



Report to the Chairwoman, Subcommittee
on Labor, Health and Human Services,
Education, and Related Agencies,
Committee on Appropriations, House of
Representatives

April 2020

FOOD SAFETY

FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell- Cultured Meat

Accessible Version

GAO Highlights

Highlights of [GAO-20-325](#), a report to the Chairwoman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives

Why GAO Did This Study

Multiple firms have produced cell-cultured meat as part of their research and development. These products appear likely to become available to consumers in coming years. FDA and USDA are the primary agencies responsible for overseeing the safety of the nation's food supply. However, some stakeholders have expressed concern about the agencies' oversight of cell-cultured meat amidst a fragmented federal food safety oversight system.

GAO was asked to review federal oversight of cell-cultured meat. This report (1) describes what is known about methods for commercially producing cell-cultured meat, and (2) examines the extent to which FDA and USDA are collaborating to provide regulatory oversight of cell-cultured meat. GAO conducted a literature review; reviewed documentation from FDA, USDA, and stakeholder groups; analyzed public comments submitted to the agencies; compared agency efforts with leading practices for interagency collaboration; and conducted site visits to selected cell-cultured meat firms.

What GAO Recommends

GAO recommends that FDA and USDA more fully incorporate leading practices for effective collaboration in the agencies' interagency agreement. FDA and USDA partially concurred and indicated a willingness to incorporate these practices in a more detailed agreement, which would also meet the intent of the recommendations.

View [GAO-20-325](#). For more information, contact Steve D. Morris at (202) 512-3841 or morris@gao.gov.

April 2020

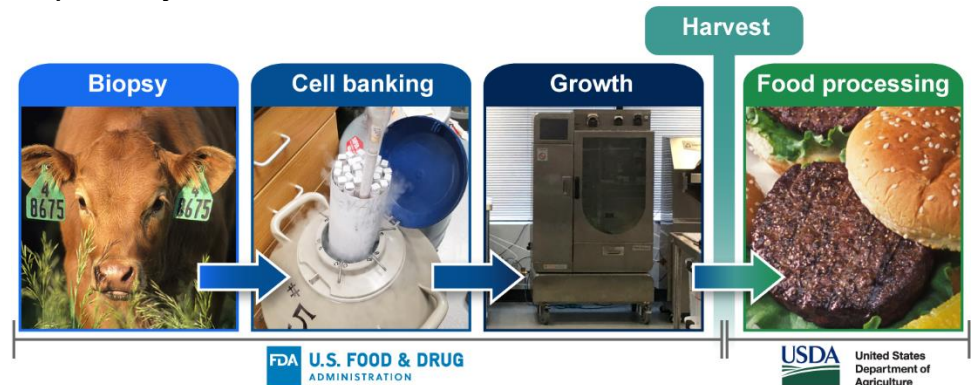
FOOD SAFETY

FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat

What GAO Found

General information about the process of making cell-cultured meat—food products grown from the cells of livestock, poultry, and seafood—is available. However, no company is commercially producing cell-cultured meat. Specific information about the technology being used, eventual commercial production methods, and composition of the final products is not yet known. The general process contains five phases: biopsy, cell banking, growth, harvest, and food processing (see figure). The technology and methods to be used for commercial production are still in development, and producers, regulators, and consumers do not have clarity about many specifics about the process and final product. For example, it is unclear whether production methods and products will use or contain genetically-engineered cells or medications such as antibiotics.

The Five Phases of Cell-Cultured Meat Production and Federal Oversight Responsibility



Sources: GAO and U.S. Department of Agriculture's Agricultural Research Service. | GAO-20-325

The Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) have begun collaborating on regulatory oversight of cell-cultured meat. For example, in 2019, the agencies signed an interagency agreement and created three working groups to carry out the terms of the agreement. However, the agreement and working groups could more fully incorporate practices to enhance and sustain collaboration, such as defining outcomes. For example, the agreement identifies the development of labeling principles as an outcome, but does not describe how the agencies will track and monitor progress toward this outcome, and the working groups identify a lead agency but not members' roles. Also, agency officials said they decided FDA would oversee cell-cultured seafood other than catfish, but they have not formally announced or documented this decision. Developing and updating written guidance and agreements is also a leading practice for interagency collaboration. By fully incorporating leading practices into their efforts to collaborate, the agencies could minimize potential overlap and fragmentation, use resources in a more efficient manner, and better ensure the public and other key stakeholders have clarity about the agencies' oversight responsibilities.

Contents

Letter		1
	Background	5
	Specific Information about Cell-Cultured Meat Technology, Commercial Production Methods, and Final Product Composition Is Not Yet Known	8
	FDA and USDA Have Begun to Collaborate on Oversight of Most Cell-Cultured Meat but Could More Fully Incorporate Leading Collaboration Practices	19
	Conclusions	31
	Recommendations for Executive Action	32
	Agency Comments and Our Evaluation	33
<hr/>		
Appendix I: Objectives, Scope, and Methodology		36
Appendix II: Key Issues to Consider for Implementing Interagency Collaborative Mechanisms		40
Appendix III: Comments from the U.S. Department of Health and Human Services		42
	Agency Comment Letter	45
<hr/>		
Appendix IV: Comments from the U.S. Department of Agriculture		48
	Agency Comment Letter	50
<hr/>		
Appendix V: GAO Contact and Staff Acknowledgments		53
	GAO Contact	53
	Staff Acknowledgments	53
<hr/>		
Tables		
	Table 1: GAO Analysis of Incorporation of Leading Collaboration Practices in FDA and USDA's Interagency Agreement on Oversight of Cell-Cultured Meat, as of December 2019	24
	Table 2: GAO Analysis of Incorporation of Leading Collaboration Practices in FDA and USDA's Working Groups on the Oversight of Cell-Cultured Meat, as of December 2019	28

Table 3: Key Issues to Consider for Implementing Interagency Collaborative Mechanisms	40
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Figures

Figure 1: The Path from Innovation to Commercialization	5
Figure 2: The General Process for Making Cell-Cultured Meat	10
Figure 3: Federal Oversight Responsibility for the Phases of Cell-Cultured Meat Production	21

Abbreviations

FDA	Food and Drug Administration
GRAS	generally recognized as safe
HHS	Department of Health and Human Services
USDA	U.S. Department of Agriculture

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April 7, 2020

The Honorable Rosa DeLauro
Chairwoman
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
House of Representatives

Dear Madam Chairwoman:

Multiple firms have produced cell-cultured meat—food products grown from the cells of livestock, poultry, and seafood—as part of their research and development.¹ Although the companies are not yet selling cell-cultured meat, some firms report that their products are likely to become available to consumers in coming years.² Furthermore, in 2017, the National Academy of Sciences identified cell-cultured meat as a biotechnology product that has high growth potential.³ Cell-cultured meat forms a part of the emerging field of cellular agriculture, which seeks to produce conventional agricultural products from cell cultures.⁴ Livestock and poultry account for over half of U.S. agricultural cash sales, often exceeding \$100 billion per year.⁵ However, the potential introduction of cell-cultured meat into the nation’s food supply has raised questions about its safety. Likewise, claims that it can be produced with less impact

¹For the purposes of our report, we use the term cell-cultured meat to describe these food products. However, others have used terms such as “cell-based meat” or “cultured meat.”

²In 2019, there were approximately 25 cell-cultured meat firms worldwide, 11 of which were located in the United States, according to various sources.

³National Academy of Sciences, Engineering, and Medicine, *Preparing for Future Products of Biotechnology* (Washington, D.C.: The National Academies Press, 2017).

⁴The Department of Health and Human Services’ Food and Drug Administration defines cell culture as a general technique used in research, industry, and medicine to provide an environment in which cells can grow outside their native environment in controlled and sterile conditions. Cell culturing has been used in biological research, vaccine production, and in the medical field to grow organs, among other things.

⁵U.S. Department of Agriculture, Economic Research Service, “Animal Products,” accessed January 16, 2020, <https://www.ers.usda.gov/topics/animal-products/>.

on the environment than conventional meat and that it may offer health and animal welfare benefits have also been questioned.

The Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are the federal agencies with primary responsibility for the oversight of food safety. USDA is responsible for regulating the safety of meat, poultry, processed egg products, and catfish.⁶ FDA is responsible for regulating the safety of virtually all other food, including most seafood. In addition, FDA is also responsible for regulating safety issues associated with animal cell culture technology in therapeutic settings, such as growing organs.

In advance of a July 2018 public meeting on foods produced using animal cell culture technology, FDA indicated it expected to be involved in regulating cell-cultured meat based on the agency's existing statutory authority and expertise in animal cell culturing.⁷ FDA and USDA jointly hosted a public meeting in October 2018 to discuss the potential hazards, oversight considerations, and labeling of cell-cultured food products derived from livestock and poultry tissue. In November 2018, FDA and USDA announced that they planned to jointly oversee the production of cell-cultured meat derived from livestock and poultry, with FDA overseeing cell collection and growth and USDA overseeing the later stages of production and labeling.⁸ The agencies explained that they believed this oversight model would leverage both FDA's experience

⁶The Food, Conservation, and Energy Act of 2008, also referred to as the 2008 Farm Bill, assigned regulatory responsibility for the inspection of catfish to USDA once the agency issued final regulations for a mandatory catfish inspection program under the Federal Meat Inspection Act. Pub. L. No. 110-246 § 11016(b), 112 Stat. 1651, 2130. The Agricultural Act of 2014, also referred to as the 2014 Farm Bill, amended the 2008 Farm Bill provisions by, among other things, replacing reference to catfish with reference to all fish of the order *Siluriformes*. Pub. L. No 113-79 § 12106(a)(1), 128 Stat. 649, 980. For the purposes of this report, we refer to fish of the order *Siluriformes* as catfish.

⁷In a notice announcing the public meeting, FDA stated that it evaluates microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients; administers safety assessment programs for a broad array of food ingredients and foods derived from genetically engineered plants; manages safety issues associated with animal cell culture technology in therapeutic settings; and manages risks associated with the processing, manufacture, and packaging of food incorporating seafood tissues. 83 Fed. Reg. 28,239 (June 18, 2018).

⁸U.S. Department of Agriculture, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Washington, D.C.: Nov. 16, 2018).

regulating cell culture technology and USDA's expertise in regulating livestock and poultry products for human consumption. Because of potential risks to public health and safety, we added federal oversight of food safety to our High Risk List in 2007, where it remains today.⁹

You asked us to review federal oversight of cell-cultured meat. This report (1) describes what is known about methods for commercially producing cell-cultured meat and (2) examines the extent to which FDA and USDA are collaborating to provide regulatory oversight of cell-cultured meat.

To address these objectives, we conducted a literature review of journal and media articles from 2016 through 2019 to inform our understanding of cell-cultured meat as well as regulatory activity in the United States and in other countries. We also reviewed documents collected from FDA and USDA, such as their 2019 interagency agreement, as well as documents collected from cell-cultured meat firms and consumer safety groups, among others. In addition, we attended FDA and USDA's October 2018 public meeting and four conferences in 2019 that included content pertaining to food safety or cell-cultured meat. We also conducted site visits to two conventional meat-processing facilities in Georgia, three cell-cultured meat firms in California, an academic cell-culturing laboratory in California, and a medical cell-culturing facility in Maryland. We identified facilities and laboratories to visit through online research and the assistance of agency officials and stakeholders.

We interviewed officials from FDA and USDA and representatives from the cell-cultured meat and conventional meat industries, academia, food and consumer safety groups, and state and tribal public health associations, among others. We identified stakeholders to interview through consultation with agency officials and other stakeholders and through our review of literature and online sources. We sought to include different types of stakeholders in order to understand the range of perspectives on producing cell-cultured meat and FDA and USDA collaboration.

For the purposes of our report, we define cell-cultured meat as food derived from animal cells grown in an environment outside the animal. We define cell-cultured seafood as a subcategory of cell-cultured meat. When referencing conventional meat, we are referring to food produced

⁹For more information, see GAO, *High Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, [GAO-19-157SP](#) (Washington, D.C.: Mar. 6, 2019).

from the traditional method of slaughtering an animal, such as a cow, hog, chicken, or fish. When referencing seafood, we are referring to shellfish, sea fish, and freshwater fish served as food.

To describe what is known about the commercial production methods for cell-cultured meat, in addition to the steps described above, we reviewed two sets of public comments submitted to FDA and USDA in 2018.¹⁰

To examine the extent to which FDA and USDA are collaborating to provide regulatory oversight of cell-cultured meat, we identified efforts the two agencies took to collaborate in this area from July 2018 through April 2020 by reviewing agency documentation and public announcements and interviewing federal officials. We then compared these efforts with the seven leading practices for interagency collaboration.¹¹ In this report and in our past work, we define collaboration as any joint activity that is intended to produce more public value than could be produced when organizations act alone. We use the terms “coordination” and “collaboration” interchangeably. We also compared the agencies’ efforts against standards for internal control in the federal government.¹²

Appendix 1 presents additional information on our scope and methodology.

We conducted this performance audit from October 2018 to April 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹⁰FDA requested comments in conjunction with its July 2018 public meeting, and FDA and USDA jointly requested public comments in conjunction with their October 2018 public meeting.

¹¹GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

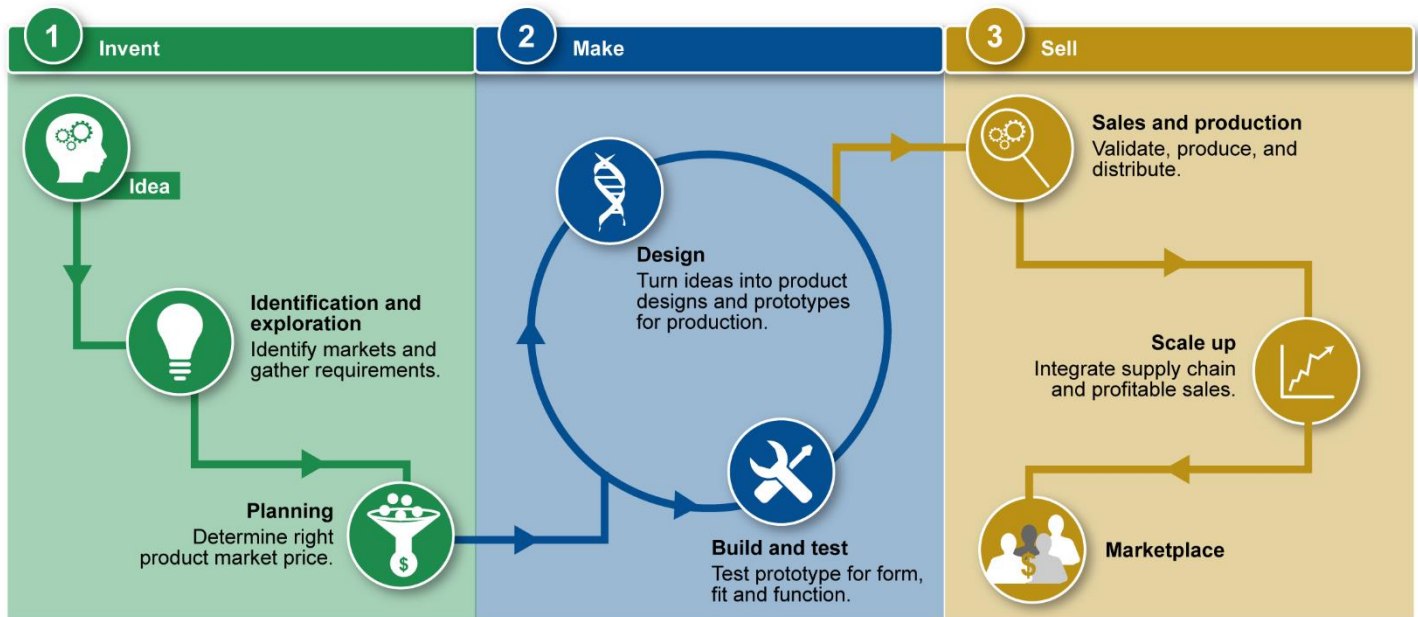
¹²GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

Background

Phases of Technological Innovation

In our prior work, we have found that technological innovation involves not only creating new ideas but also translating those ideas into a new product or service.¹³ Innovation, and the research driving it, is inherently risky because the likelihood that research can be translated into a product or service and the ultimate value of that product or service are unknown. The Department of Commerce's National Institute of Standards and Technology describes the path from innovation to commercialization as comprised of three overarching stages: inventing, transitioning to making, and selling. (See fig. 1 for a description of the path from innovation to commercialization.)

Figure 1: The Path from Innovation to Commercialization



Source: Department of Commerce's National Institute of Standards and Technology. | GAO-20-325

¹³GAO, *Science and Technology: Considerations for Maintaining U.S. Competitiveness in Quantum Computing, Synthetic Biology, and Other Potentially Transformational Research Areas*, GAO-18-656 (Washington, D.C.: Sept. 26, 2018).

Federal Agencies' Oversight of the Food Supply

FDA and USDA have responsibility for overseeing the safety of the food supply. In general, FDA is responsible for ensuring the safety of virtually all domestic and imported food products except those regulated by USDA. USDA is responsible for ensuring the safety of meat, poultry, processed egg products, and catfish. FDA and USDA cooperate with states, tribes, and local food safety and public health agencies to carry out their federal responsibilities.¹⁴ FDA and USDA carry out their responsibilities in part through inspections of facilities where food is produced. The frequency of inspections the agencies conduct varies, as follows:

- **FDA.** FDA's authority requires a risk-based approach, in which inspection rates vary depending on the level of risk associated with a food product. FDA conducts risk-based inspections of high-risk and non-high-risk food facilities. For example, the FDA Food Safety Modernization Act, signed into law in 2011, specified that FDA had to inspect all high-risk domestic facilities at least every 3 years.¹⁵
- **USDA.** Depending on the type of facility, USDA conducts inspections at least once per operating shift or maintains a constant presence. Specifically, USDA conducts carcass-by-carcass inspection at all federally inspected meat and poultry slaughter facilities and verifies that these establishments follow all food safety and humane handling requirements. At facilities that process meat and poultry products, USDA conducts inspections at least once per production shift, following the agency's longstanding interpretation of its statutes requiring it to do so.

Among other things, the Federal Food, Drug, and Cosmetic Act requires that food additives be approved by FDA before they can be lawfully used in foods.¹⁶ Substances added to food are considered unsafe unless the agency establishes that the use of the food additive, under specific

¹⁴The federal food safety system is supplemented by states, localities, tribes, and territories, which may have their own laws and agencies to address the safety and quality of food. In all, more than 3,000 nonfederal agencies perform the great majority of government food safety activities.

¹⁵Pub. L. No. 111-353 § 201 (2011) (adding 21 U.S.C. §350j(a)(2)(B)(i)).

¹⁶Food additives are substances that, when used as intended, are reasonably expected to become a component or otherwise affect the characteristics of food.

conditions for use, will be safe, or unless the substance is generally recognized as safe (GRAS) under the conditions of its intended use among qualified experts. As we reported in 2010, the Federal Food, Drug, and Cosmetic Act exempts GRAS substances from the act's general requirement that companies obtain FDA approval before marketing food containing a new additive.¹⁷ GRAS substances include hundreds of spices and artificial flavors, emulsifiers and binders, vitamins and minerals, and preservatives that manufacturers add to enhance a food's taste, texture, nutritional content, or shelf life. The GRAS exemption allows companies, without notice to or approval from FDA, to determine whether there is enough support to claim a substance is GRAS. For a company to claim a substance is GRAS, it must conclude that there is common knowledge about the safety of the substance among experts qualified by scientific training and experience to evaluate its safety.

In addition, as part of their oversight of the food supply, FDA and USDA oversee food labeling of the products under their respective jurisdictions. USDA, by statute, is charged with assuring that products under its jurisdiction, including meat, poultry, and catfish, in interstate or foreign commerce are properly marked, labeled, and packaged. USDA develops and applies the labeling requirements for these products, and food manufacturers are responsible for complying with the USDA labeling rules and adhering to the process maintained by USDA for the evaluation and approval of these product labels. Consistent with its statutes, USDA requires preapproval of all labels before manufacturers can market their products. The Federal Food, Drug, and Cosmetic Act prohibits the misbranding of food, which includes food labeling that is false or misleading. Consistent with its statutes, FDA ensures that foods within its jurisdiction are not misbranded by focusing on the labels of products already in the market. FDA establishes regulations for the enforcement of these provisions and issues guidance. Food manufacturers are responsible for compliance with misbranding provisions in the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

¹⁷GAO, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, [GAO-10-246](#) (Washington, D.C.: Feb. 3, 2010).

Regulation of New Food Technologies

From time to time, new technologies, such as those used to make cell-cultured meat, generate challenges for FDA's and USDA's regulatory structure. Other examples of new food technologies to which federal agencies have needed to adapt include the genetic modification of plants and irradiation of foods.¹⁸ In the case of genetically modified plants, there are no specific regulations addressing products resulting from the manipulation of the genetic material of living seeds. However, under FDA policy, new genetically engineered crop varieties are treated like other foods (including their conventional counterparts) under the Federal Food Drug and Cosmetic Act and may not contain either unapproved food additives or contaminants that would adulterate the food. In 1995, FDA established a voluntary pre-market consultation process through which companies are encouraged to notify the agency before marketing a food produced from a genetically modified crop and voluntarily submit a summary of the developer-performed safety assessment. FDA evaluates the safety assessment for any issues that need to be addressed and works with the developer to resolve those issues.¹⁹ In the case of irradiated foods, companies seeking approval for a source of radiation used to treat a food may submit a food additive petition to FDA demonstrating the safety of the proposed use. FDA grants approval only after agency scientists have determined that the proposed use is safe, then the process can be employed commercially.

Specific Information about Cell-Cultured Meat Technology, Commercial Production Methods, and Final Product Composition Is Not Yet Known

General information about the process of making cell-cultured meat is available, but specific information about the technology being used and the eventual commercial production methods as well as the final products

¹⁸Food irradiation is the process of exposing food products to ionizing radiation in order to, among other things, control foodborne pathogens.

¹⁹For additional information, see GAO, *Genetically Engineered Crops: USDA Needs to Enhance Oversight and Better Understand Impacts of Unintended Mixing with Other Crops*, [GAO-16-241](#) (Washington, D.C.: Mar. 15, 2016).

is not yet known.²⁰ While firms may vary in how they make cell-cultured meat, the general process they use can be described in five phases. However, the technology and methods to commercially produce cell-cultured meat are still in development, and producers, regulators, and consumers do not yet have clarity on what these will entail. The composition of the final product is also not yet known.

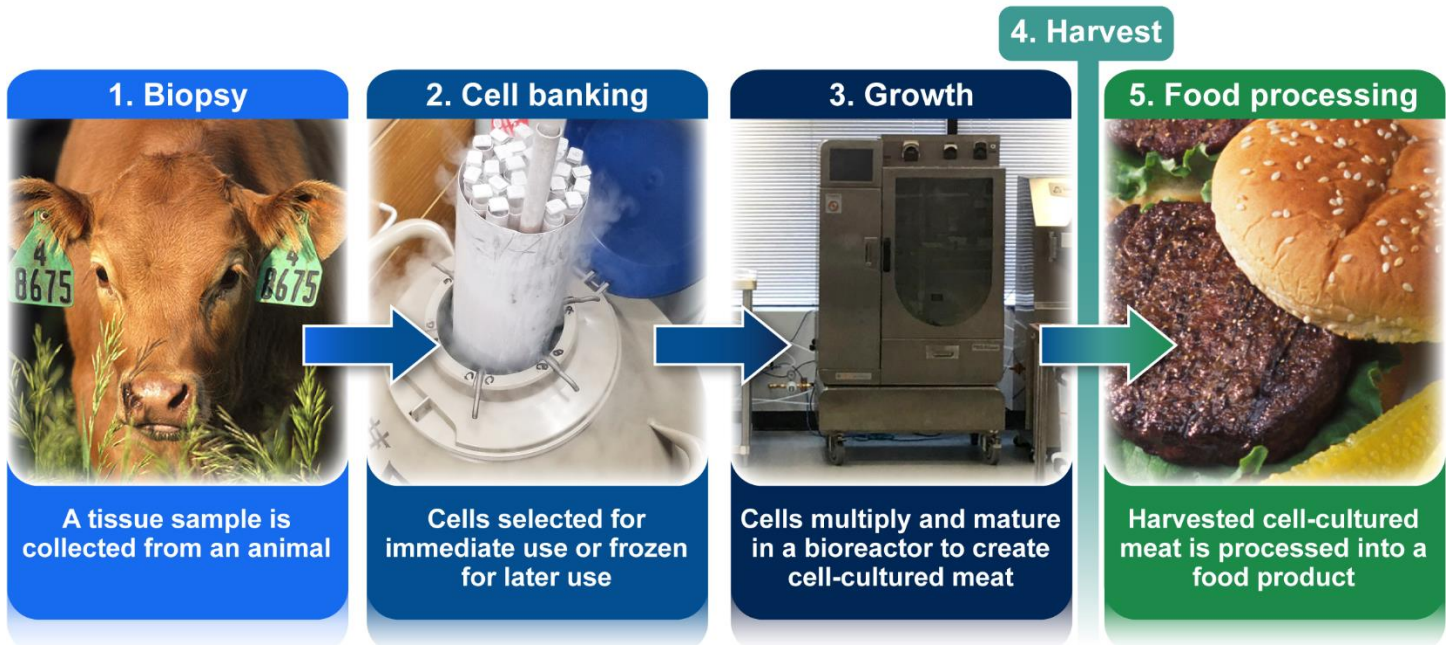
The General Process for Making Cell-Cultured Meat Contains Five Phases

The general process for making cell-cultured meat contains five phases: biopsy, cell banking, growth, harvest, and food processing.²¹ (See fig. 2.)

²⁰We use commercial production method and final product to describe a process for producing cell-cultured meat for commercial sale and the resulting product. We use the phrase food processing to describe the final phase in producing a cell-cultured meat product, when raw material is prepared and packaged into products for consumer use.

²¹While the general process for making cell-cultured meat is likely similar, individual firms' approaches may vary.

Figure 2: The General Process for Making Cell-Cultured Meat



Sources: GAO and U.S. Department of Agriculture's Agricultural Research Service. | GAO-20-325

The five-phase process is generally as follows:

1. **Biopsy.** A biopsy is taken by collecting rice-sized tissue samples from an animal, such as livestock, chicken, or fish.²² During this and subsequent phases, specific laboratory sanitation procedures are followed, and antibiotics may be used in order to avoid or minimize contamination from bacteria.

Growth Media

According to researchers and representatives from cell-cultured meat firms, the growth media for cell-cultured meat often contains fetal bovine serum, which is obtained from blood drawn from a bovine fetus at slaughter. However, researchers and representatives from cell-culturing firms we spoke with said they are working to develop growth media that do not contain fetal bovine serum. Representatives from some of these firms

²²It is unclear what type of cells firms will seek to obtain in their tissue samples. Researchers have used different types of cells, including muscle cells and stem cells, to create cell-cultured meat. Obtaining certain types of cells may use different techniques other than a biopsy.

also told us that the composition of the growth media, including the exact ingredients and their proportions, can vary based on the specific needs of the cells and the variety of serum used. For example, cell-cultured seafood may have different growth media and environmental requirements than cell-cultured livestock and poultry.



Source: Department of Health and Human Services' Centers for Disease Control and Prevention. | GAO-20-325

2. **Cell banking.** Biopsied cells with the most desirable traits are selected and either used immediately for cell growth or frozen to create a cell bank for later use.²³ These desirable traits can be obtained by either selecting existing cells or using genetic engineering methods to insert, delete, or edit the DNA to target desired traits in cells. Examples of desirable traits may include cells that divide quickly, cells that divide a greater number of times, cells that result in a reduced cholesterol or fat content or other desirable nutritional traits, or cells that are more resilient to environmental factors, such as temperature, than other cells. According to agency officials and representatives from cell-cultured meat firms, this phase represents an important opportunity to ensure that the source cells used to initiate commercial production are free of pathogens or other contaminants.
3. **Growth.** During the cell growth phase, cells are placed in a bioreactor and begin to divide and differentiate.²⁴ A bioreactor is a container that creates an environment that can sustain the growth of cells and includes the ability to control factors such as temperature, pH, and oxygen and carbon dioxide concentrations. Bioreactors can vary in size, including microwave-sized and refrigerator-sized units, but could be as large as 20 to 30 feet tall in commercial production. Bioreactors contain a growth medium, which may include ingredients such as glucose, amino acids, hormones and other growth factors, and other basic nutrients that cells need to consume in order to thrive.²⁵ In addition to the medium needed for growth, the cells may need to be attached to a structure, referred to as a scaffold, to properly develop into cell-cultured meat.²⁶
4. **Harvest.** Once the cells have divided to form a sufficiently large amount of cell-cultured meat, producers remove—or harvest—it from the growth medium and bioreactor. If a scaffold was used to provide a

²³A cell bank is a method used to preserve live cells for later use and involves producing a substantial number of cells sharing similar traits that can be separated into many small containers for freezing and later use in subsequent phases.

²⁴Differentiation in cell-cultured meat production is a process by which cells are encouraged to change into a specific type of cell, such as muscle cells, by adjusting the cell-culture environment and medium.

²⁵Growth factors are proteins that affect the growth of a cell and may be used to trigger desired changes in cells, such as differentiation or division. Hormones are components of some growth factors.

²⁶Scaffolds can either be particles that are suspended in a liquid or larger, free-standing structures, such as the walls of a bio-reactor or structures that resemble bones.

structure for cells to grow on, then the cell-cultured meat would either be separated from the scaffold during harvesting or left attached to an edible scaffold.

5. **Food processing.** The harvested cell-cultured meat is then prepared into a product such as meatballs or chicken nuggets. In the future, products similar to intact cuts of meat such as steak or chicken breast may be produced.

The Technology to Commercially Produce Cell-Cultured Meat Is in Development, and the Eventual Commercial Production Methods and Aspects of a Final Product Are Not Yet Known

The technology to produce cell-cultured meat at a commercial scale is still in development, and information about the methods to be used for commercial production and the composition of the final product are not yet known. In the continuum of moving a technology from innovation to commercialization, cell-cultured meat firms are in the middle stage of building and testing their prototypes, based on our discussions with representatives from these firms.²⁷ Consequently, they have not finalized aspects of the technology and eventual commercial production methods to be used or the composition of the final product. As a result, certain information is not yet available to stakeholders—including cell-cultured meat firms themselves, regulators, and the public—about specific aspects of the technology and commercial production methods that will be used, such as the composition of the growth medium and of the final products.

In addition to technology development, the scarcity of publicly available research on cell-cultured meat production limits information available to agency officials and the public. Each cell-cultured meat firm is developing detailed information on its own eventual commercial production methods for making cell-cultured meat. However, the firms, similar to other technology start-ups, are reluctant to disclose intellectual property and business-sensitive information due to concerns about competition. For example, one firm told us that they can reverse engineer parts of another company's commercial production method by seeing pictures of the equipment the other company is using. In addition, cell-cultured meat

²⁷As discussed earlier, the three stages of the path from innovation to commercialization are inventing, making, and selling.

firms compete with other firms for funding from sources such as venture capitalists, foreign governments, and conventional meat companies.

This competition for funding contributes to firms being reluctant to share information they consider important intellectual property, such as parts of their production processes. As a result, agency officials and other stakeholders told us that they must largely rely on whatever information the cell-cultured meat firms are willing to provide to understand details of the companies' prototype processes and products. This limitation can affect agencies' ability to make regulatory and other decisions. Specifically, FDA and USDA officials said they have limited information on cell-cultured meat production methods and products and need more in order to regulate this new food. One USDA official explained that the agency cannot establish labeling requirements if the agency does not know the nutritional profile of the final product.²⁸ For example, if the scaffold on which the cell-cultured meat is grown is not edible, the agencies may require firms to disclose certain aspects of their commercial production methods, such as how they removed the cell-cultured meat from the scaffold. However, if the scaffold is edible, it will affect the final composition of the product, which may require different labeling than a product that was developed without edible scaffolding.

This lack of information results in unanswered questions about cell-cultured meat as it relates to the eventual technology and commercial production methods to be used and the composition of the final products. Among other things, this lack of information creates challenges for industry and federal regulatory agencies as cell-cultured meat nears commercialization. The sources we reviewed and stakeholders we talked to identified a number of open questions, including the following:

- **Tissue collection.** *How often will producers need to collect biopsy samples from animals, and what animals will be used?* Some stakeholders have stated concerns about whether, and how, regulators will ensure that biopsies are collected from healthy animals. For example, one cell-cultured meat firm stated that tissue samples would be taken from slaughtered donor animals that met federal standards for conventional processing at the time of slaughter. However, USDA and FDA have not indicated whether they would

²⁸USDA later clarified that while general labeling requirements for meat and poultry products already are established by statute and regulation, USDA is as yet unaware which labeling requirements will apply to cell-cultured meat products because the agency does not know exactly how these products will be processed.

require cell-cultured meat firms to do so. Additionally, representatives from cell-cultured meat firms stated that they did not yet know how frequently they would need to collect biopsies from animals for commercial-level production. Additionally, according to researchers, there are too many unknowns to accurately estimate how much cell-cultured meat could be produced from a single biopsy of animal tissue.

- **Genetic engineering.** *Will commercial production methods involve genetic engineering?* Some stakeholders expressed concern that the use of genetic engineering in cell-cultured meat production could cause the product to experience a lengthy wait for regulatory approval, similar to that for genetically engineered salmon, which took approximately 20 years. One representative from a cell-cultured meat firm noted that uncertainty about pending government regulations could negatively affect firms' ability to attract and retain investors. Representatives from some firms said understanding what regulatory requirements will look like might influence which scientific pathways they pursue as they continue to develop their commercial production methods. According to FDA officials and representatives from one cell-cultured meat firm, it is likely that some firms will use genetic engineering in their commercial cell-cultured meat production methods. However, representatives from two other cell-cultured meat firms told us they were undecided as to whether they would use genetic engineering in their commercial production methods.
- **Antibiotics.** *Will antibiotics be used to make cell-cultured meat, and will residues be present in the final product?* According to agency officials, the presence of antibiotics in commercial production and the potential for residues in the resulting product would represent a significant potential concern for food safety and public health. Officials stated that they would not expect antibiotics to be used past the cell-banking phase. Representatives from cell-cultured meat firms we spoke to differed on whether they planned to use antibiotics in their commercial production process, but they had not finalized their decisions. According to one firm, if antibiotics are used, the use would be limited both in quantity and duration.
- **Growth medium.** *What type of growth medium will producers use, and how might variations in the media affect the final product?* According to agency officials and other stakeholders, the ingredients used in the growth medium could affect the end product's composition and raise potential safety concerns. For example, FDA officials stated that residual growth factors, such as hormones, in the final product would be something they would likely evaluate in premarket

consultations. However, representatives from cell-cultured meat firms stated that their firms have not finalized the medium they plan to use. In addition, the formulation of the medium firms use could be an important piece of intellectual property or confidential business information.

- **Scaffold.** *What type of scaffold will producers use, if any, and will it be edible or inedible?* The use of edible or food-grade scaffolds, where they are used, will affect the composition of the product and may need to be evaluated by federal agencies for safety. According to USDA officials, the composition of edible scaffolding may also create labeling and jurisdictional concerns. For example, USDA officials stated that the addition of edible scaffolding may require significant additional aspects of production to be subject to USDA jurisdiction. Additionally, researchers have commented that a chemical separation technique needed to separate some inedible scaffolds may also need to be evaluated for potential safety concerns.
- **Point of harvest.** *How will FDA and USDA define the point of harvest?* The point of harvest is the point at which FDA will transfer oversight responsibilities, including inspections, to USDA. Stakeholders have raised concerns that not having a clear definition of the point of harvest could lead to challenges such as overlapping inspection requirements or a gap in inspection. Representatives from several cell-cultured meat firms we spoke to in the spring of 2019 said it was ambiguous how FDA and USDA intended to define the point of harvest. These representatives also said it is unclear how often each agency plans to conduct inspections during the phases for which it is responsible.²⁹ Agency officials stated that they are working to develop a detailed process for the transfer of jurisdiction, including defining the point of harvest.
- **Scaling up production.** *How will firms scale up production to commercial levels?* One 2018 study conducted by researchers in the United Kingdom stated that to produce one pound of cell-cultured meat, firms would need bioreactors at least 2 1/2 times larger than what is currently available.³⁰ Similarly, a senior FDA official stated that the capacity of existing production equipment is a challenge for firms seeking to produce cell-cultured meat products at a commercial scale. As a result, the firms themselves may have to develop the equipment

²⁹As stated earlier the frequency of inspections conducted by FDA and USDA varies.

³⁰Stephens, N., L. Di Silvio, I. Dunsford, M. Ellis, A. Glencross, and A. Sexton, "Bringing Cultured Meat to Market: Technical, Socio-political, and Regulatory Challenges in Cellular Agriculture," *Trends in Food Science and Technology*, vol. 78 (2018): 155-166.

or custom order such equipment. Representatives from one cell-cultured meat firm told us that they are interacting with equipment providers to identify commercial-scale production equipment.

- **Production cost.** *How will firms sell their product at a price point that is both profitable to the firms and affordable to the consumer?* Some studies and stakeholders we interviewed, including representatives from cell-cultured meat firms, said that the high production cost of cell-cultured meat is a key industry challenge. For example, in the last two years, one firm reported that it cost \$600 to make a cell-cultured meat hamburger patty and reported that it cost about \$1,200 to produce a single cell-cultured meatball. One of the biggest cost drivers in the production of cell-cultured meat is the growth medium, according to some studies and some cell-cultured meat firms. To address issues of cost and scale, some firms may develop their own, less expensive growth media.
- **Safety considerations.** *Are potential safety hazards in commercial production methods for cell-cultured meat different from those for conventional meat, and how will eventual commercial production methods affect the overall safety of the product?* According to agency officials, cell-cultured meat may present different safety challenges compared to conventional meat. For example, according to agency officials, residues and constituents in harvested cell-cultured meat would be expected to be different from those in conventional meat, depending on the details of the production process. Representatives from one cell-cultured meat firm told us that they likely will use food processing techniques similar to those used for conventional meat, abide by similar health and safety standards, and possibly share food processing facilities. However, because specific information about commercial production methods and final products is not yet known, it is unclear whether cell-cultured meat produced on a commercial scale will pose any hazards not present in conventional meat.
- **Product composition.** *What will be the composition of any eventual products?* Agency officials told us that without knowing the composition of a cell-cultured meat product, it is impossible to predict how food safety and labeling requirements will apply. According to representatives from some cell-cultured meat firms, initial cell-cultured meat products most likely will not be composed entirely of cell-cultured meat but, rather, a mixture of cell-cultured meat and other ingredients such as binding, flavoring ingredients, and plant-based materials used in conventional food products. Some firms have developed prototypes of cell-cultured meat products as part of their research and development. In April 2019, representatives from one

firm told us that their prototype included about 90 percent plant-based ingredients and 10 percent cell-cultured meat. However, representatives from cell-cultured meat firms stated that they aim to produce products that contain more cell-cultured meat than other ingredients. For example, some cell-cultured meat firms have stated that a long-term goal is to commercially produce cell-cultured meat products that are similar to intact cuts of meat, such as steaks. As of December 2019, these firms had not provided regulators with specific information detailing the composition of their cell-cultured meat prototypes, according to FDA and USDA officials.

- **Environmental, animal welfare, and health impacts.** *How will cell-cultured meat impact the environment, animal welfare, or human health, if at all?* Cell-cultured meat firms and researchers have made various claims about the potential environmental, animal welfare, and health advantages of cell-cultured meat over conventionally produced meat. For example, some cell-cultured meat firms have claimed that cell-cultured meat production would use less water and emit less greenhouse gases than conventional meat production. Some cell-cultured meat firms have also claimed that cell-cultured meat will improve animal welfare because slaughter will be unnecessary. Additionally, some stakeholders stated that because there is less opportunity for contamination from animal feces—a potential source of contamination for conventional meat—cell-cultured meat would be less likely than conventional meat to contain foodborne pathogens.³¹ However, there are disagreements regarding the accuracy of these claims. Stakeholders told us that until commercial production methods and final products are established, these claims about impacts on the environment, animal welfare, and human health will remain unsubstantiated.
- **Timeline to market.** *When will cell-cultured meat products reach consumers?* As of December 2019, no cell-cultured meat products were available for retail sale in the United States. Stakeholders give varying estimates for when cell-cultured meat may be commercially available. Some estimates suggest that firms may be able to commercially produce some form of cell-cultured meat product as soon as 2020, while others estimate that such products may not be available for 2 to 4 years.
- **Labeling.** *How will cell-cultured meat be labeled?* Labeling was an area of concern for representatives from both conventional and cell-

³¹Foodborne pathogens are disease-causing organisms and include bacteria such as *Salmonella*, *Campylobacter*, and *E. coli*.

cultured meat firms who explained that the specific terminology, such as “clean meat” or “lab-grown meat,” can sometimes reflect bias for, or against, certain products, potentially affecting consumer acceptance of these products. Additionally, stakeholders, as well as agency officials, have emphasized the importance of labeling to ensure consumers have accurate information about what they are buying. For example, in February 2018 the United States Cattlemen’s Association submitted a petition to USDA requesting that the agency limit the term “beef” to products “born, raised, and harvested in a traditional manner” and “meat” to mean the “tissue or flesh of animals that have been harvested in the traditional manner.”³² USDA received over 6,000 comments on the petition, and the agency had not responded to the petition as of December 2019. However, according to agency officials, USDA has committed to a public process, likely rulemaking, for the development of labeling requirements for cell-cultured meat and poultry. In addition, in recent years, a number of states have passed laws that could affect the labeling of cell-cultured meat when it comes to market. For example, in 2018, Missouri enacted a law to prohibit plant-based products and cell-cultured meat from being labeled as “meat.”³³

- **Consumer Acceptance** *How will consumers respond to cell-cultured meat?* It remains unclear whether consumers will embrace and purchase cell-cultured meat products. Stakeholders we interviewed and studies we reviewed cited consumer acceptance as a challenge for commercializing cell-cultured meat. One study noted that consumers have both positive and negative views toward cell-cultured meat, which could impact their willingness to purchase and consume such products.³⁴

³²Petition, In re: Beef and Meat Labeling Requirements: to Exclude Products Not Derived Directly from Animals Raised and Slaughtered from the Definition of “Beef” and “Meat,” FSIS 18-01 (Feb. 9, 2018).

³³Representatives from some cell-cultured meat firms said that activity in state legislatures regarding labeling of cell-cultured meat and plant-based proteins adds to the uncertainty about how their product will be labeled, and one stakeholder told us that it would be helpful to the cell-cultured meat industry for USDA and FDA to communicate whether they anticipate taking steps that would preempt existing state laws.

³⁴Wilks, M., and C.J.C. Phillips, “Attitudes to in vitro meat: A survey of potential consumers in the United States,” *PLoS ONE*, vol. 12, no. 2 (Feb. 16, 2017).

FDA and USDA Have Begun to Collaborate on Oversight of Most Cell-Cultured Meat but Could More Fully Incorporate Leading Collaboration Practices

FDA and USDA have established multiple mechanisms to collaborate on regulatory oversight of cell-cultured meat. Specifically, the agencies have collaborated through a joint public meeting, an interagency agreement, and three working groups. However, the interagency agreement and working groups, which are ongoing mechanisms, do not fully incorporate leading practices for interagency collaboration. In addition, FDA and USDA have not documented which agency will oversee cell-cultured seafood not covered by the interagency agreement.

FDA and USDA Have Taken Initial Steps to Collaborate on Their Oversight of Cell-Cultured Meat through Several Mechanisms

In 2018, FDA and USDA began taking steps to collaborate on the regulatory oversight of cell-cultured meat through several mechanisms: a joint public meeting, an interagency agreement, and three working groups.³⁵ The agencies held the joint meeting in October 2018 to discuss the use of cell-culture technology to develop products derived from livestock and poultry, and topics included potential hazards, oversight considerations, and labeling. As part of this meeting, FDA and USDA held an open public comment period from September through December 2018, gathered 315 written comments, and offered interested parties the opportunity to offer comments in person. The agencies received public comments from members of the public, as well as from representatives from cell-cultured meat and conventional meat industries, food and consumer safety groups, animal welfare groups, and environmental organizations, among others. The written comments the agencies received focused on such topics as environmental considerations, labeling, potential health and safety implications, and potential regulatory and inspection processes. Stakeholders also presented multiple

³⁵Collaborative mechanisms are any arrangement that can facilitate collaboration between agencies such as interagency groups, interagency agreements, and conferences.

perspectives on these issues at the meeting. For example, stakeholders expressed different views as to whether cell-cultured meat should be regulated as a food additive, considered a GRAS substance, or whether new regulations were needed.³⁶

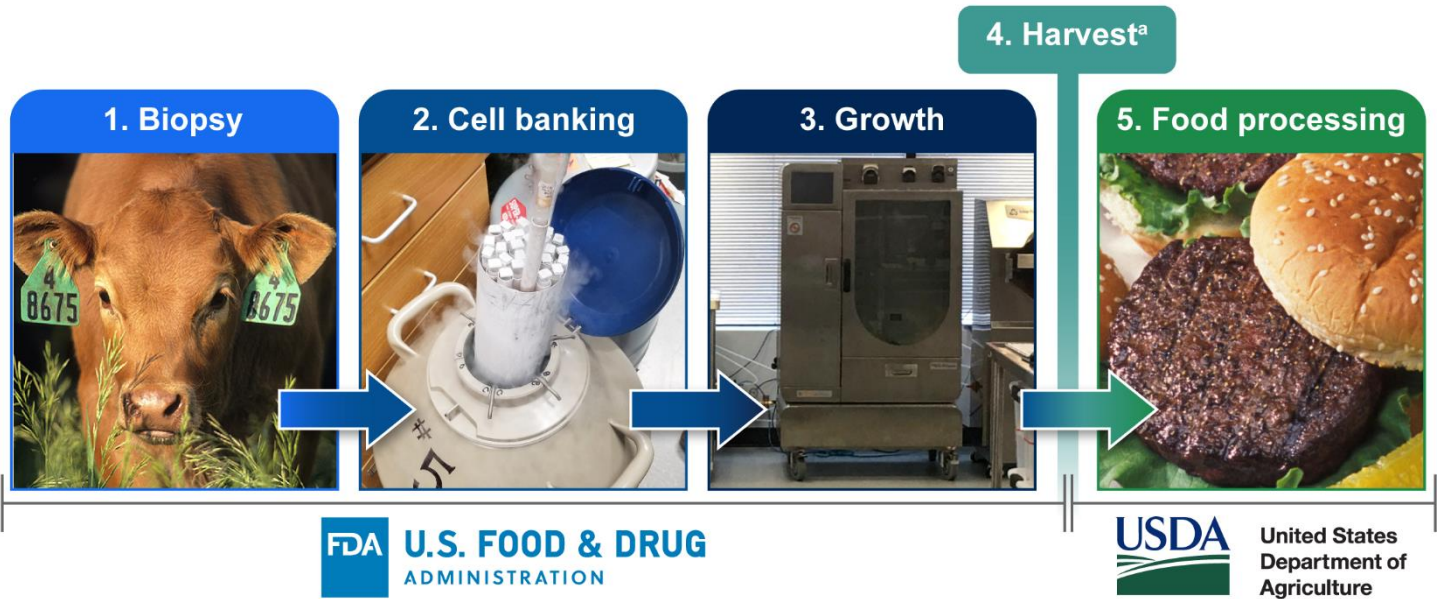
In March 2019, FDA and USDA issued a formal interagency agreement that describes the intended roles and responsibilities of each agency in overseeing cell-cultured meat. The agreement establishes the following:

- **Oversight.** FDA will oversee the early phases of growing cell-cultured meat through the point of harvest. During harvest, FDA will work with USDA to transfer regulatory oversight to USDA. USDA will then assume oversight of cell-cultured meat through the food processing phase, including labeling, as shown in figure 3.
- **Types of meat covered.** The agreement covers cell-cultured meat derived from species overseen by USDA, such as livestock, poultry, and catfish.³⁷
- **Future actions.** The agreement also details future actions the agencies plan to take, such as developing a more detailed regulatory framework or standard operating procedures and developing joint principles for product labeling.
- **Reviewing and updating the agreement.** The agreement states that the agencies have the ability to modify it as needed and will review the agreement every 3 years to determine whether they should modify or terminate it.

³⁶As explained earlier, substances added to food are considered unsafe unless the agency establishes that the use of the food additive, under specific conditions for use, will be safe. However, one notable exception to this rule is substances added to food that are generally recognized as safe (GRAS). This exemption provides the opportunity for companies, without notice to or approval from FDA, to determine whether there is enough support to claim a substance is GRAS.

³⁷The interagency agreement states that it includes food products derived from cell lines of USDA-amenable species required to bear a USDA mark of inspection, which in the agreement includes livestock, poultry, and catfish.

Figure 3: Federal Oversight Responsibility for the Phases of Cell-Cultured Meat Production



Sources: GAO and U.S. Department of Agriculture's Agricultural Research Service. | GAO-20-325

^aFDA and USDA's interagency agreement states that during the harvest phase oversight will transfer from FDA to USDA.

In June 2019, FDA and USDA created three working groups to carry out the terms of the interagency agreement. The working groups are comprised of FDA and USDA officials and operate independently, though some individuals are members of multiple groups. The groups are as follows:

- **Pre-market assessment working group.** Led by FDA, this group was created to clarify the process FDA will use for pre-market reviews of cell-cultured meat.
- **Labeling working group.** Led by USDA, this group will focus on developing joint principles for product labeling and claims.
- **Transfer of jurisdiction working group.** Co-led by FDA and USDA, this group will develop procedures for the transfer of inspection at harvest, among other things.

According to agency officials, the working groups are still in the initial phases of development, though some have progressed further than others. For example, as of December 2019, the pre-market assessment and labeling groups had met and begun to address various areas, while the transfer of jurisdiction working group was still in discussions to outline

the roles, responsibilities, and outcomes for the group and had not held a formal meeting.

The Interagency Agreement and Working Groups on Cell-Cultured Meat Could More Fully Incorporate Leading Collaboration Practices

FDA and USDA could more fully incorporate leading practices for collaboration in their interagency agreement and working groups. We have previously reported that interagency mechanisms or strategies to coordinate programs that address crosscutting issues may reduce potentially duplicative, overlapping, and fragmented efforts.³⁸ In addition, while collaborative mechanisms may differ in complexity and scope, they all benefit from certain leading practices, which raise issues to consider when implementing these mechanisms. We compared the agencies' interagency agreement and working groups with the seven leading practices to enhance and sustain interagency collaboration that we previously identified.³⁹ These leading practices, and examples of the associated issues to consider, are as follows:

- **Defining outcomes and monitoring accountability.** Is there a way to track and monitor progress toward short-term and long-term outcomes? Do participating agencies have collaboration-related competencies or performance standards against which individual performance can be evaluated?
- **Bridging organizational cultures.** What are the commonalities between the participating agencies' missions and cultures, and what are some potential challenges? Have participating agencies developed ways for operating across agency boundaries? Have participating agencies agreed on common terminology and definitions?

³⁸[GAO-12-1022](#); see also GAO, *Managing for Results: GPR Modernization Act Implementation Provides Important Opportunities to Address Government Challenges*, [GAO-11-617T](#) (Washington, D.C.: May 10, 2011). In this report and in our past work, we define duplication as instances when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries; overlap as instances when multiple agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar beneficiaries; and fragmentation as instances when more than one federal agency, or organization within an agency, is involved in the same broad area of national need, and opportunities exist to improve service delivery.

³⁹[GAO-12-1022](#).

- **Identifying and sustaining leadership.** How will leadership be sustained over the long term? If leadership is shared, have roles and responsibilities been clearly identified and agreed upon?
- **Clarifying roles and responsibilities.** Have participating agencies clarified roles and responsibilities? Have participating agencies articulated and agreed to a process for making and enforcing decisions?
- **Including relevant participants.** Have all relevant participants been included? Do participants have appropriate knowledge, skills, and abilities to contribute?
- **Identifying and leveraging resources.** How will the collaborative mechanism be funded and staffed?
- **Developing and updating written guidance and agreements.** If appropriate, have the participating agencies documented their agreement regarding how they will collaborate? (A written document can incorporate agreements reached in any or all of the following areas: leadership, accountability, roles and responsibilities, and resources.) Have participating agencies developed ways to continually update or monitor written agreements?

See appendix II for a full list of the associated issues to consider for each leading practice.

Interagency Agreement Partially Incorporates All Seven Leading Practices

We found that the interagency agreement for oversight of cell-cultured meat partially incorporates all seven leading practices for collaboration. For example:

- **Defining outcomes and monitoring accountability.** The interagency agreement partially incorporates the leading practice of defining outcomes and monitoring progress toward these outcomes. Specifically, the agreement identifies broad outcomes such as the development of labeling principles. However, the agreement does not describe how the agencies will track and monitor progress toward outcomes.
- **Identifying and sustaining leadership.** The agreement partially incorporates the leading practice of clarifying leadership structures. For example, it assigns each agency as the lead, or designates shared leadership, for different phases of the cell-cultured meat production process. However, the interagency agreement does not

identify how the agencies will sustain leadership over the long term, including through succession planning. We have previously reported that given the importance of leadership to any collaborative effort, transitions and inconsistent leadership can weaken the effectiveness of any collaborative mechanism.⁴⁰

- Developing and updating written guidance and agreements.** The agreement partially incorporates the leading practice of documenting how the agencies will collaborate. For example, the agreement includes a method for updating the document by including a provision that requires a review of the document every 3 years. This is consistent with our leading collaboration practice to continually update or monitor written agreements. However, the interagency agreement does not document how the agencies will track and monitor progress toward short-term and long-term outcomes.

Table 1 provides more detail about the agencies' incorporation of these leading collaboration practices in their interagency agreement.

Table 1: GAO Analysis of Incorporation of Leading Collaboration Practices in FDA and USDA's Interagency Agreement on Oversight of Cell-Cultured Meat, as of December 2019

Leading collaboration practice	Extent incorporated	GAO's analysis
Defining outcomes and monitoring accountability	Partially incorporated	The agreement identifies broad outcomes, such as the development of a more detailed joint framework and a joint process to identify any changes needed to statutory or regulatory authorities. The agreement does not indicate a method to evaluate outcomes or a way to track or monitor progress toward outcomes.
Bridging organizational cultures	Partially incorporated	To work across agency boundaries, the agreement states that FDA and USDA will meet periodically for activities such as program planning, coordination, evaluation, and review. FDA and USDA officials said that the agreement represents the agencies' initial steps in defining common terminology, definitions, and standards, but that more work needs to be done.
Identifying and sustaining leadership	Partially incorporated	The agreement identifies how leadership will be shared by assigning leadership by phase of the process. The agreement does not clarify how the agencies will sustain leadership over the long term, such as succession planning.
Clarifying roles and responsibilities	Partially incorporated	The agreement indicates a broad agreement on shared roles and responsibilities. The agencies have not yet articulated and agreed to a process for making and enforcing decisions.

⁴⁰[GAO-12-1022](#).

Leading collaboration practice	Extent incorporated	GAO's analysis
Including relevant participants	Partially incorporated	The agreement was developed by FDA and USDA, which are the only agencies identified in the agreement as having responsibilities. Some stakeholders provided input through public meetings and public comments. The agreement does not discuss other nonfederal participants, such as states, tribes, industry, and advocacy organizations, which FDA has acknowledged wanting to engage.
Identifying and leveraging resources	Partially incorporated	The agreement states the collaboration is subject to the availability of staffing, resources, and funds, and that each agency will fund its own responsibilities. Agencies have not evaluated resources needed, nor assessed staff or training needs.
Developing and updating written guidance and agreements	Partially incorporated	The agreement documents decisions at a broad level regarding leadership, resources, and roles, and it establishes a method for updating the document. The agreement does not document decisions about other matters, such as accountability and detailed decisions regarding responsibilities and resources.

Legend:

- Fully incorporated – FDA and USDA incorporated all aspects of this leading practice.
- ◐ Partially incorporated – FDA and USDA incorporated some aspects of this leading practice.
- Not incorporated – FDA and USDA did not incorporate any aspects of this leading practice.

Source: GAO analysis of the Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Interagency Agreement on Oversight of Cell-Cultured Meat and other information provided by FDA and USDA officials. | GAO-20-325

FDA and USDA officials told us that the interagency agreement was intended to be an initial, general outline for their collaboration. They also said that as the technology to produce cell-cultured meat develops and they implement the agreement, including developing the content of a regulatory program, they will consider incorporating leading practices for interagency collaboration. For example:

- **Clarifying roles and responsibilities.** FDA and USDA officials said in December 2019 that through the working groups the agencies would continue to explore and define the specific details of how they will manage their shared oversight responsibility.
- **Including relevant participants.** FDA officials said in December 2019 that the agency would like to engage many more stakeholders as it continues to develop its oversight of cell-cultured meat.
- **Identifying and leveraging resources.** As of December 2019, the pre-market assessment working group and the labeling working group were working to identify any human resources, physical, or financial resources they might need, according to FDA and USDA officials.

The federal food safety system is on our High Risk List due to concerns about fragmentation, which we have reported has caused inconsistent

oversight, ineffective coordination, and inefficient use of resources.⁴¹ As the agencies continue to collaborate on their shared oversight of cell-cultured meat, by more fully incorporating all seven leading practices for collaboration into their interagency agreement, they will be better positioned to address potential fragmentation in their efforts to ensure the safety of the food supply as cell-cultured meat products near commercialization and entry into the marketplace.

Working Groups Partially Incorporate or Do Not Incorporate Leading Practices

We found that the pre-market assessment, labeling, and transfer of jurisdiction working groups that FDA and USDA created to carry out the terms of the interagency agreement either partially incorporate or do not incorporate the seven leading practices for interagency collaboration. Specifically, all three working groups have partially incorporated three of the seven leading practices for collaboration, but none of the working groups have incorporated the four remaining leading practices. For example:

- **Defining outcomes and monitoring accountability.** The working groups have all defined and agreed upon their general purposes. However, FDA and USDA have not established methods, such as milestones and metrics, to evaluate the progress of any of the working groups. For example, FDA officials said in December 2019 that their next steps are to conduct a general and qualitative risk assessment of animal cell culture food technology to systematically identify particular areas of interest from a food safety perspective and prepare detailed procedural guidelines for cell-cultured meat firms to follow. However, the officials did not have time frames or a method to evaluate progress towards completing these actions.
- **Including relevant participants.** While the working groups have included relevant FDA and USDA officials, none of the groups have included state or tribal officials in initial discussions and planning. According to the state officials we spoke with, being excluded from these federal-level discussions may hinder their ability to align their safety and labeling requirements, among other things, with federal standards.
- **Developing and updating written guidance and agreements.** None of the working groups have documented how they will collaborate. For

⁴¹[GAO-19-157SP](#).

example, the working groups have not documented leadership, accountability, roles and responsibilities, or resources needed for working groups.

Table 2 provides more detail about FDA and USDA's incorporation of leading collaboration practices in the three working groups.

Table 2: GAO Analysis of Incorporation of Leading Collaboration Practices in FDA and USDA’s Working Groups on the Oversight of Cell-Cultured Meat, as of December 2019

Leading collaboration practice	Extent incorporated			GAO’s analysis
	Pre-Market Assessment Working Group	Labeling Working Group	Transfer of Jurisdiction Working Group	
Defining outcomes and monitoring accountability	Partially incorporated	Partially incorporated	Partially incorporated	General purposes of the working groups have been defined and agreed upon. Specific outcomes and methods to track and monitor progress have not been identified.
Bridging organizational cultures	Not incorporated	Not incorporated	Not incorporated	Working groups have not developed ways to operate across agency boundaries nor agreed on common terminology and definitions.
Identifying and sustaining leadership	Partially incorporated	Partially incorporated	Partially incorporated	Lead agencies have been identified for each working group. Roles and responsibilities of lead agencies have not been identified. Agencies have not decided how leadership will be sustained over the long term.
Clarifying roles and responsibilities	Not incorporated	Not incorporated	Not incorporated	Participants’ roles and responsibilities have not been clarified. No process for making and enforcing decisions has been identified.
Including relevant participants	Partially incorporated	Partially incorporated	Partially incorporated	Some relevant participants have been identified, but FDA and USDA have not determined if the participants have the appropriate ability, knowledge, and authority for their mission.
Identifying and leveraging resources	Not incorporated	Not incorporated	Not incorporated	Pre-market assessment and labeling working groups were actively assessing needed resources. Transfer of jurisdiction working group had not started an assessment of needed resources.
Developing and updating written guidance and agreements	Not incorporated	Not incorporated	Not incorporated	The groups have not documented agreement regarding leadership, accountability, roles and responsibilities, or resources needed for working groups.

Legend:

- Fully incorporated – FDA and USDA incorporated all aspects of this leading practice.
- ◐ Partially incorporated – FDA and USDA incorporated some aspects of this leading practice.
- Not incorporated – FDA and USDA did not incorporate any aspects of this leading practice.

Source: GAO analysis of information provided by Department of Health and Human Services’ Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) officials. | GAO-20-325

In December 2019, FDA and USDA officials said that as they continued to stand up these working groups, they were considering leading practices for collaboration. For example:

- **Defining outcomes and monitoring accountability.** FDA and USDA officials said they were considering means to monitor, evaluate, or report on the results of the pre-market assessment working group.
- **Including relevant participants.** FDA and USDA officials said that they were working to determine what knowledge participants in the pre-market assessment working group and the labeling working group needed to perform the work of the working group.
- **Developing and updating written guidance and agreements.** FDA and USDA officials said they were considering documenting how they will collaborate in the pre-market assessment working group, including potentially creating a charter for the working group.

We have previously reported that fragmentation has caused inconsistent oversight and inefficient use of resources in the federal food safety oversight system.⁴² The agencies' 2019 agreement to share oversight of cell-cultured meat creates a new relationship between FDA and USDA, since the agencies will oversee different stages of the production of the same food and hand off oversight at a certain point in that production. These factors contribute to an already complicated system in which the two agencies must coordinate on food safety oversight.

In this context, some industry representatives and other stakeholders have expressed concerns about potential fragmentation or overlap in oversight of cell-cultured meat, such as could occur during the harvest phase of cell-cultured meat production when FDA hands off its oversight to USDA. Additionally, representatives from one cell-cultured meat firm stated that avoiding overlap in federal oversight whenever possible was important to them. For example, representatives from one firm pointed to inspection, record-keeping requirements, and regulations as potential areas at risk of overlap. They stated that potential overlap would add unnecessary, burdensome requirements and create an uneven playing field with the conventional meat industry.

By more fully incorporating all seven leading practices for interagency collaboration early in the development of the three working groups, FDA

⁴²[GAO-19-157SP](#).

and USDA could proactively minimize potential fragmentation and overlap in their oversight of cell-cultured meat, ensure consistency and efficient use of resources, and provide clarity to key stakeholders.

FDA and USDA Have Not Documented Which Agency Will Oversee

Cell-Cultured Seafood

While FDA and USDA officials told us they have decided who will oversee cell-cultured seafood, they have not formally announced or documented this decision, and some stakeholders have reported confusion or ambiguity about which agency will oversee cell-cultured seafood other than catfish. Specifically, FDA and USDA's interagency agreement regarding cell-cultured meat states that it covers all cell-cultured meat derived from USDA-amenable species required to bear a USDA mark of inspection, which in the agreement includes livestock, poultry, and catfish. However, the agreement does not mention cell-cultured meat made from the cells of other fish, such as tuna and shellfish. FDA and USDA officials told us that FDA will have sole oversight responsibility for cell-cultured seafood other than catfish.

According to FDA officials, they have verbally communicated this decision in various meetings with stakeholders. However, FDA and USDA officials told us that formally documenting FDA's sole oversight of most cell-cultured seafood in their interagency agreement was unnecessary because FDA currently oversees most conventional seafood. According to cell-cultured meat firms, some firms are working on developing cell-cultured versions of seafood, such as bluefin tuna. However, stakeholders from two cell-cultured meat firms, including representatives of a cell-cultured seafood firm we spoke with in April 2019, stated that they did not know who in the federal government would oversee cell-cultured seafood. Representatives from one cell-cultured seafood firm said that not being able to rule out oversight by USDA prevented them from making key decisions regarding what direction to pursue in developing their commercial production method.

While FDA and USDA officials told us they had agreed that FDA would oversee cell-cultured seafood other than catfish, as of December 2019, the agencies had not formally announced or documented this agreement. Developing and updating written guidance and agreements is a leading

practice for collaboration, as we have previously reported.⁴³ In addition, standards for internal control in the federal government state that agency management should externally communicate the necessary quality information to achieve its objectives and should select appropriate methods of communication, such as a written document or a face-to-face meeting.⁴⁴ Management should also periodically evaluate the entity's methods of communication so that the organization has the appropriate tools to communicate quality information throughout and outside of the entity on a timely basis. While FDA and USDA officials have informally communicated to some stakeholders that FDA will have sole oversight of most cell-cultured seafood, FDA has not communicated this information formally or in a method readily available to all relevant stakeholders, such as in their interagency agreement or other publicly available written document.

FDA and USDA officials told us that they wanted to communicate this information through outreach to individual firms, but FDA or USDA officials said they did not think that revising their interagency agreement was necessary. By taking steps to document which agency will oversee cell-cultured seafood other than catfish, FDA and USDA will better ensure the public, including key stakeholders such as cell-cultured meat firms, have clarity about the agencies' oversight responsibilities in this area.

Conclusions

Cell-cultured meat is a new food product that raises many questions. FDA and USDA's shared oversight of cell-cultured meat poses various challenges for these agencies, as well as stakeholders such as industry. Compounding this challenge is that specific information about key aspects of cell-cultured meat, such as the technology and production methods to be used as well as the composition of the products, is not yet known.

FDA and USDA have taken steps to collaborate on their shared regulatory oversight of cell-cultured meat, including establishing an interagency agreement and three working groups. However, the interagency agreement only partially incorporates the seven leading collaboration practices that can enhance and sustain agencies'

⁴³[GAO-12-1022](#).

⁴⁴[GAO-14-704G](#).

collaborative efforts, and the working groups either partially incorporate or do not incorporate these leading practices, which has raised concerns about potential fragmentation or overlap in oversight. By more fully incorporating all seven leading practices for collaboration into their interagency agreement, FDA and USDA could build on their existing efforts and be better positioned to sustain and enhance their collaborative efforts. Moreover, by more fully incorporating all seven leading practices for interagency collaboration early in the development of the working groups, FDA and USDA could proactively minimize potential fragmentation and overlap in their oversight of cell-cultured meat and ensure they are utilizing resources efficiently or effectively.

Furthermore, the interagency agreement states that it covers USDA-amenable species required to bear a USDA mark of inspection, which in the agreement includes livestock, poultry, and catfish but does not include cell-cultured seafood other than catfish. FDA and USDA officials told us they have decided FDA will oversee most cell-cultured seafood, but the agencies have not formally documented this decision. By taking steps to document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish, FDA and USDA could better ensure that members of the public and other key stakeholders such as cell-cultured meat firms have clarity about the agencies' oversight responsibilities in this area.

Recommendations for Executive Action

We are making a total of six recommendations, three to FDA and three to USDA:

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat.
(Recommendation 1)

The Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat.
(Recommendation 2)

As the three cell-cultured meat working groups move forward, the Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes. (Recommendation 3)

As the three cell-cultured meat working groups move forward, the Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes. (Recommendation 4)

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish. (Recommendation 5)

The Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish. (Recommendation 6)

Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) for review and comment. In FDA's comments, reproduced in appendix III, the agency stated that it values GAO's recognition of the importance of collaborative mechanisms that facilitate coordination and affirmed its commitment to coordinate closely with USDA to ensure the regulatory framework for cell-cultured meat is clear and transparent to stakeholders. In USDA's comments, reproduced in appendix IV, the department stated that the report put too much focus on best practices for interagency collaboration and not enough emphasis on industry's role in providing the agencies with the information they need to move their processes forward to effectively regulate cell-cultured meat. USDA stated that it is difficult to review a developing technology and its

future regulatory oversight when so little detailed information about the technology is known.

We agree that the technology to produce cell-cultured meat is still in development and that information about the commercial production methods and composition of the final product are not yet known, as we state in our report. We also acknowledge in our report that having limited information can affect the agencies' ability to make regulatory and other decisions. We recognize that cell-cultured meat is a new food product that raises many new questions and that specific information about key aspects of cell-cultured meat is not yet known. In light of this challenging context, it is all the more important that FDA and USDA more fully incorporate leading practices for collaboration into their joint efforts in order to ensure they are in the best possible position to oversee this new food product.

FDA concurred with two recommendations and partially concurred with one. USDA also concurred with two recommendations and partially concurred with one. Specifically, both agencies agreed with our recommendations regarding (1) more fully incorporating the seven leading practices for effective collaboration in the three cell-cultured meat working groups as they move forward and (2) clearly documenting which agency will oversee cell-cultured seafood other than catfish.

FDA and USDA partially concurred with our recommendation, directed to each agency, to more fully incorporate the seven leading practices for effective collaboration into the agencies' interagency agreement for the joint oversight of cell-cultured meat. FDA stated that it concurred with the intent of incorporating the seven leading practices into the interagency agreement, and both agencies said that they are open to incorporating the practices into their development of the structure for joint oversight of cell-cultured meat. However, the agencies stated that they did not agree to revise the agreement at this time. FDA and USDA stated that the agreement is a general framework and that incorporating the leading practices would constitute an inappropriate level of detail. Instead, the agencies stated that they believe it would be most valuable to incorporate the leading practices into a more detailed joint framework or standard operating procedure they plan to issue.

We appreciate the agencies' willingness to incorporate the leading practices for effective collaboration into their efforts. The March 2019 interagency agreement states that the agencies have the ability to modify it as needed and will review the agreement every 3 years to determine whether they should modify or terminate it. Therefore, the agencies are

due to revisit the agreement in March 2022, if not sooner. Regarding the agencies' concern that incorporating the leading practices in the interagency agreement would add an inappropriate level of detail, we note that, as we state in our report, the existing agreement already partially incorporates each of the seven leading practices. We continue to believe that FDA and USDA should more fully incorporate the seven leading practices for effective collaboration into their interagency agreement for the joint oversight of cell-cultured meat. Developing a more detailed joint framework or standard operating procedure in accordance with the existing interagency agreement that incorporates those leading practices would meet the intent of our recommendation to improve the effectiveness of the agencies' collaboration.

FDA and USDA also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Agriculture, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions regarding this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

Sincerely yours,



Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

Our report (1) describes what is known about methods for commercially producing cell-cultured meat and (2) examines the extent to which the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are collaborating to provide regulatory oversight of cell-cultured meat.

For both objectives, we conducted a literature review of journal and media articles from 2016 through 2019 to inform our understanding of cell-cultured meat, as well as regulatory activity related to cell-cultured meat in the United States and in other countries. Specifically, we conducted a review of scholarly and trade news from 2016 through July 2019 for specific terms related to cell-cultured meat and regulatory approaches.¹ We conducted searches in more than 30 different academic and trade databases—such as SCOPUS, Foodline, and ProQuest’s Environmental Science Collection—and identified studies relevant to our research objectives. In addition to these formal literature searches, we also asked agency officials and stakeholders to refer us to research articles and publications on cell-cultured meat.

We also reviewed documentation from FDA and USDA, including the 2019 interagency agreement, existing memoranda of understanding between the two agencies, *Federal Register* notices about relevant public meetings, and press releases. We also reviewed documentation such as letters to regulators, presentation slides, and information on organizations’ websites from the cell-cultured meat industry, conventional meat industry, and consumer safety groups, among others. We also interviewed officials from FDA and USDA and representatives of stakeholders from the cell-cultured meat industry and industry associations, conventional meat firms and industry associations, academia, food and consumer safety groups, and state and tribal public

¹These terms included but were not limited to cell-cultured meat, cell culture food, cell culture protein, cell culture meat/poultry, cell culture technology, in vitro meat, clean meat, cell meat, animal free meat, cellular agriculture, alternative proteins or lab grown meat, challenge, unknown aspects about the process of making cell-cultured meat, insufficient research, regulatory ambiguity, cost of production, scaling up production, and consumer acceptance.

health associations, among others. We identified stakeholders to interview through consultation with agency officials and nonfederal stakeholders and through our review of literature. We conducted 17 interviews with representatives or researchers from:

- six cell-cultured meat firms or industry associations,
- four conventional meat firms or industry associations,
- three universities,
- two food and consumer safety groups,
- one state and tribal public health association, and
- one food law policy firm.

Because this is a nongeneralizable sample, the results of these interviews do not represent the views of all stakeholders involved in or with an interest in the cell-cultured or conventional meat industries or federal regulation of cell-cultured meat. However, they illustrate the range of perspectives on these topics.

We also attended public meetings and conferences and conducted site visits to several locations. Specifically, we attended FDA and USDA's public meeting in October 2018 and four conferences in 2019 that included content pertaining to food safety or cell-cultured meat. We conducted site visits to two conventional meat-processing facilities in Georgia, three cell-cultured meat firms in California, an academic cell-culturing laboratory in California, and a medical cell-culturing facility in Maryland. We identified facilities and laboratories to visit through our literature review, online research, and the assistance of agency officials and stakeholders, such as representatives from the cell-cultured meat and conventional meat industry.

To describe what is known about the process for producing cell-cultured meat and potential commercial production methods, we also reviewed two sets of public comments submitted to FDA and USDA in association with the two 2018 public meetings pertaining to cell-cultured meat. These meetings were "Foods Produced Using Animal Cell Culture Technology" in July 2018 and "Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry" in October 2018. Public comments were submitted by members of the public; representatives from cell-cultured meat firms and industry associations, conventional meat companies and industry associations, food and consumer safety groups, and animal welfare groups; and environmental organizations, among

others. We reviewed and analyzed all comments submitted to (1) FDA related to the July 2018 meeting and (2) FDA and USDA related to the October 2018 meeting. We also attended the October 2018 meeting and listened to agency officials' presentations and oral remarks made by stakeholders and members of the public. We shared our description of the process for making cell-cultured meat, and associated questions, with representatives from three cell-cultured meat firms and academic researchers at two universities for their technical review and incorporated revisions as appropriate.

To examine the extent to which FDA and USDA are coordinating to provide regulatory oversight of cell-cultured meat, we identified actions they took to coordinate from July 2018 through April 2020. To identify these actions, we interviewed agency officials, emailed agency officials written questions, reviewed agency documentation and public announcements, and attended public events such as the October 2018 public meeting. We compared the agencies' interagency agreement and working groups with seven leading practices to enhance and sustain interagency collaboration. Specifically, two independent GAO reviewers assessed the degree to which agencies' actions incorporated these leading practices.² A description of these leading practices and the associated issues to consider is in appendix II. We also assessed the agencies' actions against standards for internal control in the federal government, including standards related to communicating quality information.³ In this report, and in our past work, we define collaboration as any joint activity that is intended to produce more public value than could be produced when organizations act alone. We use the terms "coordination" and "collaboration" interchangeably in this report.

For the purposes of our report, we define cell-cultured meat as food derived from animal cells that were grown in a controlled environment outside of the animal. We define cell-cultured seafood as a subcategory of cell-cultured meat. When referencing conventional meat, we are referring to food produced from the traditional method of slaughtering an animal, such as a cow, hog, chicken, or fish. When referencing seafood, we are referring to shellfish, sea fish, and freshwater fish served as food.

²GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

³GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

**Appendix I: Objectives, Scope, and
Methodology**

We conducted this performance audit from October 2018 to April 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**Appendix II: Key Issues to Consider for
Implementing Interagency Collaborative
Mechanisms**

Table 3: Key Issues to Consider for Implementing Interagency Collaborative Mechanisms

Appendix II: Key Issues to Consider for Implementing Interagency Collaborative Mechanisms

Leading practice	Issues to consider
Defining outcomes and monitoring accountability	<ul style="list-style-type: none"> • Have short-term and long-term outcomes been clearly defined? • Is there a way to track and monitor progress toward the short-term and long-term outcomes? • Do participating agencies have collaboration-related competencies or performance standards against which individual performance can be evaluated? • Do participating agencies have the means to recognize and reward accomplishments related to collaboration?
Bridging Organizational Cultures	<ul style="list-style-type: none"> • What are the missions and organizational cultures of the participating agencies? • What are the commonalities between the participating agencies' missions and cultures and what are some potential challenges? • Have participating agencies developed ways for operating across agency boundaries? • Have participating agencies agreed on common terminology and definitions?
Identifying and sustaining leadership	<ul style="list-style-type: none"> • Has a lead agency or individual been identified? • If leadership will be shared between one or more agencies, have roles and responsibilities been clearly identified and agreed upon? • How will leadership be sustained over the long term?
Clarifying roles and responsibilities	<ul style="list-style-type: none"> • Have participating agencies clarified the roles and responsibilities of the participants? • Have participating agencies articulated and agreed to a process for making and enforcing decisions?
Including relevant participants	<ul style="list-style-type: none"> • Have all relevant participants been included? • Do the participants have: <ul style="list-style-type: none"> • Full knowledge of the relevant resources in their agency? • The ability to commit these resources? • The ability to regularly attend activities of the collaborative mechanism? • The appropriate knowledge, skills, and abilities to contribute?

**Appendix II: Key Issues to Consider for
Implementing Interagency Collaborative
Mechanisms**

Leading practice	Issues to consider
Identifying and leveraging resources	<ul style="list-style-type: none"> • How will the collaborative mechanism be funded? If interagency funding is needed, is it permitted? • If interagency funding is needed and permitted, is there a means to track funds in a standardized manner? • How will the collaborative mechanism be staffed? • Are there incentives available to encourage staff or agencies to participate? • If relevant, do agencies have compatible technological systems? • Have participating agencies developed online tools or other resources that facilitate joint interactions?
Developing and updating written guidance and agreements	<ul style="list-style-type: none"> • If appropriate, have the participating agencies documented their agreement regarding how they will be collaborating? A written document can incorporate agreements reached in any or all of the following areas: <ul style="list-style-type: none"> • Leadership • Accountability • Roles and responsibilities • Resources • Have participating agencies developed ways to continually update or monitor written agreements?

Source: GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012). | GAO-20-325

Appendix III: Comments from the U.S. Department of Health and Human Services



GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — FOOD SAFETY: FDA AND USDA COULD STRENGTHEN EXISTING EFFORTS TO PREPARE FOR OVERSIGHT OF CELL-CULTURED MEAT (GAO-20-325)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. The Food and Drug Administration (FDA), along with the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), takes seriously its mandate to ensure that food entering the market is safe for human consumption and properly labeled. The 2019 FDA-USDA formal agreement regarding oversight of human food produced using animal cell technology derived from cell lines of USDA-amenable species outlines a shared regulatory approach that will ensure these cell-cultured products are produced safely and are accurately labeled.

We value GAO's recognition of the importance of collaborative mechanisms that facilitate coordination between the FDA and USDA in the joint oversight of the production of human food products derived from the cells of livestock and poultry. Since the announcement of the formal agreement, the two agencies have continued to coordinate closely to advance the efforts of the joint working groups referenced in this report and to engage together in stakeholder outreach, such as joint conference presentations and meetings with firms. FDA remains committed to continuing this coordination to ensure that the regulatory framework for cell-cultured products is clear and transparent to stakeholders.

Recommendation 1

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat.

HHS Response

HHS concurs with the intent of Recommendation 1 to more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement. While open to incorporating the seven leading practices into the development of the structure for joint oversight over cell-cultured meat and poultry, we do not agree to revise the agreement at this time. The FDA-USDA formal agreement was developed with the intent of providing jurisdictional clarity at a high level and allowing the agencies to refine the implementation details as the working groups progressed in their thinking. The joint agreement is a general framework and incorporating the leading practices would constitute an inappropriate level of detail if added to the agreement. Furthermore, FDA believes it would be most valuable to ensure the leading principles are reflected in a more detailed joint framework or standard operating procedure for the interagency work group, as described in section 4(C) of the agreement.

Recommendation 3

As the three cell-cultured meat working groups move forward, the Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes.

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FOOD SAFETY: FDA AND USDA COULD STRENGTHEN EXISTING EFFORTS TO PREPARE FOR OVERSIGHT OF CELL-CULTURED MEAT (GAO-20-325)

HHS Response

HHS concurs with GAO's recommendation. FDA intends to more fully incorporate the seven leading practices into the processes and procedures for each of the three animal cell culture working groups.

Recommendation 5

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish.

HHS Response

HHS concurs with GAO's recommendation. USDA and FDA have already clarified publicly that FDA will retain its authority over cell-cultured seafood, other than Siluriformes fish, but agree to clarify this further in publicly available documents *other* than the joint agreement, including through upcoming webinars, web posting, technical articles, and stakeholder meetings.

Agency Comment Letter

Text of XXX

Page 1

March 6, 2020

Steve Morris
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat" (GAO-20-325).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah Arbes
Acting Assistant Secretary for Legislation

Attachment

Page 2

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED-FOOD SAFETY: FDA AND USDA COULD STRENGTHEN
EXISTING EFFORTS TO PREPARE FOR OVERSIGHT OF CELL-CULTURED
MEAT
(GAO-20-325)**

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(FSIS), takes seriously its mandate to ensure that food entering the market is safe for human consumption and properly labeled. The 2019 FDA-USDA formal agreement regarding oversight of human food produced using animal cell technology derived from cell lines of USDA-amenable species outlines a shared regulatory approach that will ensure these cell-cultured products are produced safely and are accurately labeled.

We value GAO's recognition of the importance of collaborative mechanisms that facilitate coordination between the FDA and USDA in the joint oversight of the production of human food products derived from the cells of livestock and poultry. Since the announcement of the formal agreement, the two agencies have continued to coordinate closely to advance the efforts of the joint working groups referenced in this report and to engage together in stakeholder outreach, such as joint conference presentations and meetings with firms. FDA remains committed to continuing this coordination to ensure that the regulatory framework for cell-cultured products is clear and transparent to stakeholders.

Recommendation 1

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat.

HHS Response

HHS concurs with the intent of Recommendation 1 to more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement. While open to incorporating the seven leading practices into the development of the structure for joint oversight over cell-cultured meat and poultry, we do not agree to revise the agreement at this time. The FDA-USDA formal agreement was developed with the intent of providing jurisdictional clarity at a high level and allowing the agencies to refine the implementation details as the working groups progressed in their thinking. The joint agreement is a general framework and incorporating the leading practices would constitute an inappropriate level of detail if added to the agreement. Furthermore, FDA believes it would be most valuable to ensure the leading principles are reflected in a more detailed joint framework or standard operating procedure for the interagency work group, as described in section 4(C) of the agreement.

Recommendation 3

As the three cell-cultured meat working groups move forward, the Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes.

Page 3

HHS Response

HHS concurs with GAO's recommendation. FDA intends to more fully incorporate the seven leading practices into the processes and procedures for each of the three animal cell culture working groups.

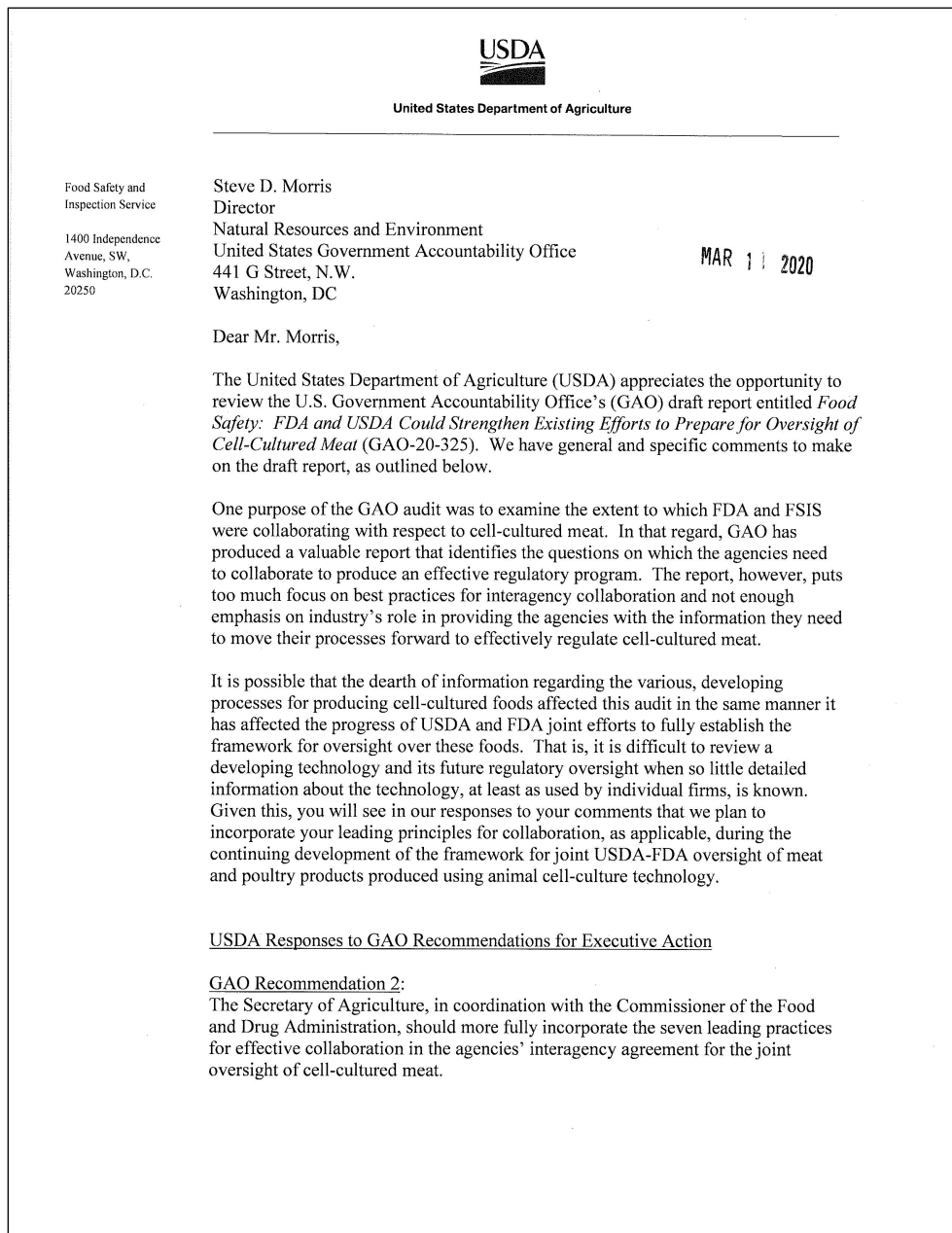
Recommendation 5

The Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish.

HHS Response

HHS concurs with GAO's recommendation. USDA and FDA have already clarified publicly that FDA will retain its authority over cell-cultured seafood, other than Siluriformes fish, but agree to clarify this further in publicly available documents other than the joint agreement, including through upcoming webinars, web posting, technical articles, and stakeholder meetings.

Appendix IV: Comments from the U.S. Department of Agriculture



**Appendix IV: Comments from the U.S.
Department of Agriculture**

Steve D. Morris
Page 2

USDA Response:

USDA partially agrees with this recommendation. Although FSIS and FDA are open to incorporating the seven leading practices into the development of the structure for joint oversight over cell-cultured meat and poultry, we do not agree to revise the joint agreement at this time. As stated in our meetings with you, the joint agreement is a general framework for sharing statutory jurisdiction over these products. The leading practices would constitute an inappropriate level of detail if added to the agreement. Note that under 4(C) of the agreement, USDA and FDA agree to “develop a more detailed joint framework or standard operating procedure to facilitate coordination of shared regulatory oversight related to the harvest of biological material.” In the documents and procedures developed as part of this “more detailed joint framework,” USDA and FDA would agree to incorporate the leading principles.

GAO Recommendation 4:

As the three cell-cultured meat working groups move forward, the Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes.

USDA Response:

USDA agrees with this recommendation. To the extent they are applicable, and appropriate, USDA intends to more fully incorporate the seven leading practices for effective interagency collaboration into the three cell-cultured meat working groups.

GAO Recommendation 6:

The Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish.

USDA Response:

USDA agrees with this recommendation. USDA and FDA have already clarified publicly that FDA will retain its authority over cell-cultured seafood, other than Siluriformes fish, but agree to clarify this further in publicly available documents *other* than the joint agreement.

Again, thank you for the opportunity to review and comment on this draft report. Technical comments were submitted under a separate cover.

Sincerely,



Dr. Mindy M. Brashears
Deputy Under Secretary for Food Safety

An Equal Opportunity Provider and Employer

Agency Comment Letter

Text of XXX

Page 1

Steve D. Morris, Director
Natural Resources and Environment
United States Government Accountability Office
441 G Street, N.W., Washington, DC

Dear Mr. Morris,

The United States Department of Agriculture (USDA) appreciates the opportunity to review the U.S. Government Accountability Office's (GAO) draft report entitled Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat (GAO-20-325). We have general and specific comments to make on the draft report, as outlined below.

One purpose of the GAO audit was to examine the extent to which FDA and FSIS were collaborating with respect to cell-cultured meat. In that regard, GAO has produced a valuable report that identifies the questions on which the agencies need to collaborate to produce an effective regulatory program. The report, however, puts too much focus on best practices for interagency collaboration and not enough emphasis on industry's role in providing the agencies with the information they need to move their processes forward to effectively regulate cell-cultured meat.

It is possible that the dearth of information regarding the various, developing processes for producing cell-cultured foods affected this audit in the same manner it has affected the progress of USDA and FDA joint efforts to fully establish the framework for oversight over these foods. That is, it is difficult to review a developing technology and its future regulatory oversight when so little detailed information about the technology, at least as used by individual firms, is known.

Given this, you will see in our responses to your comments that we plan to incorporate your leading principles for collaboration, as applicable, during the continuing development of the framework for joint USDA-FDA oversight of meat and poultry products produced using animal cell-culture technology.

USDA Responses to GAO Recommendations for Executive Action

GAO Recommendation 2:

The Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should more fully incorporate the seven leading practices for effective collaboration in the agencies' interagency agreement for the joint oversight of cell-cultured meat.

Page 2

USDA Response:

USDA partially agrees with this recommendation. Although FSIS and FDA are open to incorporating the seven leading practices into the development of the structure for joint oversight over cell-cultured meat and poultry, we do not agree to revise the joint agreement at this time. As stated in our meetings with you, the joint agreement is a general framework for sharing statutory jurisdiction over these products. The leading practices would constitute an inappropriate level of detail if added to the agreement. Note that under 4(C) of the agreement, USDA and FDA agree to "develop a more detailed joint framework or standard operating procedure to facilitate coordination of shared regulatory oversight related to the harvest of biological material." In the documents and procedures developed as part of this "more detailed joint framework," USDA and FDA would agree to incorporate the leading principles.

GAO Recommendation 4:

As the three cell-cultured meat working groups move forward, the Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes.

USDA Response:

USDA agrees with this recommendation. To the extent they are applicable, and appropriate, USDA intends to more fully incorporate the seven leading practices for effective interagency collaboration into the three cell-cultured meat working groups.

GAO Recommendation 6:

The Secretary of Agriculture, in coordination with the Commissioner of the Food and Drug Administration, should clearly document in their interagency agreement, or other publicly available document, which agency will oversee cell-cultured seafood other than catfish.

USDA Response:

USDA agrees with this recommendation. USDA and FDA have already clarified publicly that FDA will retain its authority over cell-cultured seafood, other than Siluriformes fish, but agree to clarify this further in publicly available documents other than the joint agreement.

Again, thank you for the opportunity to review and comment on this draft report. Technical comments were submitted under a separate cover.

Sincerely,

Dr. Mindy M. Brashears
Deputy Under Secretary for Food Safety

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Steve D. Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Nico Sloss (Assistant Director), Angela Miles (Analyst-in-Charge), Sahar Angadjivand, Tim Bober, Kevin Bray, Colleen Candrl, Pin En Annie Chou, Tara Congdon, Heather Dowey, Kim Gianopoulos, Gina Hoover, Hayden Huang, Robert Lepzler, Serena Lo, David Lysy, Marc Meyer, Michael Polak, Danny Royer, Sara Sullivan, and Sarah Veale made key contributions to this report.

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