While nutritional enhancements do not add much to consumer appeal overall, they may be an effective way to provide tangible benefits to more skeptical consumers. Cell culture meat company executives will want to dig into the findings of the study as they develop strategic marketing communications plans targeting certain public segments, which will include claims and key messages they want to have on packaging.

A recent study of interest to companies developing cell culture seafood was reported on April 30, 2021. It was conducted by Kelton Global research and commissioned by the Good Food Institute.[34] Titled *Choosing Alternative Seafood: Key Insights from Research on Consumer Needs, Preferences, and Motivations,* the study underscored that taste was the most important aspect that could get consumers to try and eat more cell culture seafood. Other features and benefits of seafood trailed far behind but each would contribute to bringing more consumers along to try the new seafood. (See Figure 3, following page.) The findings were based on Total Unduplicated Reach and Frequency Analysis (TURF).



The GFI study found that general consumers need more information about the benefits and taste of alternative seafood in order to feel compelled to try it. The primary concerns are taste and texture of the products. While taste is primary for cell culture seafood, messaging about a product's environmental, health, and functional benefits can bring additional consumers into the category.

The Nomenclature Dilemma: What to Label this Novel Food

The Aleph study and several prior consumer surveys have included questions about what labeling terminology would provide consumers with clear understanding and more comfort in purchasing cell culture meat. In the Aleph research, consumers had equal preference for "cultivated" and "cultured" as descriptor terms for the meat product, identifying them as overall more appealing. Despite finding these names slightly less descriptive, consumers nonetheless preferred "cultivated" and "cultured" over "cell-based" and "cell-cultured" in both a social and a labeling context.

A number of studies have found that nomenclature has a significant impact on cell culture meat acceptance. These studies have largely demonstrated that consumers have a more positive reaction to neutral and benefit-focused terms, in comparison to less appealing terms such as "lab grown meat," which tend to invoke concerns about naturalness. 31, 32, 33

A recent science communication project assessed nomenclature against several criteria: neutrality, appeal, and descriptiveness, and differentiating from other meat types.[30] In consumer studies, "cultivated" meat was found to meet these criteria,[30] and in a focus group study, participants assessed

these criteria and preferred "cultivated meat" over others.[34] The most common names currently in use by the companies include "cultivated meat," "cultured meat," and "cell-based meat."

While BlueNalu uses the term "cellular aquaculture" as a branding tool, the company refers to its seafood as "cell-based." This is a research-based choice. BlueNalu commissioned Dr. Bill Hallman of Rutgers University to do a consumer study of terminology best suited to help consumers understand cell culture seafood. Titled *An Empirical Assessment of Common or Usual Names to Label Cell-Based Seafood Products*, the unrestricted research involved more than 3,000 consumers. It found that 'cell-based' met key differentiation criteria for seafood.[32]

The study used images of realistic packages of three types of seafood that a consumer might encounter in a supermarket. The terms tested were, "cell-based seafood," "cell-cultured seafood," "cultivated seafood," and "cultured seafood" and the phrases, "produced using cellular aquaculture," "cultivated from the cells of ____," and "grown directly from the cells of ____," where the blanks are filled by the name of the seafood product. Five criteria were used for evaluation, including each term's ability to:

- enable consumers to distinguish cell-based seafood from wild and farmed fish,
- signal potential allergenicity,
- be seen by consumers as an appropriate term to identify the product,
- not disparage either cell-based or conventional products, and
- not evoke thoughts, images, or emotions that are inconsistent with the idea that the products are safe, healthy, and nutritious.

The results showed that "cell-based seafood" outperforms the other names tested. It enables consumers to recognize that the products are neither wild caught nor farm raised, signals potential allergenicity, is seen as an appropriate name for describing the technology/process, and it performs well with respect to measures of consumer acceptance, particularly in comparison to conventional products.

Other cell culture seafood companies are using these terms: Cultured Decadence and Finless Foods use "cell-cultured" and Wildtype uses "cell-cultivated." In its submission to FDA in response to the agency's request for information, including recommended label nomenclature for seafood, Memphis Meats in March 2021 expressed preference for the term "cell-cultured." The comment from the Alliance for Meat, Poultry and Seafood Innovation and the National Fisheries Institute also endorsed "cell-cultured" for both seafood and meat/poultry.[35]

The Good Food Institute's response to FDA's questions suggested FDA allow producers to disclose differences from conventional products using a range of appropriate terms or explanatory language, so long as the language is clear to consumers and not misleading. GFI urged FDA to give guidance on permissible labeling approaches, including descriptive phrases such as "grown from cells" that may convey the nature of the production process more clearly to consumers than any single term. This regulatory strategy would allow consumers time to become more familiar with the new cell culture food products, and for common terminology used by consumers to evolve and help guide the final labeling requirements.[36]

Since USDA will be making the decision with regard to beef, pork and chicken it is possible this term could differ from what is required on seafood. The six companies nearest commercialization of these beef, pork and chicken meat products currently are using just a few terms on their websites and in interviews with media. Artemys Foods, Fork and Goode, and New Age Meats use the term "cultivated"

meat; GOOD Meat (Eat Just) and UPSIDE Foods (Memphis Meats) use "cultured" meat; and Mission Barns uses "cultivated" for its fat product.

Hybridization May Enhance Product Sensory Characteristics While Reducing Cost

The full extent to which planned cell culture meat and seafood products may incorporate ingredients that are plant-based or created through fermentation is not known. The best example of a combined product that still retains the identity of cell culture meat would be the chicken bites/tenders being sold in Singapore under the GOOD Meat label. This product is approximately 70 percent minced cell culture meat and 30 percent mung bean protein and perhaps small amounts of other ingredients that are not disclosed. The hybrid product seems to have received acceptance as being chicken, both by consumers and by Singapore regulatory authorities, with ongoing purchases of it in two Singapore restaurants and for home delivery.

Other companies have taken notice and are planning their own versions of hybrid meat products. Artemys Foods has said its product, the Artemys Burger, will be a similar hybrid. Lab Farm Foods held a taste test in New York for its chicken nuggets that came in two formulations. One was half cell culture chicken and half plant-based protein. The other was half cell culture chicken and half conventional farmed chicken. New Age Meats has said its minced pork sausage and dumplings will include plant-based ingredients for taste, texture and nutrition. Mission Barns is planning various species of fat and meat that will include plant-based proteins. And GOOD Meats/Memphis Meats will be offering a cell culture chicken meat but has not stated whether it will contain plant-based or other proteins.

One reason other than sensory characteristics that hybrid products have gained favor with some companies is economic. The cell culture meat companies nearing commercialization are coming to grips with cost factors that are slowing their progress toward price parity with conventional meats. Producing cell culture meat is very capital intensive and complex. The primary drivers on the front end of the cost spectrum are growth media or growth factors and the scaffolding the cells proliferate on within the bioreactor.

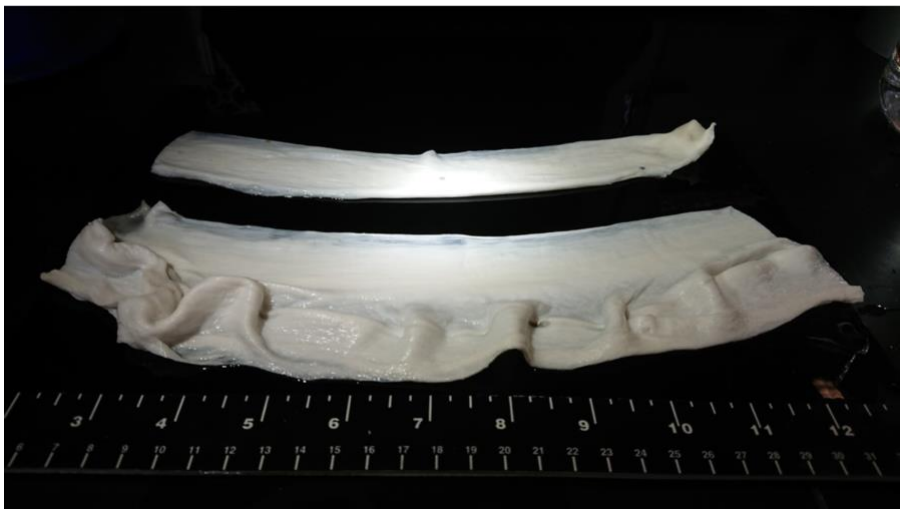
Successful technological transition of cell culture meat to the marketplace requires production systems that are low-cost, scalable, food-safe, and free of animal-derived inputs. Cell culture growth media is a particularly problematic hurdle for several reasons. First, cell culture media comprises the majority of the cost (greater than 99 percent) of current production systems.[37] Second, the culturing of meat-relevant cells has traditionally relied on fetal bovine serum (FBS), a notoriously expensive, unsustainable, and inconsistent component, which is inherently antithetical to the aims of cell culture meat. FBS comes from the blood drawn from a bovine fetus via a closed system of collection at the slaughterhouse. FBS remains the most widely used serum-supplement for cell culture, but the current cost is $490 per liter.[56]

When serum-free media for satellite cells have been explored, they are either complex, ineffective compared to serum-containing media, reliant on proprietary or animal-derived additives, or contain additives (e.g., synthetic steroids) that could cause regulatory concern. Further, no serum-free media has been validated for the sustained expansion of muscle satellite cells over multiple passages. As such, serum-free media remains one of the most pressing limitations to cost parity and is one reason why many company executives predict price parity, and the higher volume of potential sales, is at least five to 10 years away. Scientists with a few of the cell culture meat companies have said they have cracked the serum problem and no longer use FBS. But what they are using instead is shrouded in patents or trade secrets.

In the meantime, the economics work better if cell culture meat companies can essentially cut the amount of meat needed for a piece of chicken and replace that with far less costly and already federally approved plant-based protein. If there is a downside risk to blending plant-based protein with "clean" meat it is that adding flavorings and ingredients may introduce the possibility of genetic modification or animal source aspects that will be counter to the positioning and claims of the meat product. It also may invite further regulatory scrutiny or require additional traceability while muddling the "transparency" message of the cell culture meat manufacturing process.

Hybridization of the final product also suggests cost savings on scaffolding, which provides the three-dimensional platform along which the cells can proliferate and take the shape of actual cuts of meat. Either eliminate the need for scaffolding, which some cell culture meat companies claim to have accomplished, or cut the amount of scaffold-dependent meat in a final morsel of the meat.

The scaffolding issue also can be resolved by other technologies, such as the spun fibers of Boston Meats (see the company profile in Appendix A).



Boston Meats adapted a cotton candy type of machine to spin edible meat fibers from pig-derived gelatin, ethanol and water. The resulting fibers are long, malleable, can cross-link, and form a food-safe edible scaffolding on which animal cells are seeded, can attach, and proliferate. (Harvard University photo).

Another way cell culture meat companies might save cost is through collaboration, both with one another and with suppliers who have determined that their contribution to the cell culture protein industry would be to solve the problem of growth media, scaffolding, or even immortal cell lines, and license that technology to companies that need it. The Boston Meats fiber technology can be licensed by other cell culture food companies. Of course, a cell culture meat company that needs a solution could buy a competitor or a supplier that has solved the problem. That hasn't happened yet, but there are predictions that mergers and acquisitions will happen in the next few years.[38, 39]

In addition to cost cutting, the marriage of cell culture meat and plant-based protein does seem to offer advantages of taste, texture and nutrition, as noted by New Age Meats for its pork, expected to seek regulatory approval as soon as possible. The consumer research suggests that cell culture meat may be real meat but blending in plant-based proteins or other ingredients can add even more nutritional aspects (or subtracting undesirable ones) than conventional meat. That should lure more consumers to try it.

Plant-based meats have had some of their own problems of taste and texture, but sales of the category have increased significantly and some products have provided a model of commercialization strategy

that cell culture meat companies may want to emulate. The win-win of the hybrid cell culture and plant-based products is that the sensory qualities of both products may improve depending on the blend.

A more subtle feature of hybrid products is a further enhancement of the sustainability and ecological footprint marketing strategies of these foods. While cell culture meat and fats produce fewer CO^2 emissions than traditional beef, for example, plant protein systems are even more sustainable.[64]

Fermentation Provides Functional Finesse, New Protein Opportunities

As creative new food technologies continue to spark and evolve, cell culture meat producers may have new opportunities for enhancements and efficiencies with the spillover from seemingly unrelated alternative protein sources. Hybrid food products combining cultured material that is not animal-based with plant-based proteins is one of those fast developing areas where there may be spillover to cell culture meat for better production technology or ingredients.

Fermentation is a booming sector within the alternative protein industry. Ingredients from this ancient technology, which is always being updated and put to new uses, are beginning to offer cell culture meat products another source of sensory, nutritional or functional added value and appeal. Fermentation has multiple roles in alternative protein. While used to enhance plant-based meat, egg and dairy products, fermentation also is used to create its own categories of alternative protein products.

On September 21, 2021, the Chicago-based start-up Aqua Cultured Foods announced its emergence from "stealth" mode to seek funding as it develops seafood alternatives through biomass fermentation and a proprietary strain of fungi.[65] The company plans to develop "the world's first" whole-muscle cut, sushi-quality, fillet as well as shrimp and calamari alternatives. Their seafood analogs will include tuna and whitefish. The company's founders saw fermentation as a largely unexplored technology for growing seafood alternatives.

Recently cell culture meat producers have begun to consider ways fermentation can contribute ingredients for their products, and fermentation companies likewise have seen opportunities in these collaborations. The Good Food Institute's 2020 State of the Industry Report on fermentation for meat, eggs and dairy outlined several of these possibilities.[40] Cell culture meat companies looking for models for their own commercialization may want to look at how some traditional and biomass fermentation processes offer well-established examples of scalability and cost reduction, a precedent for both economic viability and true industrial scale.

GFI notes that fermentation in the alternative protein industry refers to cultivating microbial organisms for the purpose of processing a foodstuff or food ingredient; obtaining more of the organism itself as a primary source of protein; or deriving specialized ingredients, such as flavorings, enzymes, proteins, amino acids, vitamins, and fats, for incorporation into cell culture meat. Functional ingredients fermentation can produce include growth factors for cell culture meat production. Turtle Tree Labs has been working on using filamentous fungi to produce growth factors, some of which could be less expensive than those now used by cell culture meat companies.

The alternative protein industry uses fermentation in three primary ways:
1) **Traditional fermentation** has been used for thousands of years to produce items such as bread and beer. It uses intact live microorganisms to modulate and process plant-derived ingredients, resulting in products with unique flavor and nutritional profiles and modified texture.

2) **Biomass fermentation** leverages the fast growth and high protein content of many microorganisms to efficiently produce large quantities of protein. This biomass serves as either the predominant ingredient of a food product or one of several primary ingredients in a blend.
3) **Precision fermentation** uses specially designed microbial hosts as "cell factories" for producing specific functional ingredients. These ingredients are powerful enablers of improved sensory characteristics and functional attributes of plant-based products or cell culture meat.

Scaffolding is a key component of cell culture meat production for most products. It can make cell culture meat look, feel, and taste like a steak, pork cutlet, chicken breast or fish fillet. The problem is that current scaffolding material in most instances is not scalable because it is costly and does not enable the co-culturing of fat and muscle cells necessary to achieve marbling throughout the cultured muscle.

Fermentation could soon be providing new options in scaffolding for cell culture meat companies. Fermentation is used to produce mycelium, which is the filament-like roots of mushrooms, for edible biomass or functional ingredients for plant-based meat, eggs and dairy. Mycelium also can be used by cell culture meat companies as scaffolding. One mycelium producer, AtLast Foods Co. in New York state has been doing testing and development of mycelium scaffolding with a few cell culture meat companies, including WildType.[44] These companies require edible scaffolding strong enough to maintain structure, but sufficiently porous to allow growth media through to nourish the cells. The testing includes adjusting the structure and porosity of the scaffolding to fit the type of cells and meat being cultivated.[42]

AtLast's parent company Ecovative Design has created the brand Excell focused on providing mycelium scaffolding for cell culture meat companies that want to create more complex 3D structures such as steaks, chicken breasts or fillets of seafood. To date, it has supplied product to several cell-based meat companies.[43] Excell has a scaffold culture kit companies use experimentally to assess how the scaffolding functions in their production system. The scaffolding serves different cell sources such as avian or bovine muscle and fat cells. The testing involves tissue engineering in applications to determine the optimal combinations of the right cells, the right materials, and the right environment to enable biochemical and physiochemical factors to induce cell growth, differentiation, and maturation into a whole cut of lab-grown meat. The Excell material is promoted as a biomaterial product that is cost-effective, scalable, and edible. [44]

AtLast uses existing edible mushroom strains that have GRAS (generally recognized as safe) determination when grown in conventional mushroom farms. That GRAS designation is for mushroom caps, and the scaffolding uses roots, which creates some uncertainty about the status of the scaffolding. The company is working on a GRAS filing for the roots. The nutritional, chemical composition and other aspects are similar between the different structures of the mycelium tissue. Labeling of mycelium scaffolding as an ingredient in the final meat product is another matter to be resolved.

There are several other fermentation companies working with mycelium, including at least three in the U.S. – the Boulder, Colorado company Meati Foods, formerly Emergy Foods; Fybraworks Foods, Minneapolis, and Prime Roots, San Francisco. AtLast seems to have carved out a niche working on scaffolding with cell culture meat companies, and time will tell whether some cell culture meat products include a little mushroom root. AtLast is showing how a business-to-business (B2B) supplier collaborating with cell culture meat companies can benefit both sides.

Another B2B company, Novel Farms in Berkeley, California, also is creating improved scaffolding for cell culture meat by using synthetic biology and fungi to develop low cost and tunable 3D bioscaffolds for the production of structured cell culture meat products. Its technology not only will improve the structure and marbling of cell culture meat but will also have the potential to reduce manufacturing costs.[45] With its technology, Novel Farms, Inc. aims to "recreate the taste and texture of exquisite, marbled cultured meats."

Cell culture meat companies need more than just less costly and more productive scaffolding. Identifying plant-based proteins for hybridization and/or ingredients for improving sensory aspects of their products also can be a priority. Additional B2B companies have formed to be suppliers and service providers for the alternative protein industry and want to help business-to-consumer (B2C) companies improve their branded products. GFI notes that the B2Bs are citing scale, cost and functionality as how their technologies can augment the efficiency and accelerate price parity for alternative protein products seeking consumer acceptance. How these B2Bs can collaborate with cell culture meat companies remains to play out, but the potential and the need is evident. GFI noted the following developments in the B2B supplier and service sector in 2020.

- Geltor has announced a new Ingredients-as-a-Service computational biology platform to work with companies from concept to development to commercialization of tailored ingredients for functional properties such as texture and amino acid profiles. The service makes it easier to innovate quickly without risk.

- In the production of natural, microbe-derived flavoring Myco Technology's pea and rice protein fermented by shiitake mycelia is now part of OZO brand plant-based meat by Planterra, a subsidiary of the global meat giant JBS. And Motif Foodworks is expanding manufacturing capacity of an initial product that adds meaty flavor to beef alternatives.

- In the production of microbe-derived bulk proteins for consumer products, 3F Bio's mycoprotein is now used in a vegetarian product line at a major United Kingdom retailer. Mycoprotein is a protein made from *Fusarium venenatum*, a naturally occurring fungus. Spores are fermented along with glucose and other nutrients, resulting in a doughy mixture with a meat-like texture that's high in protein and fiber. 3F Bio has announced a prototype tuna steak made with mycoprotein produced via a 3D printer from the company Natural Machines. Other companies producing mycoprotein include Kernel Mycofood and Pura.

Fats are key contributors to the sensory experience of eating meat, egg, and dairy products. By using microbial fermentation, companies can produce a wide array of fats—including fats that are critical to the nutrition, sensory characteristics, or functionality of animal products but challenging to source from the plant kingdom.

- Companies working with microalgae are producing functional ingredients along with plant-based seafood products. Good Catch uses microalgal Omega-3 oil in its plant-based tuna, an indication of how cell culture meat companies could enhance Omega-3 in their products. Microalgae cultivation is used to produce algal Omega-3 fatty acids, such as EPA and DHA, which are not produced by terrestrial plants. Companies such as Algarithm, DSM, iWi, and Corbion produce algal- or fungal-derived Omega-3s. Odontella makes a structured salmon and analogue using seaweed along with and microalgae.

- C16 Biosciences uses microorganisms with altered lipid synthesis pathways to produce desirable fats, and the technology is so promising it has drawn investment from backers including Breakthrough Energy Ventures led by Bill Gates.

Companies are finding new ways to develop flavor and texture enhancements for plant-based foods and for dairy alternatives, and new categories of protein. GFI's summary of 2020 product development advances and breakthroughs[40] cited several achievements across many categories.

- Noblegen has introduced "the egg," a protist-derived powdered whole egg replacement. Protists are another type of microbe that can produce edible biomass or functional ingredients, usually for plant-based meat, eggs and dairy, but also for cell culture meat cultivation, such as growth factors used in bioreactors or fermentation. A protist is an organism whose cells contain a cell nucleus but they are not an animal, plant or fungus. Protists are a diverse collection of organisms. While exceptions exist, they are primarily microscopic and made up of a single cell. The cells of protists are highly organized with a nucleus and specialized cellular parts and mechanisms called organelles.
- Clara Foods uses advanced yeast engineering and fermentation processes to produce egg whites and also a pure, clean protein. In partnership with Ingredion, Clara Foods has developed the world's first animal-free pepsin enzyme. Pepsin breaks down proteins into smaller peptides. It is produced in the gastric chief cells of the stomach lining and is one of the main digestive enzymes in the digestive systems of humans and many other animals, where it helps digest the proteins in food. Commercial pepsin has been prepared from pig stomachs may be used in cheese production, among other uses.

- Notable fermentation-powered dairy developments include the new Tofurky line of dairy-free cheese shreds made from fermented cultures and fava bean protein. Tofurky is teaming with San Diego-based Triton Algae Innovations to commercialize new algae-based meat innovations. Perfect Day's animal-free ice cream uses recombinant casein and whey protein. Perfect Day's milk proteins casein and whey do not come from cow mammary glands and will enable a new generation of cheese, ice cream, yogurt and butter. Other companies including New Culture, Change Foods, Cultivated, and LegenDairy have recently emerged to create dairy proteins and fats.

Bond Pet Food uses microbes to produce specific animal muscle proteins and in 2020 introduced their first product, which is a high-protein dog treat produced from a novel strain of yeast. GFI points out that fermentation can create proteins that are scarce in plants but desirable for animal-free products such as pet foods. Many aspects of the research and technology developments in pet food also can be "borrowed" and adapted by producers of human food, including cell culture meat companies.

Fermentation technology and products are valuable in their own right with less cost, more functionality and rapid scalability, GFI states. Aspects of fermentation offer spillover applications in cell culture meat, enabling new generations of proteins, fats, and other functional ingredients that combine with cell culture and plant-based components to mimic whole-cut meats, egg replacements, animal-free dairy proteins, seafood products, and more. Cell culture meat companies have much to discover in the potential for collaboration.[40]

Forecast: The Prospects of Cell Culture Food, and the Problems

Most observers don't expect cell culture meat to completely replace conventional meat production and set all the livestock free, not even 30 years from now. For one thing that would unemploy all but a fraction of the farmers, ranchers, auctioneers, traders, truckers, meat processors, and packers, their

suppliers and speculators associated with the $1.8 trillion global conventional meat business known and developed for the past 100+ years.

But encroachment is foreseeable. Allied Market Research (AMR) published an analysis and outlook report in May 2021 on the global cell culture meat market's prospects in the years 2022-2030 and predicted the industry could generate $1.64 million in 2021and reach $2.78 billion by 2030, a compound annual growth rate (CAGR) of 95.8 percent during the period.[47] AMR believes the seafood segment will witness the highest CAGR of 125.1 percent from 2022 to 2030. This is attributed to increased awareness regarding the benefits of seafood and changes in dietary preferences of consumers. Scenes of oceans clogged with islands of floating plastic waste also may convince some consumers to rethink their seafood source.

Research and Markets (R&M) foresees the global cell culture meat market to be valued at $206.6 million in the year 2025.[48] The reasons expected to facilitate growth of the market are rapid urbanization, changing dietary preferences of people, and growing concerns for animal welfare. Further, the increased awareness about the cell culture meat and other health related benefits will help lead the market in the forecast period. The rising demand for meat and repugnance for the slaughter of animals will force a move towards the consumption of cell culture meat.

The figure of $2.78 billion about eight years from now doesn't sound like much considering the size of the overall global market for meat. Between 2016 and 2020, venture capital invested in the segment totaled a little over $500 million, with $366 million coming in 2020. The seafood segment of that included $17 million in 2019 and $45 million in 2020.[1] These, by the way, are disclosed investments, not the real totals from unknown private sources, which are not publicized.

Almost all the major U.S. cell culture meat companies plan to launch products through restaurants, particularly high-end ones where prominent chefs can develop menu items around products such as Bluefin tuna and sushi-grade coho salmon. Patrons of these restaurants probably won't mind or notice the cost of the cell cultured seafood, and it will be an adventure for them. Even though GOOD Meat's product is a chicken nugget type of piece, the two restaurants launching it in Singapore are more than a few price points above McDonalds.

AMR's forecast is that the food service segment will hold the highest share of cell culture meat sales in 2021, contributing to 93 percent of the global cell culture meat market, and will maintain its highest contribution through 2030. This is attributed to increased consumption of fast food and ready-to-eat food products. However, the household segment is expected to portray the fastest CAGR of 124.5 percent during the forecast period, owing to rise in disposable income, increased awareness regarding the benefits of cell culture meat, and an upsurge in expenditure on premium food products.

If projections hold true that cell culture meat will attain cost parity with its conventional counterparts by about 2032 it would set the table for substantial year-over-year sales and increase the size of the nibble the sector will be taking out of that $1.8 trillion market for meat. By that time cell culture meat may well be an option at some of the world's biggest fast food companies. Whether an Artemys Burger will ever replace the Whopper is anyone's guess, but a plant-based burger is already on the Burger King menu, so anything can happen. A cell culture meat company could be delighted providing all the meat for a major international burger chain, no matter what they name it.

Even without cost parity over the next 10 years, more cell culture meat companies are nearing commercialization on at least a pilot scale. The acceleration of investment is expected to continue – with eyes wide open. AMR notes the high cost of production and the availability of healthier substitutes (from plants, fermentation, vegetarian products) will hinder the market growth for cell culture meat. Indeed, Boston Consulting Group (BCG) and Blue Horizon Corporation (BHC) predicted cell culture meat will achieve cost parity with animal-based meat in 2032. But they also forecast cost parity for plant-based meat in 2023 and micro-organism-based meat in 2025.[49] That's a long gap while the other alternate proteins gobble up market share and eat cell culture meat's lunch.

While R&M was optimistic in assumptions about cell culture meat's future, they also worked up a pessimistic scenario in which cell culture meat would fail to gain consumer acceptance and thus true commercialization. In this scenario, strict regulations lengthen the overall process of product commercialization, making it more cost-intensive. Other factors would be consumer unacceptance due to failure in meeting their expectations for taste and texture coupled with higher prices compared with traditional meat. Another downside would be a possible lack of advanced R&D facilities, a failure to reduce high growth media and equipment costs. These would further slow cell culture penetration of the global meat market.

The R&M downside scenario seems gloomy indeed and unlikely given he strides of technology and venture capital the cell culture meat companies have enjoyed to date. Yet even the BCC-BHC projections came with the cautions that the industry must:

- Increase metabolic efficiency to speed the output of the culturing process.
- Decrease growth media cost and improve its efficiency by switching from costly pharmaceutical-grade media ingredients, including growth factors, to less costly food-grade ingredients.
- Replicate the fibrous quality of conventional meats by adding nonmeat ingredients to induce the cells to form fibers and meat-like fat, which will provide savory qualities to please consumers.

Companies in Israel and the Netherlands are aggressively resolving these issues, and some U.S. companies claim to have addressed them. As suggested earlier, the fermentation sector may be able to contribute methods that help cell culture meat partners.

The final big uncertainty is, of course, the U.S. regulatory requirements. Most company executives don't seem too worried. Perhaps they are encouraged by pre-market discussions with FDA and USDA. Still, terminology requirements could make consumers ask questions, doubt answers, and shy away from cell culture meats. Then there is another big unknown – misinformation. That is no small consideration, and U.S. companies are hopeful that transparency in their operations and how the meat is made will create a consumer comfort level with products.

On the other hand, BCC-BHC can foresee cost parity even sooner and market penetration greater if:

- Companies are indeed making real progress in metabolic efficiency and growth media changes
- Government policies and regulations are more supportive, such as widespread taxation of greenhouse gas emissions or reallocation of agricultural subsidies to support the transition to alternative proteins.

GFI and others supporting the cell culture meat industry have urged additional government investment in research and development of the sector. While every industry would like to dip into the public treasury, and none does that better than fossil fuels, transportation and agriculture, public investment in

cell culture food production could accelerate the industry's progress while forcing it to be more open sourced and transparent. It's a process that has begun. The University of California at Davis received a $3.5 million grant from the NSF to research cell culture meat. The EU set up a fund of $37.7 million for research into more sustainable protein options such as cell culture meat and plant-based protein. The Spanish government granted BioTech Foods $6.3 million to investigate the health benefits of cell culture meat. Spain also provided $307,500 to NovaMeat to further develop its 3D printed meat alternatives. [50]

Much of this investment is geared to food security after the Coronavirus disruptions, climate change as reflected in weather extremes of recent years, and concerns that new proteins are needed to feed 10 billion humans by 2050 when the planet's resources are already under stress.

With reasonable regulatory requirements, additional investment from government and the private sector, breakthroughs in cell culture technology, consumer indulgence, and truly great tasting products the future for cell culture meat seems likely to pleasantly surprise everyone by 2050.

Information Gaps

Over the past few years the amount of information about alternative protein sources, manufacturing and products has increased substantially. The overlap between the three categories (cell culture, plant-based and fermentation) is increasing, and rather than competing for the consumer's acceptance and dollars, the three are more aligned than they may seem. That alignment means questions and issues that face one sector may overhang another.

Currently a major information gap is how the U.S. government will proceed with guidance and regulatory oversight of the cell culture food industry. What product names will be allowed or disallowed? Do cell culture food products that are "hybrids" need a new label name or descriptive?

The response of the vested conventional meat industry stakeholders is not fully known, though organizations of cattle and pork producers may seek influence in how cell culture products are labeled. The U.S. Cattlemen's Association (USCA) refers to cell culture meat as "lab-grown fake meat," which suggests the meat turf blowback could be strong from some producer and allied organizations.[61] USCA petitioned USDA/FSIS in February 2018 asking that FSIS exclude from the definitions of "beef" and "meat" any products not derived directly from animals raised and slaughtered in the traditional manner.[62] This would impact cell culture and plant-based products. On September 16, 2021, FSIS denied the petition, saying the agency lacks authority over plant-based meat labels and noting that with regard to cell culture neat labels FSIS has begun an advanced notice of proposed rulemaking (ANPR) that will address those meat labels. Meanwhile, giant meat companies such as Tyson and JBS that depend on livestock producers as their suppliers have also shown interest in participating in any consumer switch from conventional to alternative meats.

Public statements by vested seafood industry organizations have been less confrontational than livestock interests. The Alliance for Meat, Poultry and Seafood Innovation (AMPS Innovation), a coalition that includes BlueNalu and Finless Foods, and the US seafood trade association the National Fisheries Institute (NFI) jointly responded to FDA's call for nomenclature comments. Their comment supported requirements for labeling these new products descriptively, accurately and consistently regarding what the products actually are and how they are made. The NFI sees a potential challenge for traditional seafood sellers, many of whom are concerned that improper labeling will mislead consumers.[57] Descriptive nomenclature also will be helpful to those with allergies to some seafood, such as shellfish.

There are several fishery organizations focused on specific seafood (lobster, Bluefin tuna, regional commercial fishing), but their postures toward cell culture seafood have varied. Some segments of the industry may see synergies rather than threats in collaborating with cell culture technology. For example, in research to develop cell culture lobster, founders of the Wisconsin company Cultured Decadence went to Maine and met with lobster fishermen, lobster researchers at the University of Maine, and some large lobster processors and distributors based in Maine.[63] One purpose was to understand potential opportunities to "collaborate and work together" to address supply side constraints and certain natural factors hampering the interests of those stakeholders. Cultured Decadence founders said they want to "help create a better understanding of the biology of those animals so we can offer useful insights to scientists and to the industry, which we hope ultimately will improve the status of lobster populations in the future." There has not been any negative pushback from anyone in the existing industry, one of the founders said, and they want to continue engaging to talk through the implications of cell culture technology for everyone involved in the market.

Another information gap and an important aspect of the regulatory regime will be how production is inspected for product safety. Consumers may be reassured if there is clear communication and transparency in those processes, particularly with FDA's long-standing expertise in regulating and oversight of bioreactors in production of pharmaceuticals and other regulated biological systems. The public would need to know that experienced and knowledgeable inspectors are part of the production system. Consumers will want to know how inspectors are being trained, how they do inspections, what they look for, how departures from acceptable practices are handled. What are the standards and practices the agencies will apply to cell culture meat production?

Another unknown is whether and how the Federal government, through its agencies and commissions, and perhaps land-grant universities, will be supporting the industry. The NSF grant to UC at Davis for research on cell culture meat is a modest start. What additional types of funding might be available? Does public funding send the message that cell culture food has strategic value within the nation's food supply and is expected to contribute to economic growth and food security? How does cell culture meat integrate with the increasing awareness and concern regarding climate change? Cell culture meat can be produced virtually anywhere, without the need for pastures, feedlots and long-haul transportation to cities. Singapore, Qatar, Israel and other nations that must import much of their food are looking to the cell culture industry to reduce that dependency. Qatar and Just Food announced on August 31, 2021 that Just Food will build a manufacturing plant there to produce and market the company's GOOD Meat cell culture chicken, in addition to the previously announced manufacturing plant in Singapore.

No nation other than Singapore has established its regulatory framework, much less had cell culture meat production plants and products pass through it for approval. That leaves a considerable gap of information regarding if or how the U.S. and other countries will coordinate their regulatory regimes. Is the Singapore system a model for the U.S. or is it irrelevant? How will the U.S. handle the imports of cell culture meat from other countries to assure safety? Israeli companies are already talking about their plans for exports to the U.S. or even constructing manufacturing plants here. Will the U.S. be ready?

Another unknown is how the commercialization of cell culture meat will impact the labor force. Managing or working in a slaughterhouse requires one skill set, but producing cell culture meat requires something quite different. In its recent report on cell culture meat commercialization issues and outlook, "Cultivated Meat: Out of the Lab, into the Frying Pan,"[51] McKinsey & Company noted the possibility that after scale-up the same number of jobs will be available as in conventional meat production. The big difference is that up to 20 percent will be for bio-processing engineers. Other jobs will involve

development of key inputs such as growth media and cell lines, and equipment such as bioreactors, and executing R&D in labs associated with production. Every one of the 17 U.S. companies is already posting job openings for scientists and engineers, and the demand would appear to be steadily increasing. The talent search is global as well, so highly skilled workers need not immigrate for one of those good jobs. The U.S. industry needs that kind of talent, right now, and it's likely the bidding war is on for graduates and experienced professionals.

Now that cell culture meat is nearing commercialization, some harder questions are being asked of the industry and regulators, but there is no reason to expect that satisfactory answers will not be forthcoming. If nothing else, follow the money. Venture capitalists specializing in start-up companies and new technologies have been pouring record amounts of funding year-over-year into the alternative protein category. While cell culture meat and seafood have yet to achieve the funding levels of plant-based and fermentation food start-ups, the gap is narrowing.

Appendix A
Profiles of 17 U.S. Cell Culture Meat Companies

The following profiles of U.S.-based cell culture meat companies are based on public information from company websites, social media postings, company news releases, etc. Other sources included articles in the online and print business press covering the food, investment, and science industries, along with news and feature stories in the consumer and mainline press such as Bloomberg, Forbes, Consumer Reports, the New York Times, the Washington Post, The Guardian, etc. The information in these company profiles is current as of mid-2021. Some companies are still in early start-up "stealth" or low-profile mode. Other companies are generating significant news, and they are posting detailed information about their founders, technical staff, investors, current R&D technology, their mission and objectives, plus digital links to media stories about the company. The list of companies may not be complete since there could be unannounced companies beginning to work in the cell culture meat industry. Those companies would be more likely to be several years from launching products or scaling up for commercialization.

Note: These profiles are in a PDF file. Click on the first page shown (following page) and the PDF should open at higher resolution in your PDF software such as Adobe Acrobat Reader. There are 17 of the profiles and they total 55 pages.

AIR PROTEIN™

relationships with retailers, food service operators, chiefs, and major food companies.[2]

Product Positioning:
The Air Protein™ flour is an ingredient that can be given the texture and flavor of seafood, chicken, pork or beef. Contains no pesticides, hormones, antibiotics, or genetically modified organisms. Air-based meat is the most sustainable, nutritious way to feed a growing population. Compared with beef, Air Protein™ flour uses 5 million fewer acres and 15,000 times less water. And it converts CO2 instead of emitting greenhouse gases.[2]

Product Claims:
The Air Protein™ flour has 80 percent protein content and all (nine) the essential amino acids, along with minerals and vitamins including B-12. Messaging will focus on the products' "superior protein levels and unparalleled benefits to the planet."[5]

Category Claims:
Ultra-sustainable air-based proteins vs. land-based proteins. The protein is produced in just a few days with very little environmental impact because no animals, feed, and farmland are needed. The process is the most resource efficient, resilient and secure way to produce protein due to independence from arable land and climate. By using a recycled greenhouse gas as its core input, Air Protein can produce large quantities of protein "to order" in a matter of hours. Unlike other fermentation processes, Air Protein technology does not require feedstock sugar, which requires land and crop inputs. Eventually direct-air capture facilities could supply carbon dioxide direct from the air into the Air Protein™ process.[3,6]

Labeling:
Not determined. Product is different from animal-based, plant-based or fungi-based products, and is more accurately considered "culture-based." Air Protein™ flour could provide enhanced protein for cellular meat products, or meatless products. Air Protein™ would be a primary protein vs. a supporting one.[6]

Company Technology:
The Air Protein™ flour technology produces protein in sustainable, vertical "farms" that can be built virtually anywhere, making it highly scalable and extremely "planet friendly." Air Protein™ flour is not derived from animals or plants, but from beverage-grade carbon dioxide, nitrogen, water, nutrients and microbes (single-cell hydrogenotrophs). These and whole ingredients and extracts are combined in a proprietary "probiotic" process in fermentation vessels to output large quantities of biomass protein powder. The hydrogenotrophs consume the CO^2 and other elements to produce amino acids.[6]

Regulatory Pathway:
Seeking GRAS (Generally Recognized as Safe) determination.[6]

Financing:
$32,113,995 in Series A equity led by ADM Ventures, Barclays and GV (formerly Google Ventures). Planned uses: Launch an innovation research and development lab, accelerate product development and commercialization, recruit and build a high-level company team.[1]

Potential Setbacks:
Air Protein™ flour is so singular it doesn't really fit in any food category and may require additional time for regulatory approval. Consumers may perceive the protein from air as "too good to be true." Cell culture meat companies may see no need for additional protein, though plant-based meat products can be protein deficient.

Information Gaps:
Company statements remain vague regarding commercialization timetable and whether they will produce an actual meat product of their own requiring labeling, and what claims they may make for the product.

1. Air Protein news release, January 7, 2021
2. Air Protein news release June 16, 2020
3. Vegan Business Magazine, May 26, 2020
4. Food Navigator, January 7, 2021
5. Fast Company, November 12, 2019
6. Food Navigator, January 7, 2021
7. The Spoon, April 10, 2021

Photo from Air Protein website

Appendix B
Social, Environmental Issues Give Rise to Cell Culture Food Claims

FDA and FSIS ultimately will provide the policies and labeling that will govern cell culture food, but claims about the benefits and features of the products originate with the companies producing them. Four such categories of product information include: (1) What *is* in the product – essential vitamins and minerals, for example; (2) What *is not* in the product – genetically modified organisms, contaminants, antibiotics, growth hormones, etc.; (3) How the product *is* made – with pathogen-free sterile stainless steel equipment; inspection by FDA and/or USDA, for example; and, (4) how the product *is not* made – no animals were slaughtered, no fisheries were depleted. Whatever the claim, it must be substantiated by science and the facts of product production and content.

Federal Trade Commission and FDA have indicated that regulating labeling, product identity, and advertising are a priority. Additionally, the House Appropriations Committee directed the FDA to prioritize some of these labeling and product identity issues to increase clarity for consumers. false advertising food and beverage cases ramped up in 2020, continuing a trend with 177 in 2019, 164 in 2018, 145 in 2016 and 2017, and just 53 in 2011.[58] Many high-profile cases involved claims for beverages. For example a certain pomegranate juice lost a challenge to an FTC ruling that the brand deceptively advertised its products by claiming that the juice could treat or aid heart disease, prostate cancer and erectile dysfunction. The lesson for cell culture food companies is that there will need to be scientific evidence to back up bold claims, whether on the product label or elsewhere.

FDA notes that among the claims that can be used on food and dietary supplement labels are three categories of claims that are defined by statute and/or FDA regulations: health claims, nutrient content claims, and structure/function claims.[22]

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition. There are three ways in which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a conventional food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after reviewing and evaluating the scientific evidence, either in response to a health claim petition or on its own initiative; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research; and 3) as described in FDA's guidance entitled Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, the agency reviews petitions for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. If FDA finds that the evidence supporting the proposed claim is credible and the claim can be qualified to prevent it from misleading consumers, the agency issues a letter of enforcement discretion specifying the qualifying language that should accompany the claim. Other product statements may be considered dietary guidance, not a health claim, but still must be truthful and non-misleading. A heath claim based on an authoritative statement also may be permitted, but should be from scientific bodies of the U.S. Government or the National Academy of Sciences. FDA has issued guidance on how a firm can submit such a notification and make use of authoritative statement-based health claims.

Nutrient Content Claims under the NLEA are permitted if they characterize the level of a nutrient in a food and if they have been authorized by FDA and are made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient in the product, using terms such as *free, high,* and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more, reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not otherwise "characterize" the nutrient level may be used to describe the amount of a nutrient present. However, a statement such as "only 200 mg of sodium" characterizes the level of sodium by implying that it is low. Therefore, the food would have to meet the nutritional criteria for a "low" nutrient content claim or carry a disclosure statement that it does not qualify for the claim (e.g., "not a low-sodium food"). Most nutrient content claim regulations apply only to those nutrients that have an established Daily Value. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high* or *low*, are used consistently for all types of food products and are thus meaningful to consumers. *Healthy* is an implied nutrient content claim that characterizes a food as having "healthy" levels of total fat, saturated fat, cholesterol and sodium, as defined in the regulation authorizing use of the claim. Percentage claims for dietary supplements are another category of nutrient content claims.

Structure/Function Claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements and procedures for using structure/function claims. For conventional foods, structure/function claims focus on effects derived from nutritive value. FDA does not require conventional food manufacturers to notify FDA about their structure/function claims, and disclaimers are not required for claims on conventional foods. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "antioxidants maintain cell integrity." General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient. Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread the disease is in the United States. Structure/function claims may not explicitly or implicitly link the claimed effect of the nutrient or dietary ingredient to a disease or state of health leading to a disease. Further information regarding structure/function claims can be found in FDA's January 9, 2002 Structure/Function Claims Small Entity Compliance Guide.

Since no company has yet attempted to launch a packaged cell culture meat or seafood product in the U.S., no labels or specific label claims have been formally evaluated by FDA or USDA. Still, the companies have been articulating and publishing what could be construed as claims for their proposed products, their technology, and their mission. Since the launch of the U.S. industry in 2015, company websites and comments for news stories have tended to focus on environmental and social issues the products address, and also human nutrition and health. In recent months as companies begin to establish and position brand names and move nearer to commercialization the talking points have begun to include taste, texture, and "same as" or "real" in comparison with current meat and seafood products. The companies seem to believe that even if a product soothes the conscience, satisfies the brain's need for reason, and is nutritious, it's really the look, flavor, mouthfeel, aroma, and other sensory experiences that will get people to try their cell culture food, come back, and keep buying it.

Overall, the messaging is similar for each of the 17 U.S. companies and also for the overseas companies that may become their competitors in the future when the cell culture meat industry globalizes. The

issues the companies variously highlight, depending on the species of meat they are developing, come down to variations on the following themes.

Animal Welfare: No animal or fish died to make this food. No animal was severely confined, mistreated, or fed antibiotics, and since there was no slaughterhouse there was no exposure to pathogens. Most fish today die in a very inhumane manner – asphyxiation, live evisceration, and the effects of depressurization, freezing or boiling. And in some fish ponds the close proximity of fish to one another can result in an increased risk for disease and stress while they are provided a diet that is not their natural one.[11]

Labor practices and human rights violations that occur in certain parts of the world's fishing industry, and the significant occupational safety risks and hazards that are associated with commercial fishing, create further concerns.[11] When COVID-19 hit meat packing plants, the human health toll, supply line vulnerabilities, and grocery price sensitivities became obvious. This underscored the concerns with regard to current animal-based food production systems.

Environmental Issues: No ocean was polluted, no greenhouse gas generated, no rain forest cut down, no arable land converted for animal feed crops, no water diverted or polluted. Global demand for seafood is soaring, but the world's oceans are over-fished and many species are being depleted by industrial scale fishing fleets that kill non-target fish and marine mammals while the bottom trawling damages the ocean floor. Wild-caught fish often are contaminated with plastics, heavy metals, and pathogens. Fish farming creates its own set of pollution and pathogen problems. Current meat production systems devour enormous amounts of land devoted to crops raised not for human foods, but for feeding cattle, hogs, and chickens. Industrial scale concentrated animal feeding operations (CAFOs) generate vast amounts of animal waste that when mismanaged pollutes land, streams and groundwater. Shipping animals and fish hundreds or thousands of miles for processing adds more air pollution and burns more fossil fuels. Whereas once the rain forests sequestered carbon, the vast scale of clearing trees for grazing and crop production, usually by deliberate fires, has resulted in the forests putting more carbon into the atmosphere than they remove.[23]

There is a new type of claim that may find its way to labels soon. Some companies in other industries are beginning to put carbon labels on products. These labels estimate a product's environmental impact from cradle to grave as a carbon equivalent that reflects the greenhouse gas emissions or CO^2 spent in its creation, transportation, use and end of life, as measured in grams or kilograms of carbon.[52]

Health Concerns: Baked into each of those animal welfare and environmental issues is concern about the current meat and seafood production impact on human health. Respiratory diseases increase with air pollution. Gastrointestinal diseases are triggered by pathogens in slaughtered and processed meat. Ingesting plastics and heavy metals even at a "nano" level could lead to neurological problems. Consumer concerns about seafood include a wide array of substances that may be incorporated in the fish, crustaceans, mollusks and other seafood products. These substances include: mercury, toxins and poisons; pathogens, viruses, and parasites; micro-particles of plastics; and a variety of potential environmental pollutants.[11]

Not much of this is likely to migrate from websites and presentations to actual product claims on packaging. While the FTC can monitor the accuracy of printed and posted material, what the consumer reads about a product at the meat counter or in the restaurant is the concern of FDA and USDA.

Whether the product is beef, pork, poultry, seafood or some other animal-based food product, companies are making statements about many of those issues as they refine and sharpen their product positioning and claims. Some of these companies are a few years from commercialization and regulatory compliance, so current statements may change or be abandoned.

Appendix C
Regulatory Regimes in Other Nations

While FDA and USDA work through the final processes of developing guidelines and regulations for the U.S. domestic cell culture meat industry and for potential imports from overseas, other nations also are moving ahead with their regulatory systems. Some are using existing novel food regulations and others are adding or formulating new systems to assess the new products. The Good Food Institute has been involved in monitoring regulations and adoption of cell culture meat in several key areas of the world. Documents from GFI published in 2021 provide the following summary of important regulatory development pathways in those countries as of 2020.[1, 6]

Singapore

In late 2020, the Singapore Food Agency (SFA) became the first national regulator to approve the sale of a cell culture meat product. The approval of Eat Just's cell culture chicken, for use as an ingredient in the company's chicken bites, was the culmination of a regulatory process developed over more than two years. The SFA's review was informed by a panel of outside experts who assessed the composition of the product, manufacturing process, integrity of the cell line, and potential for pathogenic contamination. More than 70 percent of Eat Just's GOOD Meat cultured chicken is composed of cell culture chicken cells, while the remainder is primarily mung bean protein.

This regulatory approval is considered a monumental milestone. Importantly, it is not a blanket approval of cell culture meat products; it is specific to Eat Just's product and manufacturing process. Companies hoping to market cell culture meat or seafood in Singapore must still submit regulatory filings for their specific formulations. The SFA has not indicated whether this recent approval may eventually form the basis for a more encompassing regulatory framework. In November, the SFA updated a year-old guidance document on novel food safety assessments, which lists some information requirements specific to cell culture meat products. However, the guidance provides few new details as to standards manufacturers will need to satisfy to obtain approval of their products. The SFA strongly encourages companies interested in marketing cell culture meat products in Singapore to contact the regulatory body early in the R&D and commercialization planning process.

On July 28, 2021, the SFA granted a license and approval to the Singapore contract manufacturing company Esco Aster to begin production of cell culture chicken, including Eat Just's products, at a facility in Singapore.[59] SFA will conduct safety assessment reviews during production. It is unclear whether the production agreement with Esco Aster fulfills the stated objective or Eat Just to build a plant in Singapore.

The European Union

In the EU, the Novel Foods Regulation governs pre-market authorizations for foods produced from animal cell or tissue culture. If genetic engineering is used in the production of cell culture meat, the regulation on genetically modified food and feed may apply instead. Companies must apply to the European Commission (EC) for pre-market authorization of their products. In the risk assessment stage, the European Food Safety Authority (EFSA) assesses the information submitted by the applicant about the compositional, nutritional, toxicological and allergenic properties of the novel food, information on production processes, and the proposed uses.

After the risk assessment, the EC considers EFSA's opinion. If the opinion is positive, the EC drafts an implementing act that lays out the specific conditions of use, labeling requirements, and monitoring arrangements after placing the product on the market and adding it to the official list of novel foods. The implementing act then needs to be adopted by a committee representing all EU member states. The length of the entire novel foods approval process for cell culture meat can range from 18 to 36 months. As of May 2021, no cell culture meat company had yet formally applied for pre-market authorization in the EU.

Pre-market authorization is handled centrally, meaning that once the EC and representatives from the EU member states approve a product, the approval applies across all 27 member states. New EU rules came into effect in March 2021 that allow for limited pre-submission consultations between companies and EFSA. Companies seeking to apply for novel foods authorization are obliged to notify the EFSA of any study commissioned in preparation of an application.

In May 2020 the EC published its Farm to Fork Strategy, identifying an intention to move toward a more sustainable and healthy food system. Although the strategy does not explicitly mention cell culture meat, it endorses increased funding for research and innovation in alternative proteins.

United Kingdom
With its exit from the EU, the UK is no longer participating in the EU's common food authorization procedures. As of May 2021 any cell culture meat companies wanting to sell their products in the UK need to apply for authorization to the UK Food Standards Agency (FSA). But the UK retained relevant EU law and the substance of the risk assessment of both novel foods and genetically modified food authorizations remains the same as in the EU. The FSA provides guidance on how to submit an application.

The most substantial difference between the UK and EU regulatory approval concerns the final approval decision. In the UK, it will be government ministers making the decision as opposed to the EU, where final approval is governed by the committee procedure involving the European Commission and representatives from all 27 EU member states.

Israel
In December 2020 Benjamin Netanyahu, then the Israeli prime minister, became the first head of government to sample a cell culture meat product provided by the Israeli cell culture meat company Aleph Farms. Also introduced was a proposed national policy plan that would establish Israel as a cell culture meat and alternative protein powerhouse. Netanyahu announced that he had directed the Cabinet Secretary to "appoint a body to serve these industries in order to connect and oversee all the stakeholders operating in this field." This is an encouraging step toward cell culture meat commercialization in one of the world's most tech-forward nations. At the same time, the National Food Control Service (NFCS)—the nation's agency responsible for food regulation and standards—has dedicated a team of experts to further evaluate the required safety assessments for a cell culture meat regulatory framework. Some Israeli industry experts suggest that the NFCS is unlikely to develop an original framework and will instead follow the lead of U.S. or EU regulatory agencies.

Japan
There is some indication that selling cell culture meat in Japan is permitted. Cell culture meat (depending on the production method) already falls within the existing regulatory regime in Japan and might not require a pre-market assessment or approval. Nonetheless, the Japanese government is

working to develop a specific regulatory framework to properly shape the market while ensuring food safety and consumer acceptance. In April 2020 the Ministry of Agriculture, Forestry and Fisheries (MAFF) launched the Food Tech Research Group, including more than 100 companies. It aims to foster the food industry and strengthen Japan's food security through technology. The group has met to share industry information, to understand structural challenges that start-ups and established companies are facing in the food technology field, and to enable the development of appropriate policies. The group's focus is not limited to cell culture meat, and it is anticipated that the group will dive deeper into various food technology subfields to identify priority issues to be addressed.

Another important initiative is creation of the Japan Association for Cellular Agriculture (JACA), collaboration between government, academia and some of the country's largest food companies. JACA is meeting twice monthly to develop rules for cell culture meat, egg, and dairy products in order to contribute to their commercialization in Japan. JACA is led by the Center for Rulemaking Strategy (CRS) at Tama University, a Japanese think tank, and includes 30 companies, including a number of international cell culture meat firms. CRS's focus is to design rules (law, industrial standards, self-regulation guidelines, etc.) for emerging technologies and important concepts to be implemented into Japanese society. In the past JACA has successfully created a range of domestic rules and institutions through the Liberal Democratic Party's parliamentary group on rulemaking strategy. Fields include blockchain technology, hydrogen energy, and economic statecraft. Unlike the Food Tech Research Group, JACA's primary focus is on cell culture meat, with discussions of potential regulatory frameworks.

Australia-New Zealand

Australia and New Zealand share a joint food regulatory framework and a joint food regulatory agency, Food Standards Australia New Zealand (FSANZ). FSANZ develops food standards governing the composition, production, handling, promotion, sale, and transport of food. Under FSANZ's "novel food" regulation, cell culture meat and seafood manufacturers must apply to have their products included in the schedule of approved novel foods if they wish to make sales in either country. This requires a FSANZ safety assessment of the production process, likely lasting at least 14 months. The safety assessment must establish with reasonable certainty that "no harm will result from the intended use of the food." In assessing the risk of harm, FSANZ is required to use the best available scientific evidence. At the same time, the enforcement of the code lies with the government of each participating jurisdiction (that is, of New Zealand and of each Australian state and territory). As a result, those governments ultimately also may have a voice in cell culture meat and seafood approvals.

Canada

In Canada, cell culture meat and seafood are characterized as "novel foods" requiring the submission of detailed information in an application for pre-market approval. The required information for the novel food submission includes evidence that the food is safe for consumption, including molecular characterization, nutritional composition, toxicology and allergenicity, and types and levels of chemical contaminants. A three-part approval is required: (i) a letter of no objection for human food use through the novel food assessment process, (ii) a pre-market assessment for new animal feed (due to the possibility of supply chain crossover, and regardless of whether the product is intended for use as animal feed), and (iii) an environmental assessment under the New Substances Notification regulations. Companies may not market their products in Canada until they have all three approvals.

Cell culture meat produced with the use of genetic engineering (GE) will likely be considered "genetically modified." This is defined broadly to include any "change [to] the heritable traits of a plant,

animal or microorganism by means of intentional manipulation." This definition encompasses traditional methods such as conventional breeding and mutation, as well as more recent methods such as rDNA technology or gene-editing.

For cell culture meat produced using GE techniques, certain additional information may be required in the novel food application. This could include documentation of the nutrient makeup to gauge whether the cell culture meat is nutritionally comparable to the unmodified meat or seafood analog; evidence that the food does not contain toxins or allergens introduced through genetic modification, and that the possibility of any such introduction is remote; and evidence that levels of undesirable substances associated with the conventional analog have not increased in the GE version. The point of contact in Canada is Health Canada's Food Directorate for discussions of the nature and content of a novel food submission.

Appendix D
Research Information Sources and Citations

1. 2020 State of the Industry Report, Cultivated Meat, the Good Food Institute.
2. Wildtype news release, June 24, 2021.
3. Eat Just news releases of December 1, 2020 and May 18, 2021.
4. UPSIDE Foods news release of May 12, 2021.
5. BlueNalu news release, June 18, 2020.
6. Derbes, Elizabeth, Cultivated Meat is Gaining Momentum – and Pathways for Regulatory Approval, Good Food Institute, June 3, 2021.
7. Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species. https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell
8. Formal Agreement Between the U.S. Department of Health and Human Services Food and Drug Administration and the U.S. Department of Agriculture Office of Food Safety. https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Formal-Agreement-FSIS-FDA.pdf
9. Poinski, Megan, FoodDive.com, Dec. 15, 2020
10. Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information. https://www.federalregister.gov/documents/2020/10/07/2020-22140/labeling-of-foods-comprised-of-or-containing-cultured-seafood-cells-request-for-information.
11. BlueNalu company website.
12. Cultured Decadence website.
13. Finless Foods company website and blog.
14. Wildtype Foods company website.
15. Air Protein company website.
16. GOOD Meat company website.
17. Memphis Meats/UPSIDE Foods company website.
18. Artemys company website.
19. Orbillion Bio company website.
20. Fork & Goode company website.
21. New Age Meats company website.
22. Label Claims for Conventional Foods and Dietary Supplements, FDA website. https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements
23. Gatti, Luciana, et.al. Amazonia as a Carbon Source Linked to Deforestation and Climate Change, Nature, Vol. 595, July 15, 2021, p 388.
24. Szejda, K., et.al. U.S. and U.K. Consumer Adoption of Cultivated Meat: A Segmentation Study, Foods 2021, 10, 1050. https://doi.org/10.3390/foods10051050.
25. Bryant, C.J., Culture, Meat and Cultured Meat, Journal of Animal Science, 2020, 98, 1-7.
26. FoodDive, May 16, 2021.
27. FoodDive, March 25, 2021.
28. Bryant, Christopher, and Courtney Dillard, The Impact of Framing on Acceptance of Cultured Meat, Frontiers in Nutrition, July 3, 2019, https://www.frontiersin.org/articles/10.3389/fnut.2019.00103/full
29. Bryman, A., Social Research Methods, 5th ed.; Oxford University Press, Oxford, UK, 216, pp 1-747
30. Szejda, K, et.al. Meat Cultivation: Embracing the Science of Nature, The Good Food Institute, Washington, DC, 2019.

31. Bryant, C.J.; Barnett, J.C. What's in a Name? Consumer Perceptions of *in vitro* Meat Under Different Names, Appetite, 2019, 137, 1040113.
32. Hallman, W.K.; Hallman, W.K. An Empirical Assessment of Common or Unusual Names to Label Cell-Based Seafood Products, Journal of Food science, 2020, 85, 2267-2277. https://pubmed.ncbi.nlm.nih.gov/32691419/
33. Szejda, K., et.al. Initial Consumer Perceptions of Cellular Agriculture Nomenclature: A Qualitative Analysis of Word Associations, The Good Food Institute, Washington, DC, 20198. December 2, 2019.
34. Dillard, C.; Szejda, K. Consumer Response to Cellular Agriculture Messaging and Nomenclature: A Focus Group Pilot Study, The Good Food Institute, Washington, DC, 2019.
34. Kelton Global Research, Choosing Alternative Seafood: Key Insights from Research on Consumer Needs, Preferences, and Motivations, Good Food Institute, April 30, 2021. https://gfi.org/wp-content/uploads/2021/04/Choosing-alternative-seafood.pdf
35. Food Navigator, March 9, 2021.
36. Comment to FDA re Request for Information on Cultivated Seafood Labeling, Good Food Institute, March 8, 2021. https://gfi.org/comment-letters/comment-to-fda-re-request-for-information-on-cultivated-seafood-labeling/
37. Stout, Andrew J., et.al., Simple and Effective Serum-Free Medium for Sustained Expansion of Bovine Satellite Cells for Cell Cultured Meat, BioRxiv, May 28, 2021. Https://www.researchgate.net/publication/351975636_Simple_and_effective_serum-free_medium_for_sustained_expansion_of_bovine_satellite_cells_for_cell_cultured_meat
38. CellAgri Weekly, May 23, 2021.
39. Eat Just (GOOD Foods) news release, May 18, 2021
40. 2020 State of the Industry Report, Fermentation: Meat, Eggs, and Dairy, Good Food Institute. https://gfi.org/wp-content/uploads/2021/05/2020-State-of-the-Industry-Report-Summaries-Plant-based-Cultivated-meat-Fermentation.pdf
41. The Science of Cultivated Meat, Good Food Institute. https://gfi.org/science/the-science-of-cultivated-meat/
42. Food Navigator-USA, September 11, 2019.
43. Food Navigator-USA, March 11, 2020
44. Evocative Design website, https://ecovativedesign.com/news/excell-ing-in-the-lab and Excell website, https://www.excell.bio/
45. Big Idea Ventures website, https://bigideaventures.com/employer/novel-farms-inc/
46. Food Navigator-USA, June 23, 2021.
47. Allied Market Research, "Cultured Meat Market by Type, End User: Global Opportunity Analysis and Industry Forecast 2022-2030." https://www.alliedmarketresearch.com/cultured-meat-market-A06670
48. Research and Markets, Global Cultured Meat Market Report 2021-2030: Focus on Poultry, Beef, Seafood, Pork - Market is Expected to be Valued $206.6 Million in 2025. https://www.globenewswire.com/en/news-release/2021/05/20/2233169/28124/en/Global-Cultured-Meat-Market-Report-2021-2030-Focus-on-Poultry-Beef-Seafood-Pork-Market-is-Expected-to-be-Valued-206-6-Million-in-2025.html
49. Boston Consulting Group and Blue Horizon Corporation, "Alternative Proteins in Context," 2021. https://web-assets.bcg.com/a0/28/4295860343c6a2a5b9f4e3436114/bcg-food-for-thought-the-protein-transformation-mar-2021.pdf
50. The Spoon, June 16, 2021.
51. "Cultivated Meat: Out of the Lab, into the Frying Pan," McKinsey & Company, 2021.
52. Washington Post, June 17, 2021.
53. East Just company news release, Business Wire, August 31, 2021.

54. GreenQueen, September 1, 2021.
55. Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, A Proposed Rule by the Food Safety and Inspection Service on 09/03/2021. https://www.federalregister.gov/documents/2021/09/03/2021-19057/labeling-of-meat-or-poultry-products-comprised-of-or-containing-cultured-animal-cells
56. Is Lab Meat About to Hit Your Dinner Plate? Mother Jones, August 2, 2021.
57. National Fisheries Institute, IntraFish newsletter, March 8, 2021.
58. FoodDive, August 23, 2021.
59. GreenQueen, September 15, 2021 and The Straits Times, September 15, 2021.
60. BlueNalu news release, September 13, 2021.
61. National Cattlemen's Beef Association 2021 policy position posting, https://www.ncba.org/policy.
62. USDA/FSIS letter to the U.S. Cattlemen's Association regarding their petition to exclude the use of the words "beef" and "meat" on labels for cell culture and plant-based foods.
63. SeafoodSource.com, April 21, 2021.
64. Food Navigator-USA, September 21, 2021.
65. Aqua Cultured Foods news release, September 21, 2021.