

# Innovative Foods: A Guide to Responsible Investment in Cell-cultured Meat and Seafood



# Contents

<b>Executive summary</b>	<b>2</b>
<b>Introduction</b>	<b>3</b>
<b>Principle 1</b> Ensure cell-cultured meat and seafood products are safe for human consumption	<b>6</b>
<b>Principle 2</b> Continuously improve the overall environmental footprint of cell-cultured meat and seafood products as compared to the foods they are intended to replace	<b>8</b>
<b>Principle 3</b> Advocate programs that maximize the net societal benefits of cell-cultured meat and seafood products	<b>11</b>
<b>Principle 4</b> Enable consumers to make informed choices about cell-cultured meat and seafood products with accurate labeling and marketing	<b>13</b>
<b>Conclusion</b>	<b>15</b>
<b>More EDF insights on cell-cultured products</b>	<b>16</b>



# Executive summary

Global livestock production has an enormous environmental footprint, accounting for approximately [14.5%](#) of global greenhouse gas emissions. As populations increase and developing countries grow wealthier, demand for meat is projected to [grow even further](#). The challenge of providing nutritious food for growing populations under a changing climate requires bold and innovative solutions. Cell-cultured meat and seafood and plant-based products have been introduced as popular, lower-impact alternatives to conventional meat products. But it's critical that all solutions, including innovative foods that come to the market, are safe and provide net environmental benefits.

Companies and investors are enthusiastic about cell-cultured meat and seafood as potentially lucrative and climate-friendly

alternatives to conventional meat and seafood.<sup>1</sup> Because they have the greatest understanding and control of the products and the processes used to make these products, companies should demonstrate leadership by adopting the following four principles:

- 1 Ensure cell-cultured meat and seafood products are safe for human consumption;
- 2 Continuously improve the overall environmental footprint of cell-cultured meat and seafood products as compared to the foods they are intended to replace;
- 3 Advocate for programs that maximize the net societal benefits of cell-cultured meat and seafood products; and
- 4 Enable consumers to make informed choices about cell-cultured meat and seafood products with accurate labeling and marketing.



# Introduction

Improving sustainable food production is one of the most pressing challenges as the world population is expected to reach 10 billion people by 2050. The effects of climate change, the implications of food waste, and the environmental impacts associated with conventional food production and consumption patterns have many in search of new solutions.<sup>2</sup> Current food production accounts for [25% of global emissions](#), with animal agriculture representing the largest share of that footprint, therefore making this industry a particularly attractive innovation opportunity.<sup>3</sup>

Innovative foods — products incorporating unconventional ingredients or using pioneering food processing technologies to produce new products or significantly alter conventional ingredients — have promising potential to improve efficiency, cut emissions and reduce waste in the global food system.<sup>4</sup> Additionally, these products could potentially eliminate exposure to toxins such as mercury in seafood and pathogens that limit shelf life, increase food waste and threaten health. They also have the potential to reduce the pressure on fragile ocean ecosystems.

As more food companies set sustainability goals and consumer interest in meat alternatives grows, we're seeing the market respond. The largest meat producing companies in the world — [Tyson Foods](#), [Hormel](#), [Cargill](#), [Smithfield Foods](#) and [JBS](#) — have launched alternative-meat product lines, including plant-based options. Additionally, [tech investors and major meat producing companies](#) are supporting the development of cell-cultured meat and seafood products.



The cell-cultured meat or seafood production process involves culturing cells in tanks and forming them into consumable products, with or without other ingredients, using extrusion, 3-D printing or other processes. The resulting product is designed to be nutritionally identical to conventional meat or seafood. In 2017, the National Academy of Sciences concluded that “animal cell-culture-derived products such as cowless meat” were one of four product categories that had high growth potential.<sup>5</sup>

**Consumer and investor interest in alternative meat and seafood products are often driven by claims that these alternatives improve health and have lower environmental impacts.<sup>6</sup> But, the evidence for claims of health and environmental benefits is limited.<sup>7</sup>**

To date, the life cycle assessments (LCAs) for innovative foods are insufficient to assess claims of environmental benefits, since the underlying data for conducting LCAs are often not available for emerging technologies and products still in the development phase. Moreover, because innovative foods have the potential to disrupt complex food production systems that include billions of farmers, ranchers, fishers, food processors and others, there is risk of unanticipated ripple effects and adverse socioeconomic impacts that are not consistently considered.

The agencies that oversee food safety regulation responded to the increasing momentum around cell-cultured meat and seafood in March 2019 when the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) formally agreed to share regulatory oversight of cell-cultured meat and seafood products.<sup>8</sup> A year later, the U.S. Government Accountability Office (GAO), in response to a request to review the FDA/USDA efforts, released a report calling on the agencies to strengthen their efforts to prepare for oversight of cell-cultured meat and seafood.<sup>9</sup> And in October 2020, the FDA requested comments on the labeling of cell-cultured seafood products because they may soon enter the marketplace.<sup>10</sup>



## Nearly 1 in 4 Americans

report eating less meat in the past year than they had previously. Health, the environment and animal welfare are all cited as major reasons why.



## 66% of U.S. consumers

are willing to try cell-cultured meat according to one study.

## Creating a responsible path forward

If done well, the potential growth and beneficial impacts of cell-cultured meat and seafood is significant. Companies that develop these products and the agencies that oversee them need to ensure responsible growth of this promising industry. Companies, who have the greatest understanding and control of the products and the processes used to make them, should demonstrate leadership by adopting the following four principles:

- 1 Ensure cell-cultured meat and seafood products are safe for human consumption;
- 2 Continuously improve the overall environmental footprint of cell-cultured meat and seafood products as compared to the foods they are intended to replace;
- 3 Advocate for programs that maximize the net societal benefits of cell-cultured meat and seafood products; and
- 4 Enable consumers to make informed choices about cell-cultured meat and seafood products with accurate labeling and marketing.

By adhering to these principles, companies could potentially improve access to global markets, be prepared for government oversight and reduce the risk of consumer backlash because a product fails to meet marketing claims.



The global cultured meat market is estimated to be valued at

**\$214 million**

in 2025 and is projected to reach

**\$593 million**

by 2032.

# Principle ①

## Ensure cell-cultured meat and seafood products are safe for human consumption

Producing meat and seafood by culturing cells in tanks and forming them into a safe and nutritious product that looks and tastes like its conventionally produced counterpart would be a technological achievement. The technology would require tightly controlled conditions that are a significant departure from our current systems for wild-caught seafood and concentrated animal feeding operations.



To succeed in the marketplace, cell-cultured meat and seafood must first and foremost be safe while also meeting consumer expectations for taste, nutrition, convenience and cost. A misstep by a company regarding safety can jeopardize public health and undermine both the industry's credibility and the company's reputation.<sup>11</sup>

While we anticipate that companies will make safety a top priority, the potential for mistakes is too great and the conflicts of interest too strong for them to unilaterally make decisions without independent oversight. Therefore, it is essential that companies ensure that:

- A government agency with expertise and authority to regulate the product conduct a thorough review and affirm that the manufacturing process is indeed safe; and
- The agency conducting the review makes its decision public by a credible means that is sufficiently transparent to allow public and scientific scrutiny.

While there is need to protect the trade secrets essential to realizing the technological achievement, it must be balanced with the need for transparency and oversight.

In the United States, the FDA has the expertise and the responsibility under the law to ensure that the ingredients and the manufacturing processes used to make food are safe.<sup>12,13</sup>

This responsibility includes assessing the effects of significant manufacturing process changes, including emerging technologies like those cell-cultured meat and seafood developers will employ.<sup>14</sup>

### The FDA provides two primary routes for a company to seek review:

- 1. Food additive petition:**<sup>15</sup> EDF recommends that companies use this route since it provides protection for trade secrets while offering a meaningful opportunity for public and third-party scientific scrutiny as well as accountability. According to the law, the agency must make a final decision on a petition within 180 days of filing. However, the agency's track record in meeting this deadline is poor and has a performance goal of making a final decision in one year. The agency can and must do better to meet its deadlines.
- 2. GRAS notification:**<sup>16</sup> The other route companies could consider is self-certifying that the use of a substance in food is "generally recognized as safe" (GRAS) and then submit a voluntary notification to the FDA. EDF has challenged the FDA's GRAS rule in court as contrary to the law and is awaiting a court decision as of August 2021.<sup>17</sup>

Regardless of the court decision, just because a company may self-certify a substance's use as safe does not mean it should. Use of the GRAS loophole without notifying the FDA by any company risks undermining consumer trust in the food and, therefore, the prospect for the industry's overall success. If a company files a voluntary notice, it may find the process difficult because trade secrets are strictly limited in order to support a claim that safety is generally recognized.

Alternately, the FDA has discussed expanding its biotech consultation process designed for genetically-modified organisms, such as new plant varieties or proteins, to include a review of cell-cultured meat and seafood products.<sup>18</sup> This process is similar to the informal review of GRAS notifications but without the transparency. EDF does not recommend this approach because it lacks transparency, public and third-party scientific scrutiny, and accountability. We maintain that its use is likely to undermine the credibility of the company's and, perhaps, the industry's products.<sup>19</sup>



## Principle ②

# Continuously improve the overall environmental footprint of cell-cultured meat and seafood products as compared to the foods they are intended to replace



Conventionally produced meat and certain types of seafood have a substantial environmental footprint.<sup>20</sup> For example, ruminant livestock production drives tropical deforestation, requires large amounts of fresh water, and produces over one-quarter of anthropogenic methane emissions. Wild fisheries and aquaculture production can cause overfishing, nutrient pollution, habitat destruction, food web impacts and biodiversity impacts via bycatch of non-target species. Because of widespread environmental pollution, seafood can also become contaminated with mercury, microplastics and other substances.

**While some companies and marketers claim that their cell-cultured meat and seafood substitutes will reduce these harmful ramifications and have positive environmental benefits, the environmental impacts and trade-offs associated with the entry of these substitutes into the marketplace are far from clear.<sup>21</sup>**

Studies comparing hypothetical models of cell-cultured beef production to conventional operations suggest potential climate benefits, but credible LCAs that address the potential scale of the market will be necessary to comprehensively evaluate this claim.<sup>22</sup> In contrast, the benefits from cell-cultured alternatives for conventional poultry and pork may be no better.

A March 2021 report by the Good Food Institute highlights the potential of cell-cultured meat and seafood as compared to conventional products, including the ability of companies to reduce the overall environmental footprint.<sup>23</sup> The modeling of a future, large-scale facility showed how by 2030, cultivated meat and seafood “could reduce overall environmental impacts, [have] a lower carbon footprint, and be cost-competitive with some forms of conventional meat.” The report found that this was true for some forms of meat, especially beef, whether cultivated meat is produced using conventional energy mixes or renewable energy, but the

reduction in environmental impacts and carbon footprint is greatest when cultivated meat is produced using renewable energy. In addition, the footprint depends on the productivity of the cell-culture.<sup>24</sup>

Given that the majority of these products are still in the developmental stage, primarily in pilot scale settings as opposed to commercial production facilities, and that most processes are considered intellectual property and not disclosed, any current analyses may be largely anticipatory at this point. The implications on energy, water, waste streams and antibiotic use from the manufacture of these products at scale are among the impacts insufficiently quantified and assessed. As manufacturing technology is likely to evolve rapidly leading up to, and after, commercialization, LCAs should be revisited and refined periodically with appropriate acknowledgement of uncertainties and data gaps.

Whether cell-cultured meat and seafood will replace conventionally produced meat and seafood at all, or to what extent replacement might take place, is unclear. However, where the environmental claims rest on the assumption that consumption of these products will reduce the demand for conventionally produced products, thereby reducing the intensity of production processes — for example, in animal husbandry, fishing and aquaculture — the impacts on the billions of people who engage in these activities should also be expected at scale. In some cases, displacement of people and livelihoods could result in negative environmental impacts.

Cell-cultured products may indeed improve environmental outcomes, but leadership means considering the full ramifications of implementation.



## Cell-cultured products may indeed improve environmental outcomes,

but leadership means considering the full ramifications of implementation.

To improve planetary health, companies engaged in cell-cultured meat and seafood development should work with governmental agencies, academics, and non-governmental organizations (NGOs) to:

- **Use LCAs and systems analyses to identify opportunities and priorities for improving environmental outcomes.** Independent, third-party LCAs are the only valid way to verify environmental sustainability claims pertaining to the production processes. LCAs should include impacts to the climate, air quality, water use and quality, material use, waste and biodiversity, and the results should be compared to LCAs for conventional meat/seafood production of the relevant species. Systems analyses can reveal previously unanticipated ripple effects of disruptive technologies such as cell-cultured seafood and meat.
- **Pursue processes and practices that improve environmental sustainability.** Use the results of LCAs and systems analyses to find ways to reduce the full range of potential environmental and social impacts from commercial cell-cultured meat and seafood production. Marketing claims of advantages of cell-cultured products over conventional products should be well substantiated with publicly available data ([see Principle 4](#)).
- **Create accountability processes to ensure sustainability.** Analyses conducted in this early stage of industry development will contain many uncertainties. Hence, regular reviews as more data become available will be necessary. Moreover, because even the best plan cannot result in sustainability if it is not implemented well, governments and companies should articulate environmental performance standards, and governments should implement measures to independently



monitor actual performance relative to standards and to hold companies accountable for poor performance and making false environmental claims.

- **Choose the seafood species to be made as new cell-cultured products carefully to maximize environmental benefits while minimizing negative social and economic impacts.** Species choice will obviously depend strongly on consumer demand, but it can also have strong differential effects on the environment and on communities. For example, producing a cell-cultured version of the iconic giant fish maw may have little beneficial impact on fisheries, while producing cell-cultured shrimp could reduce the intensity of harmful shrimp farming and harvesting practices ([see Principle 3](#)).

## Principle ③

# Advocate programs that maximize the net societal benefits of cell-cultured meat and seafood products



Large-scale market disruptions from cell-cultured products may have disproportionate economic and food security impacts on vulnerable, small-scale producers of conventional meat and seafood.

About a quarter of the world's ice-free land is used for grazing and nearly a third of agricultural land is used for livestock feed production. This translates into more than 1.7 billion people whose livelihoods are supported by the livestock sector globally.<sup>25</sup>

In developing countries, 60% of rural households are supported by livestock. Similarly, there are about 40 million people directly engaged in fishing and 20 million engaged in aquaculture, with tens of millions more indirectly involved through support services, fish processing and seafood distribution.<sup>26</sup> About 90% of fishers live and work in developing countries, most of them highly dependent on fishing with few livelihood alternatives.

**To ensure resilient rural communities and economies, companies engaged in cell-cultured meat and seafood development should work with governmental agencies, academics and NGOs to:**

- **Identify potential social disruptions, incorporate them into any assessment of benefits and undertake measures to mitigate negative impacts.** The shifting production systems may create social disruptions and impact animal and crop agriculture, fishing and aquaculture sectors and communities. These disruptions need to be understood and measures taken to mitigate negative impacts and ensure just transitions. The measures need to encompass the full range of potential impacts from commercial cell-cultured meat and seafood production, especially economic challenges for fishing and farming communities.
- **Support government, academics and NGOs to use systems analysis or similar approaches to consider the impacts of disrupting the food system.** Even qualitative consideration of how cell-cultured products may affect complex food production systems can yield valuable insights. Such insights can prevent unanticipated negative impacts by revealing second- or third-order effects on people who are not directly related to the production of cell-cultured products but who would interact with or be affected by these products in a variety of ways, such as consumers, ranchers, farmers, fishers and aquaculturists.
- **Choose the seafood species to be made as new cell-cultured products carefully to maximize environmental benefits while minimizing negative social and economic impacts.** Species choice will obviously depend strongly on consumer demand, but it can also have strong

differential effects on the environment and on communities. ([see Principle 2](#)). For example, some fisheries employ thousands of relatively marginalized people with few economic alternatives while others employ far fewer people who have other options and/or a social safety net.



## Principle ④

# Enable consumers to make informed choices about cell-cultured meat and seafood products with accurate labeling and marketing



Transparency is the linchpin to building consumer trust in a new product, particularly when the product is an innovative food. Mislabeling or overstating the sustainability or nutritional value of a product can undermine the credibility of the entire marketplace. The ability of consumers to choose among food options is only as good as the information made readily available to them.

**In the United States, the USDA must approve the labelling of meat and catfish. The FDA has authority to ensure that labels are not misleading for seafood other than catfish. Companies should ensure that:**

- **“Cell-cultured” is used to describe the products in labelling and marketing.** Companies must ensure that labeling does not mislead consumers into thinking the product is conventional meat or seafood. The label should also be neutral and not pejorative. The description should be verified as consistent with consumer expectations through an independent scientific review that is peer-reviewed and publicly available. To avoid market confusion, companies should use the term “cell-cultured” which is widely supported in studies by Hallman and Hallman II in 2020 and 2021 and by responses to a request for information by the FDA from the Alliance for Meat, Poultry and Seafood Innovation and the National Fisheries Institute.<sup>27, 28, 29, 30</sup>
- **Label identifies nutritional and food safety handling differences.** Because cell-cultured meat and seafood are manufactured not grown, there may be differences in their nutritional value from conventional foods. They may also be less likely to have pathogens, thereby providing consumers with more flexibility in how the products are handled and cooked. Companies should label products to make consumers aware of these differences. Where cell-cultured and conventional meat and seafood are blended, companies should identify the percentage of each.<sup>31</sup>
- **All health claims have been reviewed by the appropriate government agency.** Companies should ensure that all health claims on the food label or in online or other marketing materials have been reviewed by a



government agency with expertise in the issue ([see Principle 1](#)). In the United States, the FDA needs to conduct the review pursuant to its 2009 Evidence-based Review System for Scientific Evaluation of Health Claims.<sup>32</sup> If the “significant scientific agreement” standard required for an authorized health claim is not met, companies must secure a “letter of enforcement discretion” for “qualified health claims.”

- **Any environmental, sustainability, climate-resilience or health and safety claims are supported by scientific evidence.** Companies should ensure that any claims are supported by a rigorous, independent analysis that is publicly available and consistent with the peer-reviewed scientific evidence ([see Principle 2](#)) and the Federal Trade Commission’s Green Guides.<sup>33</sup>
- **Consumers must be able to access the information easily.** Information supporting product claims should be readily accessible via the product’s website, marketing materials, the product label and online label aggregator platforms such as SmartLabel.<sup>34</sup>

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## Conclusion

Opportunities exist for forward-thinking companies to play a critical role in solving the urgent challenge of sustainably feeding a growing population. By adopting these principles, industry can lead us forward on a path in which cell-cultured meat and seafood products benefit our environment and human health.<sup>35</sup>





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## More EDF insights on cell-cultured products

For over 50 years, EDF has been committed to preserving the natural systems on which all life depends – protecting human health and the planet. We have traditionally worked to improve the environmental sustainability of agriculture and fisheries. Over the past two years, we have studied innovative foods, especially cell-cultured meats and seafoods. Beginning in 2019, we have highlighted the issues surrounding innovative foods including cell-cultured seafood in five blogs:

- [The promise and peril of manufactured seafood](#) August 2019;<sup>36</sup>
- [Without a food safety overhaul for additives, the innovative food craze could spiral out of control](#) October 2019;<sup>37</sup>
- [Cell-based, cultured... or something else? The new seafood labeling challenge](#) September 2020;<sup>38</sup>
- [FDA's short-sighted approach to building trust in the safety of cell-cultured meat and seafood products](#) June 2021;<sup>39</sup> and
- [Cell-cultured it is!](#) June 2021.<sup>40</sup>

## Endnotes

- 1 In this document, we use the term “cell-cultured” based on the research by [Hallman and Hallman II in 2020 and 2021](#), which indicated that “cell-based” was the most appropriate term for seafood closely followed by “cell-cultured.” We opted for “cell-cultured” because the Alliance for Meat, Poultry and Seafood Innovation and the National Fisheries Institute reached a consensus decision in comments to the Food and Drug Administration that they preferred that term. <https://www.regulations.gov/comment/FDA-2020-N-1720-0022>
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- 12 The Federal Food, Drug, and Cosmetic Act of 1938 (Public Law 75-717, 52 Stat. 1040) as amended.
- 13 Note that USDA also has jurisdiction for the safety of meat and catfish (but not other seafood).
- 14 FDA, Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives, June 2014. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging>.
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