









11/18/22 • BIG FOOD > NEWS

FDA Declares Lab-Grown Chicken 'Safe to Eat' — But Scientists, Food Safety Advocates Have Questions

Describing the development as "a food revolution," the U.S. Food and Drug Administration on Wednesday said chicken produced using animal cell culture technology that takes living cells from chickens and grows the cells in a controlled environment is safe for human consumption.

By Michael Nevradakis, Ph.D.

Image credit: UPSIDE Foods

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Describing the development as "a food revolution," the U.S. Food and Drug Administration (FDA) on Wednesday declared lab-grown chicken meat developed by Berkeley, California-based food-tech firm Upside Foods is safe for human consumption.

Upside Foods "will use animal cell culture technology to take living cells from chickens and grow the cells in a controlled environment to make the cultured animal cell food," the FDA said.

The news — widely reported as an FDA "approval" of lab-grown meat — signifies the completion of the first, and biggest, of the three regulatory steps Upside Foods must complete before its "cultivated" chicken attains full approval and can be sold to the public, according to TIME.

Although two more steps must follow before the FDA can grant the product full approval, the agency's language suggests the approval is a foregone conclusion.

Upside Foods, on its website, all but confirmed that FDA approval is on the way:

"This landmark regulatory decision means the FDA accepts our safety conclusion, and Upside's cultivated chicken will be available following USDA inspection and label approval."

The FDA and some media outlets cheered the news — but others, including scientists and food safety advocates, expressed concerns about the adequacy of the FDA's preliminary review process.

Experts who spoke to The Defender also questioned the safety of lab-grown meat, which is produced with geneedited cells, and some scientists argued that, despite claims to the contrary, the production process for labgrown "meats" is energy-intensive and not, as advertised, beneficial to the environment.

Some also questioned Upside Foods' connections to figures and entities such as Cargill, Bill Gates, Jeff Bezos, Richard Branson, Kimbal Musk, brother of Elon Musk and co-founder of The Kitchen, "a growing family of

businesses that pursues an America where everyone has access to real food," and the World Economic Forum (WEF).

FDA hasn't yet granted 'approval' — but most significant step in that process completed

The Center for Food Safety said this about the FDA's announcement:

"The U.S. Food and Drug Administration (FDA) recently completed its preliminary review of the first lab grown 'chicken' to be sold as food. The FDA and the U.S. Department of Agriculture are both reviewing 'meats' which are grown in vats from cells extracted from living animals.

"This week's announcement by the FDA that it was reviewing a cell-cultured chicken 'meat' is the first indication that these products might come to market in the U.S."

According to the FDA, this first stage — known as a "pre-market consultation" — was the first time the agency completed such a consultation "for a human food made from cultured animal cells."

As part of this consultation, according to the FDA:

"The FDA's pre-market consultation with the firm included an evaluation of the firm's production process and the cultured cell material made by the production process, including the establishment of cell lines and cell banks, manufacturing controls, and all components and inputs.

"The voluntary pre-market consultation is not an approval process. Instead, it means that after our careful evaluation of the data and information shared by the firm, we have no further questions at this time about the firm's safety conclusion."

In an exclusive interview with The Defender, Jaydee Hanson, policy director for the Center for Food Safety, questioned the FDA's "pre-market consultation":

"The FDA regulatory process in general relies on company testing of their products.

"The FDA, in this case, seemed to mostly review what the company sent them, but did not require additional tests and did not require the company to disclose its methods in a complete and transparent manner."

The next steps in the regulatory process involve the U.S. Department of Agriculture and its Food Safety and Inspection Service (FSIS) before full approval is granted.

Upside Foods' Emeryville, California, production facility will be ready to produce more than 50,000 pounds of "cultivated" products, including a chicken fillet, per year, upon receipt of regulatory approval, the company stated.

Upside Foods, FDA, media describe lab-grown meat as a 'food revolution,' 'watershed moment,' but regulatory process questioned

The FDA described the news of Upside Foods coming a step closer to full approval as part of "a food revolution" that the world is experiencing, in which the FDA "is committed to supporting innovation in the food supply."

TIME used remarkably similar language in its story, describing the FDA's announcement as "setting the stage for a new food revolution in which the world's meat is grown in bioreactors instead of on factory farms."

Bruce Friedrich, president of the Good Food Institute (GFI), told NPR the FDA's announcement is "a critical milestone towards the future of food" that will benefit "consumers who desire their favorite foods made more sustainably."

And Dr. Uma Valeti, CEO and founder of Upside Foods, described the news as "a watershed moment in the history of food" in a statement, adding that "U.S. consumers will soon have the chance to eat delicious meat that's grown directly from animal cells."

In the same announcement, Valeti added:

"We started Upside amid a world full of skeptics, and today, we've made history again as the first company to receive a 'No Questions' letter from the FDA for cultivated meat.

"This milestone marks a major step towards a new era in meat production."

Valeti is a member of the GFI's advisory council, although this conflict of interest was not mentioned by NPR in its recent report.

The Center for Food Safety questioned the FDA's regulatory process, stating the "experimental product" was "woefully deficient":

"In short, the documents shared by the FDA and the Upside Foods Co. show us where more research and more transparent data are needed, but this is a woefully deficient review by the FDA.

"In its review of the company's documents, the FDA states it has 'no further questions' about this experimental product's safety — but we have many more questions. In the name of protecting public health, consumers and policymakers deserve better."

While the FDA claims that it had "no further questions" regarding Upside Foods' self-reported safety evaluation, which formed the basis of the FDA's decision to complete its "pre-market evaluation," the Center for Food Safety questioned the process by which the cells for lab-grown meat are cultured and the FDA's oversight of this process:

"The FDA's review of the first-ever cell-cultured food for U.S. approval is a start, but grossly inadequate. In this 'pre-market consultation,' neither the company nor the FDA presented the actual data from tests looking at the effects of raising these cells in fetal bovine serum and enzymes from the intestines and pancreas of animals.

"Likewise, while the company notes that it uses genetic engineering to keep the cells growing, it fails to share which genes are being used. This is vital information that consumers and policymakers need to know to make informed decisions in the best interests of public health. We should make certain that genes linked to cancer are not being used."

Experts raise alarm about genetically engineered cells and risk of cancer

In his interview with The Defender, Hanson said that far from the company's claims that cultivating lab-grown meat will save animals, the bovine serum used as part of this process requires that animals be slaughtered:

"The science used by Upside to culture in vats is essentially the same as that used to culture cells for experiments in medical labs.

"Upside is using a mixture of bovine serum (most likely from fetal calves found in cows being slaughtered) and enzymes from the pancreas and intestines of animals. Upside indicates that it is trying to switch to other kinds of growth mediums."

Hanson also questioned the use of genetically engineered cells as part of the production process, telling The Defender that such cells "can promote cancers" and highlighting that the Upside Foods has not listed the exact genes it is using:

"The company also notes that it is using genetic engineering to promote continuous growth of the cells. This is disturbing, in that it is likely that the genes being manipulated can promote cancers.

"Medical cell cultures use cancer cells for testing of drugs, etc., but cancer-causing genes should not be used in food production. Food additives that cause cancer are illegal. Unfortunately, the company does not list exactly which genes it is using for genetically engineered cells."

The genetic engineering process employed by Upside Foods appears to involve CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), a gene-editing technology that acts as a "precise pair of molecular scissors that can cut a target DNA sequence, directed by a customizable guide."

Put differently, this technology allows scientists to edit sections of DNA by "snipping" specific portions of it and replacing them with new segments. Gene editing is not a new concept, but CRISPR technology is viewed as being cheaper and more accurate.

In 2019, it was revealed that Memphis Meats — the former name of Upside Foods prior to a 2021 rebrand — was employing CRISPR as part of its process for curating lab-grown meat, and even received a patent for this purpose.

As recently reported by The Defender, while CRISPR has been touted as a potential solution to global hunger and food shortages, many scientists question this claim.

In an October 2022 interview with The Defender, Claire Robinson, M.Phil., managing editor of GMWatch, said the gene editing process may have unintended effects that can adversely impact human health:

"These were also risks with the old-style GMOs [genetically modified organisms], and they are still risks with these gene-edited GM plants with animals.

"The risks, if you're gene editing them ... are that there will be knock-on effects on the animals, welfare or health that we can't anticipate, such as deformities or changes in the function of certain genes in the animal."

Michael Antoniou, Ph.D., in an October 2022 interview with The Defender, agreed, stating that, "innately, gene editing also can bring about unintended DNA damage ... even at the site of your intended edit or elsewhere in the DNA of your target cells, with unknown downstream consequences."

A report published in the Journal of Genetics and Genomics in 2020 found CRISPR gene-editing in rice resulted in numerous unintended and undesirable on-target and off-target mutations.

Antoniou described this as "a grave oversight, because we know that gene editing is not precise ... the evidence is there to show that you will always have unintended DNA damage in addition to what you want ... a whole spectrum of unintended DNA damage that accumulates at the multiple steps of the gene editing process."

"If you don't take this into account, as is happening at the moment," said Antoniou, "you will launch a product that could have marked changes in its biochemistry and therefore composition. And included in that chain-altered composition could be the unintended production of toxins and allergens," including in food for human consumption.

Robinson and Antoniou also raised ethical concerns regarding CRISPR. "These unexpected effects of CRISPR are very well recognized," Robinson said. "They're written about in the scientific literature."

"Scientists know that these things are not ready yet to go into clinical trials," she added. "On the whole, they're certainly not ready to be used on [the public]."

In a Nov. 14 interview on NPR's "Morning Edition," Valeti said he launched Memphis Meats in 2015 based on an idea he came up with while previously "working with heart attack patients at the Mayo Clinic more than 15 years ago, growing human heart cells in a lab."

He realized that "it should be possible to grow meat with similar science," according to the NPR interview.

Experts: lab-grown meat poses grave environmental concerns, despite claims to the contrary

Upside Foods says it is developing a way to grow real meat, poultry and seafood directly from animal cells, without the need to raise and slaughter animals," claiming its products "are real meat, made without the animal."

According to the company, the process for curating lab-grown meat is much friendlier for the environment than "conventional meat" because "the cells from a single chicken allow for the cultivation of the same amount of poultry that now comes from hundreds of thousands of farmed birds."

The company also claims that "at scale, we project cultivated meat will use 77% less water and 62% less land than conventional meat. And we expect these numbers to get better over time. We currently use 100% renewable energy at our production facility."

CBS News, drawing from a report in the journal Nature, also took this view, writing, "Scientists say roughly a third of all human-produced greenhouse gasses stem from food production, especially cattle. Proponents of labgrown meat say it would help cut back on methane emissions and help combat global warming."

Scientists and experts who spoke to The Defender argued, however, that the process of cultivating lab-grown meat is heavily energy-intensive. According to Hanson:

"Many proponents of cell-cultured meat and poultry argue that it is a way of avoiding climate change. However, this ignores that cell-cultured processes are incredibly energy-intensive."

In her recent interview with The Defender, Robison expressed a similar perspective, describing such claims of environmental friendliness as:

"A pipe dream, because the energy costs and the resource costs of bioreactor technologies are actually huge, and it simply won't be possible, especially in a climate of rising energy bills.

"It simply won't be possible to feed thousands or millions of people on the products of these technologies."

Aside from high energy consumption, Hanson raised other potential environmental concerns involved with the process of developing lab-grown meat.

Hanson told The Defender:

"Cell cultures require the use of antibiotics to assure that the culture is not overtaken by pathogens. It is difficult to be sure that the cells that the company would take from poultry or meat animals are not infected with prions, viruses or bacteria.

"Finally, the waste produced by the culturing process needs to be disposed of. The chemicals from the waste will likely be dumped into local sewer systems. Without more data on the chemicals being used and the amounts of electricity being used, it is difficult to know how much environmental impact this production system has."

Indeed, the FDA's scientific memo accompanying its recent announcement, contained a three-page list of "potential identity, quality, and safety issues" involved with Uphill Foods' manufacturing process, including:

- Cells from different line or species inadvertently used.
- Carryover of adventitious agents such as bacteria, fungi, viruses, parasites, and prions during isolation.
- Introduction of contaminants in laboratory reagents.
- Introduction of contaminants from animal-derived reagents (e.g. bovine serum, trypsin).
- Unintended effects of immortalization.
- Contamination, and facility environment contamination, with adventitious agents through inadequate sterilization of bioreactors.
- Presence of elemental contaminants (toxic heavy metals) after harvest.
- Presence of residual unintended material from genetic engineering.

However, despite those potential risks, the memo stated that "at this time we have not identified any information indicating that the production process ... would be expected to result in food that bears or contains any

substance or microorganism that would adulterate the food."

As part of the next steps in the process, the "real meat" produced by Upside Foods will need to be inspected, as will the "the safety of manufacturing facilities as well as the cleanliness of the meat production process," TIME reported.

According to the FDA, its next steps will be in close coordination with the FSIS, as per a formal March 2019 agreement between the two agencies creating a "joint regulatory framework" overseeing lab-grown food products.

Of note, cultivated seafood, which Upside Foods also aims to develop, is "only regulated by the FDA and [does] not fall under USDA jurisdiction," according to TIME, meaning that it "could pass through the system even more quickly."

Lab-grown meat, brought to you by Bill Gates, Jeff Bezos and the WEF?

Upside Meats says it was "founded as the world's first cultivated meat company in 2015 [and] has achieved numerous industry-defining milestones, including being the first company to produce multiple species of meat (beef, chicken and duck)," noting that it "has won various industry awards, including New York Times' Good Tech Awards."

The company said it raised a total of \$608 million, while crunchbase.com estimates Upside's market valuation as ranging between \$1 billion and \$10 billion.

The company brought in investors such as Bill Gates, Cargill and Richard Branson during its Series A funding round in 2017.

Gates is on record saying, "All rich countries should move to 100% synthetic beef."

The Daily Mail, quoting the Associated Press, noted Gates is considered the largest private owner of farmland in the U.S., having "quietly amassed" close to 270,000 acres.

Antoniou told The Defender:

"Bill Gates has bought into [CRISPR] bigtime and increasingly, because he's been a staunch advocate of genetic modification of crops for decades now ... because of his staunch belief in technological fixes to everything, I'm not surprised that now he's bought into the gene editing sector as well."

According to Upside Foods, other investors in the company include Tyson Foods, the world's largest poultry producer, Whole Foods — owned by Jeff Bezos and Amazon — and Whole Foods CEO John Mackey, who is also part of the GFI advisory council along with Valeti.

The largest donor to GFI is listed as the Open Philanthropy project, one of whose main funders is Dustin Moskovitz, co-founder of Facebook along with Mark Zuckerberg.

As previously reported by The Defender, the project also funded the Johns Hopkins Center for Health Security, Rockefeller University and the entities behind a remarkably accurate monkeypox pandemic "simulation."

Gates, Branson, Cargill, Tyson Foods and Kimbal Musk also invested in Upside during its Series B funding round in 2020, which raised \$161 million. According to Upside Foods, this funding was intended "to build a pilot production facility" and "grow its world-class team and bring products to market."

Notably, Kimbal Musk was named "a 2017 Social Entrepreneur by the Schwab Foundation, a sister organization to the World Economic Forum, for his impactful, scalable work to bring Real Food to Everyone."

The WEF has repeatedly praised lab-grown meat, claiming it "can help end hunger."

Following the Series B funding round in 2020, Branson, founder of the Virgin Group, remarked:

"I am proud to invest once again in Memphis Meats [now Upside Foods], the world's leading cell-based meat company.

"In the next few decades I believe that cell-based meat will become a major part of our global meat supply. I cannot wait for that day!"

In turn, Elizabeth Gutschenritter, managing director of Cargill's alternative protein team, stated at the time:

"To meet the growing global demand for protein, it will take all of us working together — we need both animal and cell-based.

"Our continued investment in Memphis Meats underscores our inclusive approach to the future of meat. We need all options on the table to meet customer and consumer needs now and in the future."

Despite Upside Food's claims of being friendly to both the environment and humanity, Cargill, as one of its major investors, has been linked to the use of slave labor on the lvory Coast and Uzbekistan, union busting in the U.S., land grabbing in Colombia, deforestation in Brazil, tax evasion in the U.K. and the proliferation of factory farms known for animal cruelty and environmental destruction in the U.S.

Gates, Cargill and Tyson Foods invested in Upside Foods' Series C funding round earlier this year, along with the Abu Dhabi Growth Fund. \$400 million was raised by the company during this round.

Kimbal Musk also invested during this round, joined by his wife Christiana Musk, "founder of Flourish*ink, a platform for curating and catalyzing conversations on the future of food and invests in companies driving food system change through Flourish Ventures."

Upon the completion of Series C, Brian Sikes, CEO of Cargill, remarked:

"We're excited to support this next chapter of Upside Foods' growth.

"Our continued support for Upside's innovative work underscores Cargill's commitment to an inclusive approach to wholesome, sustainable protein that will meet customer and consumer needs now and in the future."

Highlighting the broader interest of major investors, including those coming from Big Agriculture, Big Food and Big Tech, in the synthetic food industry, more than 100 companies are currently developing various forms of "cultivated" meat.

The FDA said it "is ready to work with additional firms developing cultured animal cell food and production processes to ensure their food is safe and lawful under the Federal Food, Drug, and Cosmetic Act."

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Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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