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Is Lab-Grown Meat Healthy and Safe to Consume?

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SEPTEMBER 20, 2020 SHARE THIS:

It goes by many names: cultured, cell-based, cultivated, lab-grown meat, etc. As the names imply, it is a meat alternative made in a lab via animal cells and a cultured medium, like fetal bovine serum or a proprietary mix of sugars and salts. Several companies around the world are promoting this new technique as a way to cultivate a meat alternative

that is supposedly "cleaner" and safer than traditional meat.

(We are only looking at those products that culture cells taken from animals into a new meat-like formulation. There are many other products that culture plant, fungi, or algal cells into a meat substitute, but we are not reviewing them here.)

29 companies are planning to bring lab-cultured "meat" to market in the form of chicken, beef, pork, seafood, pet food, and beyond. These companies include **Memphis Meats, Aleph Farms, Mosa Meat, Meatable, SuperMeat, and Finless Foods**. These companies are backed by huge investments from meat industry corporations (**Cargill and Tyson**), venture capitalist firms (**Blue Yard Capital, Union Square Ventures, S2G Ventures, and Emerald Technology Ventures**), and billionaires (such as **Bill Gates and Richard Branson**).

While the hype is certainly there, is lab-cultured "meat" actually better? Its proponents tout it as an environmentally responsible, cruelty-free, and antibiotic-free alternative to current meat production. While the goal of producing sustainable "meat" without killing animals is admirable, lab-cultured "meat" is in its infancy and the science behind the production methods requires more scrutiny.

Of particular concern is the genetic engineering of cells and their potential cancer-promoting properties. To be able to better assess whether the products are being produced by methods that involve genetic engineering and use genetic constructs (***-called onco-genes, typically used to make stem cells keep growing;*** *this is not a problem for lab experiments, but could be for food products-*) that

experiments, but could be for food products) that might encourage cancer cells, we need more information on how the cells are engineered and kept growing. Many of the companies are claiming this information is confidential and a business secret. These companies are not yet patenting their production processes wherein this information would be more fully disclosed. Some suggest that the production will follow the FDA cell culture guidelines, but the FDA's cell culture guidelines do not apply to this because they're not **designed for food.**

Lab-cultured "meat" is not always cruelty-free

To produce lab-cultured "meat," many producers extract animal cells from living animals. This is typically done via biopsy, a painful and uncomfortable procedure that uses large needles. If a company could scale up with this method, it would require a consistent supply of animals from which to acquire cells and innumerable painful extractions. To make the cell-based product more consistent, the producer may biopsy the same animal many times for the cells that growing "meat" requires.

Growing animal cells (typically muscle cells) also requires a growth medium. When lab-cultured "meat" production first began, companies depended on fetal bovine serum (FBS) as a growth medium. Producing FBS involves **extracting blood from the fetus of a pregnant cow** when the cow is slaughtered.

New methods for scaling up

Given its high cost, it appears that FBS is usually only used during small-scale lab trials. Additionally, increasing production capacity using FBS comes with

its own set of concerns. Even disregarding the high cost of FBS, non-genetically engineered animal muscle cells only proliferate or increase to a certain degree. In order to overcome this limitation, large companies such as and Memphis Meats claim they've found an FBS alternative that does not involve animals along with an effective way to expand production. For Memphis Meats, this process involves the utilization of a **bioreactor** and the creation of **immortal cell lines.**

> **Curious about how we make our Memphis Meat? See below! #sogood pic.twitter.com/co5d7OY0bl**
> **- Memphis Meats (@MemphisMeats) May 8, 2018**

These companies are using a bioreactor — essentially a very large vessel for containing biological reactions and processes — to implement a scaffold-based system to grow "meat," which uses a specific structure for cells to grow on and around. The scaffolding helps the cells differentiate into a **specific meat-like formation**. Researchers cite using cornstarch fibers, plant skeletons, **fungi**, and **gelatin** as common scaffold materials. Instead of animal muscle cell precursors (otherwise known as myosatellites), researchers have been using cultured stem cells. This distinction is important because extracted muscle cells will only proliferate to a certain extent. Companies are trying cultured stem cells as an alternative type of cell(s) that could proliferate exponentially so that they could scale up production, and later differentiate the cells into the various cell types that make up animal meat (muscle, fat, and blood cells) in a bioreactor.

In this process, the stem cells still come from animals

In this process, the stem cells still come from animals or animal embryos, but what differentiates the two methods is that in the scaffold-based system, the cells can be genetically engineered to proliferate indefinitely. These cells are otherwise known as pluripotent (which make many kinds of cells, like stem cells) or totipotent (which make every kind of cell, as do embryos). This would greatly expand a company's capacity to make lab-cultured "meat," but the methods by which companies make these cells proliferate come with human health and **food safety ramifications**.

Human health and food safety concerns about genetically modified cell lines

While the FDA has previously reviewed enzymes, oils, algal, fungal, and bacterial products grown in microorganisms, these new animal cell-cultured products are much more complicated in structure and require a more thorough review. The scale required for making lab-cultured "meat" feasible for mass consumption will be the largest form of tissue engineering to exist and could introduce new kinds of genetically engineered cells into our diets. Further research will also be needed to confirm or dispel uncertainties over various potential safety issues. Candidate topics for research include the safety of ingesting rapidly growing genetically-modifed cell lines, as these lines exhibit the characteristics of a cancerous cell which include overgrowth of cells not attributed to the original characteristics of a population of cultured primary cells. If lab-cultured "meat" enters the market, there are several human

health concerns associated with this new production method, specifically that these genetically-modified cell lines could exhibit the **characteristics of a cancerous cell**.

While these companies don't disclose much to the public about their processing methods, their public patents reveal the creation of **oncogenic, or cancer-causing, cells**. A Memphis Meats **patent** on the creation of modified pluripotent cell lines involves the activation or inactivation of various proteins responsible for tumor suppression. **Another patent from JUST Inc**. describes the utilization of growth factors as part of its growth medium. This process **could promote the development of cancer-like cells in lab-cultured "meat" products**. Additionally, **it is possible certain growth factors can be absorbed in the bloodstream after digestion.**

If they are using stem cells, cell-based meat companies need to pay attention to the risk of cancer cells emerging in their cultures. **A research team** from the Harvard Stem Cell Institute (HSCI), Harvard Medical School (HMS), and the Stanley Center for Psychiatric Research at the Broad Institute of MIT and Harvard has found that as stem cell lines grow in a lab environment, they often acquire mutations in the TP53 (p53) gene, an important tumor suppressor responsible for **controlling cell growth and division**. Their research suggests that inexpensive genetic sequencing technologies should be used by cell-based meat companies to screen for mutated cells in stem cell cultures so that these cultures can be excluded.

Cancer-causing additives are prohibited in our food supply under the Delaney Clauses in the 1958 Food

Additive Amendments and the 1960 Color Additive Amendments. These new rapidly growing cell lines might be considered color additives **Federal Food, Drug, and Cosmetic Act (FFDCA) if they are being used to produce the color in the "meat "**

being used to produce the color in the "meat."
The federal statutes regulating meat also prohibit the selling of animals with symptoms of illness, such as cancerous cells in meat. Regardless, all of these new ways of making cells that continue to grow or differentiate should require a **safety assessment** to determine if they contain cancerous cells before they can be sold.

In describing the scaffolding and growth media being used, lab-cultured "meat" companies need to be fully transparent about what ingredients they're using. During the above-mentioned industry nonprofit's presentation, the presenter suggested the growth media could be composed of a variety of different ingredients like proteins, amino acids, vitamins, and inorganic salts **classified under the GRAS (Generally Recognized As Safe) process** that allows companies to do their own testing and not submit to a new FDA food additive review. Since companies are not required to fully disclose the composition of their scaffolding or growth media, potentially exposing consumers to novel proteins and allergens, the new mixture of ingredients should be reviewed under a full FDA supervised food additive review, not GRAS.

Another major issue associated with processing methods using cell lines and/or culture medium is contamination. Unlike animals, cells do not have a fully functioning immune system, so there is a high likelihood of bacterial or fungal growth, mycoplasma, and other human pathogens growing in **vats of cells.** While lab-cultured "meat" companies emphasize that this type of "meat" production would be more sterile than traditional animal agriculture, it's unknown how that is true without the use of antibiotics or some other pharmaceutical means of pathogenic control.

pathogenic control.

Based on commentary from various companies, antibiotic usage across the industry is still very unclear. While the industry's promoters have outlined many uses for antibiotics in lab-grown "meat" production in preventing contamination, they have not disclosed the amount of antibiotics being used in the various processes. Instead, **they suggest** that because mass production of lab-grown "meat" will be done in an industrial rather than lab setting, with bioreactors and tanks, there will be **higher safety oversight than in medical labs**. It is suggested that the many preventative measures in the industry will maintain a sterile boundary and **deter antibiotic use in production**. It remains a question of how a food production plant would be more sterile than a medical lab.

Companies such as **Memphis Meats** claim they are genetically engineering cell lines to be antibiotic-resistant, which would suggest they plan on using antibiotics, but don't want their **"meat" cells to be affected bacterial and viral contamination plague medical cell culture**, so they generally use antimicrobials. Still, any large-scale production that requires antibiotic use even if just for a short-term duration should require such lab-cultured "meat" undergo even stricter USDA drug residue testing, pathogen testing, and FDA tolerance requirements than conventionally-produced meat. Many other companies claim they don't plan to use antibiotics in expanded production which begs the question, in

addition to supposed sterile bioreactors, are they using other undisclosed processes to prevent contamination? For example, Future Meat Technologies describes the use of a "special resin" to **remove toxins.**

The companies have also not disclosed plans for how they will dispose of the toxins from bioreactors, scaffolding, and culture media like growth factors/hormones, differentiation factors, often including fetal calf serum or horse serum, and antimicrobials (commonly added to cultured cells to prevent bacterial and fungal contamination, particularly in). In conventionally-produced meat, animals dispose of these toxins in their urine and feces. If companies can't find a way for this "meat" to dispose of these toxins, **the long-term cultures could potentially build up within the "meat" itself.** Given the lack of clarity of these companies and their processes, there must be continuous monitoring of the cell lines and growth media/bioreactor for contaminants and some sort of standardization established across the industry to ensure safety.

Final considerations and regulatory recommendations

The industry is new and the exact production process and inputs needed for large-scale, lab-cultured "meat" production are unknown (or not being disclosed by the companies). It is the responsibility of both FDA and USDA to ensure that all inputs used in production and the final product are safe for human and animal consumption. These agencies must ensure that lab-cultured "meat" is labeled

appropriately, including if any of the product ingredients are genetically modified or if the ingredients are produced using unmodified cells from animals. These agencies must also ensure that this product doesn't introduce new allergens into the food supply, that any hormones or antibiotics used are not found at unsafe levels in the final product,

and that the product doesn't contain any compounds or oncogenic (cancer-causing) cells that have not been approved for use in food.

Lab-cultured "meat" should not be allowed to use the Generally Recognized As Safe (GRAS) regulatory loophole wherein **companies can hire their own experts to evaluate their products**, often in secret without any notice to the public or FDA. GRAS is an inappropriate designation because the consensus among knowledgeable experts regarding the safety of lab-cultured "meat" does not yet exist. Instead, FDA should require that lab-cultured "meat" products be regulated more thoroughly as food additives. "Meat" companies should submit complete food additive petitions for each of the novel ingredients used to produce these "meats" as well as a final food approval petition for the entire product. The production facilities, like all meat processing plants, should then have USDA inspectors on-site monitoring the process and inspecting the "meat." The **USDA announced in August** that it will start the process of developing regulations for these new kinds of "meat. Adequate regulation will be necessary to address the concerns raised in this blog.

Overall, due to the novel nature of lab-cultured "meat," the lack of transparency from the companies involved, and the myriad potential health risks to consumers, rigorous regulation of this product is vitally important.

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