



December 2, 2021

Submitted Electronically via regulations.gov

U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW, Mailstop 3758 Washington, DC 20250-3700

Re: Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells - Advance Notice of Proposed Rulemaking, Food Safety and Inspection Service, U.S. Department of Agriculture; Docket No. FSIS-2020-0036, RIN 0583-AD89

Dear USDA-FSIS Officials,

BlueNalu values the opportunity to supply comments on the Advance Notice of Proposed Rulemaking (ANPR) regarding Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, Docket NO. FSIS-2020-0036 and to provide scientific data to support our response. We commend both FSIS and FDA for the agencies' proactive and collaborative approach to regulating cell-cultured products and applaud your commitment to developing joint principles to ensure products regulated by both FDA and FSIS are labeled consistently and transparently.

BlueNalu is the leader in developing cell-cultured seafood products. Like both FSIS and FDA, BlueNalu recognizes the importance for consumers to have an accurate and consistent approach for naming products produced using animal cell-culture methods. In March of this year, BlueNalu responded to FDA's Request for Information (RFI) with our comments on the labeling of seafood products under FDA's jurisdiction made using animal cell culture technology (*Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information; 85 FR 63277*). We encourage FSIS to review our comments to FDA's RFI, which we have attached to these comments, as FSIS and FDA have identified many of the same issues for consideration.

Although BlueNalu currently intends to develop only cell-cultured seafood products, which will fall under FDA's jurisdiction, we believe we have an important perspective to share with FSIS given our deep involvement in this emerging category. Fundamentally, we believe that all stakeholders benefit from ensuring a common framework, methodology, and decision-making process across FSIS and FDA so that meat, poultry, *and* seafood products are labeled appropriately. This coordinated effort will ensure that consumers understand the nature of the products in the marketplace and that businesses can compete on an even playing field.

As a science-based, data-driven company, BlueNalu also believes that good regulatory policy should be grounded in data, and we encourage FSIS to consider the available scientific research and to conduct research if needed to close any gaps.

We also recognize that an objective of our US regulatory agencies is to minimize confusion and potential misrepresentation or mischaracterization of cell-cultured products with conventional meat, poultry, and seafood products, while still ensuring that consumers know that this product will contain allergens (if applicable).

In our response to FDA's RFI, BlueNalu explained how we addressed these challenges. BlueNalu sponsored one of the nation's leading experts on food safety communications, William Hallman, Ph.D., to conduct independent empirical research to identify the most appropriate name for cell-cultured seafood products. Dr. Hallman's research study identified five criteria to ensure that a common or usual name communicates needed information to consumers, is least likely to create potential confusion, and complies with FDA regulations. We believe a modified set of principles like those established in Dr. Hallman's cell-cultured seafood research would also apply to cell-cultured meat and poultry products to help generate empirical data to identify the best name for these products. Consistent with the methodology Dr. Hallman developed for seafood products derived from fish cells, these principles for comparable meat and poultry products would include:

1. Enable consumers to distinguish cell-cultured meat and poultry from conventional products.
2. Signal that those with allergies or sensitivities to conventional meat or poultry products, if applicable, should not consume cell-cultured meat or poultry products.
3. Be seen by consumers as an appropriate term to identify the product.
4. Does not disparage cell-cultured meat or poultry products or conventional products that consumers may compare.
5. Does not evoke thoughts, images, or emotions inherently inconsistent with the idea that cell-cultured meat and poultry products are safe, healthy, and nutritious.

Adopting a similar set of guiding principles across both FSIS and FDA will help drive a consistent approach to naming cell-cultured products across all categories.

BlueNalu believes it is essential that cell-cultured products bear a common or usual name uniformly. We encourage FSIS to work with the FDA to ensure terms used for cell-cultured meat and poultry products and cell-cultured seafood products are appropriately uniform. BlueNalu recognizes that a single term used across seafood, meat, and poultry product categories will reinforce and strengthen consumer understanding. As these products commercialize and reach the market in the United States, it is essential they are labeled clearly and uniformly within the seafood category and consistently across the broader protein categories to protect consumer expectations and build consumer familiarity with these products.

BlueNalu urges FSIS to apply a scientifically rigorous approach to evaluating potential approaches to product naming, consistent with that employed in the research that Dr. Hallman has published. Importantly, empirical research reveals essential information about how consumers truly understand product names. For example, we learned through Dr. Hallman's research that some commonly proposed names for these product categories may also create the greatest amount of confusion with

consumers (e.g., the names "cultivated" or "cultured" had a great deal of *appeal* to consumers of seafood products derived from fish cells, but they were also the terms that created the greatest amount of potential *confusion* and were frequently associated with their conventional and aqua cultured seafood counterparts).

As a result of Dr. Hallman's research, BlueNalu believes that "cell-cultured" is the most appropriate term for seafood products derived from fish cells, and this term was also supported by the National Fisheries Institute and the Alliance for Meat Poultry and Seafood Innovation in a joint letter signed by both organizations in response to the FDA's RFI (See Appendix E). Unfortunately, there is no similar rigorous peer-reviewed research study following Dr. Hallman's validated methodology that has been conducted to date to determine the most appropriate name for meat and poultry products derived from animal cells. In the absence of such studies, BlueNalu feels the term cell-cultured would carry over and be appropriate for these products and provide consistency across categories. ***Therefore, we encourage FSIS to strongly consider the term "cell-cultured" for the products it regulates as well.***

BlueNalu respectfully submits our response to the questions posed by FSIS in the ANPR in Appendix A and appreciates your consideration. We have also attached copies of our response to FDA's RFI related to cell-cultured seafood (Appendix B) and copies of Dr. Hallman's leading nomenclature research for your reference (Appendices C and D). We look forward to continued collaboration with USDA and FDA to foster effective and efficient regulation of this innovative technology.

Sincerely,



Lou Cooperhouse
President and CEO
BlueNalu



Noreen Hobayan
Director of Quality Assurance and Regulatory Affairs
BlueNalu

Enclosures:

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APPENDIX A

Issues for Comment

APPENDIX A

II. Issues for Comment

FSIS invites comments on the issues discussed in this ANPR to help inform future rulemaking on the labeling of products made using animal cell-culture technology. Specifically, FSIS seeks responses to the questions listed below. Please explain the reasoning behind your responses in detail. Also, provide any data, studies, or other evidence that supports your response. To help FSIS review comments efficiently, please identify the question to which you are responding by its associated number and letter (e.g., "2a") or whether you are commenting on a topic not listed below.

1. Should the product name of a meat or poultry product comprised of or containing cultured animal cells differentiate the product from slaughtered meat or poultry by informing consumers the product was made using animal cell culture technology? If yes, what criteria should the agency consider or use to differentiate the products? If no, why not?

Yes, we believe that meat and poultry products produced using cell culture technology should be labeled in a truthful, non-misleading, descriptive, and clear way to inform consumers of what the products are and how they were produced. Consumers increasingly expect to be provided information about the nature of their food, including whether it was produced using novel methods.

In the ANPR, FSIS explains that if a new method of production or processing alters the biological, chemical, nutritional, or organoleptic properties of meat or poultry such that the resulting product no longer aligns with consumers' expectations, then the agency must establish new label requirements to meet consumers' expectations. Therefore, it is critical that these products are differentiated from and are clearly identifiable compared to their conventional counterparts. We believe the best way to do this is through an accurate, descriptive, and consistent qualifying term.

Our recommendation is consistent with FSIS rules that require products to be named to define them accurately. Processors can accomplish this by using the name established in a standard of identity or, if none exist, the common or usual name. Several companies are developing cell-cultured meat and poultry products throughout the U.S., but none are currently on the market. Therefore, no standards of identity exist, nor does an established common or usual name.

BlueNalu sponsored one of the nation's leading experts on food safety communications, Dr. William Hallman, to conduct independent empirical research to identify the most appropriate name for cell-cultured seafood products. In Dr. Hallman's study, he identified five criteria to ensure that a common or usual name communicates needed information to consumers, is least likely to create any potential confusion, and complies with FDA regulations¹ (FDA's product naming regulations are consistent with FSIS's). We believe a modified set of principles like those established in this research would apply to cell-cultured meat and poultry products and can be used to help generate empirical data to identify the best name for cell-cultured meat and poultry products. Consistent with the methodology Dr. Hallman developed for seafood products derived from fish cells, these principles for comparable meat and poultry products would include:

1. Enable consumers to distinguish cell-cultured meat and poultry from conventional products.

¹ Hallman, W.K. and Hallman, W.K., II (2020). An empirical assessment of common or usual names to label cell-based seafood products. *Journal of Food Science*, 85, 2267- 2277. <https://doi.org/10.1111/1750-3841.15351>.

2. Signal that those with allergies, sensitivities or personal or religious objections to conventional meat or poultry products should not consume cell-cultured meat or poultry products.
 3. Be seen by consumers as an appropriate term to identify the product.
 4. Not be disparaging to cell-cultured meat or poultry products or conventional products that consumers may compare.
 5. Not evoke thoughts, images, or emotions inherently inconsistent with the idea that cell-cultured meat and poultry products are safe, healthy, and nutritious.
2. **What term(s), if any, should be in the product name of a food comprised of or containing cultured animal cells to convey the nature or source of the food to consumers? (e.g., "cell cultured" or "cell cultivated.")**

We believe the term "cell-cultured" should be used in the product name of food comprised of or containing cultured animal cells to convey the nature and source of the food to consumers. This term is science-based and accurate and has been shown in robust and rigorous studies by Dr. Hallman described in the section above to be appropriately descriptive for such products and to enable consumers to differentiate these products from their conventional counterparts without being disparaging. These results are consistent with those of smaller consumer studies performed by the Good Food Institute in 2018 and 2019, where the term "cell-cultured" scored highest in descriptiveness and differentiation from other types of meat."²

a. How do these terms inform consumers of the nature or source of the product?

The term "cell" indicates the source material, and the term "culture" refers to the production process. Taken together, the qualifying language of "cell-cultured" would inform consumers of the nature and source of the food. When used together, these terms also have the benefit of being clear and concise, conveying the most essential information in only a small amount of space.

b. What are the benefits or costs to industry and consumers associated with these terms?

Industry would benefit from using the term cell-cultured to distinguish their products because it fosters transparency and consumer confidence. At the same time, the neutral and non-disparaging term promotes a level playing field across FSIS-regulated products, both conventional and cell-cultured alike. There would be some costs to cell-cultured meat and seafood companies who have already adopted alternate terms for describing their products, but because no product is on the market today and there is no associated packaging or labeling to change, those costs would be minimal and be far outweighed by the benefit to the consumer.

Consumers would benefit from products that are labeled consistently and transparently. The term "cell-cultured" is descriptive and represents what the products are and indicates how they

² Szejda, K., Allen, M., Cull, A., Banisch, A., Stuckey, B., & Dillard, C., & Urbanovich, T. (2019). Meat cultivation: Embracing the science of nature. Project Report. Washington, DC: The Good Food Institute (pg.16) Available at <http://go.gfi.org/meat-cultivation-project>

are made, thus ensuring robust consumer transparency. Consistently applying such a term will minimize consumer confusion, maximize understanding, and facilitate informed purchasing decisions. These benefits would be further enhanced by FSIS and FDA taking consistent positions.

- c. **If meat or poultry products comprised of or containing cultured animal cells were to be labeled with the term "culture" or "cultured" in their product names or standards of identity (e.g., "cell culture[d]"), would labeling differentiation be necessary to distinguish these products from other types of foods where the term "culture" or "cultured" is used (such as "cultured celery powder")?**

BlueNalu feels strongly that the term "cultured" by itself is not appropriate, as potential consumer confusion may result based upon the research conducted by Dr. Hallman. Therefore, the term "cell" must also be included with "cultured," **resulting in the most appropriate term "cell-cultured."** This would be sufficient and appropriate to differentiate cell-cultured meat and poultry from other cultured foods.

3. **If a meat or poultry product were comprised of both slaughtered meat or poultry and cultured animal cells, what unique labeling requirements, if any, should be required for such products?**

To promote transparency and enable consumer choice, the label of meat or poultry products comprised of both slaughtered meat or poultry as well as cultured animal cells should indicate the presence of both on the front of the label and in the ingredients statement. For example, "Italian Style Meatballs, Made with Beef and Cell-Cultured Beef" on the front of the package and "Beef, Cell-cultured beef, ..." would also appear in the ingredients statement in order of predominance per existing labeling regulations.

4. **What term(s), if used in the product name of a food comprised of or containing cultured animal cells, would be potentially false or misleading to consumers? For each term, please provide your reasoning.**

Terms that are disparaging to either cell-cultured or conventional products would likely be false or misleading by conveying an incorrect impression that a given product is less safe or inherently inferior. For example:

- "Lab-grown meat": Food innovation starts in a laboratory, but large-scale production occurs in a sanitary food processing facility. This fact makes any term including "lab" in it misleading. In addition, laboratories house chemical and biological hazards which are not conducive to safe food production. Using the term "lab" is also disparaging because it implies the food was prepared under unsafe conditions creating distrust and consumer aversion to purchasing.
- "Synthetic meat": This term is false and misleading. Synthetic products are made from chemicals and often describe something artificial in nature. Cell-cultured meat production is a biological process, not a chemical synthesis, and the products are composed of actual animal cells just as meat is and are not imitations.

See also the examples provided in response to Question 5.

5. **What term(s), if used in the product name of a food comprised of or containing cultured animal cells, would potentially have a negative impact on industry or consumers? For each term, please provide your reasoning.**

As with our response to Question 4, terms that disparage a product or category are inappropriate and would have a negative impact on industry or consumers by conveying false or misleading impressions. In addition to the examples provided in response to Question 4, terms such as the following would likely be misleading and have a negative impact:

- "Artificial meat" or "meat alternative" These terms would be potentially harmful to consumers. The products will be comprised of *actual* animal cells, which are the same basic building blocks found in conventional meat and poultry. A consumer who is allergic, has sensitivities, or objects to consuming animal products for personal or religious reasons must understand the real animal cell nature of the products to avoid an allergic reaction, illness, or violation of religious belief or personal choices.
- "Clean meat": This term is disparaging to conventional meat because it implies traditional products are not clean.
- "Slaughter-free meat" or "Cruelty-free meat" These terms disparage conventional meat for obvious reasons.

6. **Should names for slaughtered meat and poultry products established by common usage (e.g., Pork Loin), statute, or regulation be included in the names or standards of identity of such products derived from cultured animal cells?**

Due to the complexity of existing meat and poultry products and the detailed standards and regulations, the answer may need to be determined on a case-by-case basis. In general, if the cell-cultured meat or poultry product composition and the definition is equivalent to the slaughtered version described in common usage, statute, or regulation, then it would be appropriate to describe the cell-cultured product in the same manner, provided the qualifying term, cell-cultured, is added. For example, "cell-cultured meatball" or "meatball, made with cell-cultured beef and cell-cultured pork" may be appropriate, but because only cells are grown in culture, a term like "cell-cultured duckling" implies the whole animal of a certain age or size and would not be appropriate.

- a. **If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate?**

The term "cell-cultured" is appropriate and should be used on the front label and in the ingredients statement for any meat or poultry product containing portions derived from animal cell culture.

- b. **Do these names, with or without qualifying language, clearly distinguish foods comprised of or containing cultured animal cells from slaughtered products?**

Adding qualifying language "cell-cultured" to the name would be required to clearly distinguish foods comprised of or containing cultured animal cells from slaughtered products.

7. **Should terms that specify the form of meat or poultry products (such as "fillet", "patty", or "steak") be allowed to be included in or to accompany the name or standard of identity of foods comprised of or containing cultured animal cells?**

Yes. Terms such as "patty" or "steak" have established meaning to consumers and help identify the different forms in which meat or poultry is presented. Consumers have an established understanding of how various cuts of meat and poultry look and function when cooking. Cell-cultured meat or poultry offered in a form comparable to an existing cut such as a patty or steak should be identified accordingly to facilitate consumer selection.

- a. **Under what circumstances should these terms be used?**

When a cell-cultured product is processed in the same form as an established cut, such as a patty, and the product looks and functions accordingly, it is appropriate to use the same term (e.g., "patty") to communicate that to the consumer.

- b. **What information would these terms convey to consumers?**

Consumer understanding of these terms is rooted in the shape of the piece of meat (e.g., thickness and shape) and corresponding cooking attributes. Consumers expect a patty, for example, to be round, free of bones, and ready to cook. Consumers often seek out a specific cut based on the cooking application. These terms provide consumers with the information they need to make a purchasing decision.

8. **Should FSIS establish a regulatory standard of identity under its authorities in the FMIA and the PPIA (21 U.S.C. 607(c) and 457(b)) for foods comprised of or containing cultured animal cells?**

No, cell-cultured meat or poultry products are still in development, and their final composition is currently unknown. Creating an accurate standard of identity would be problematic and potentially stifle the innovation required to bring these products to market. Therefore, FSIS should not seek to establish a standard of identity for foods comprised of or containing cultured animal cells at this time, but consider doing so in the future if necessary and appropriate.

- a. **If so, what would be the standard and how might compliance with the standard be verified?** N/A

- b. **If so, what would be the labeling terminology for products that do and do not meet a formal standard of identity? What would be the anticipated categories of use? For example, mechanically separated poultry that does not meet the standards of identity outlined in 9 CFR 381.173 may be diverted for production in broths and bases, as well as reaction flavors, i.e., flavors produced by the heating of the protein source in the presence of a reducing sugar.** N/A

- c. **If so, what are the benefits and costs to industry if the standard of identity is established? Please provide quantitative and qualitative feedback in your response and explain the basis of any quantitative estimates.** N/A
- d. **If so, what are the consumer benefits and costs to the standard of identity recommended?** N/A

9. What nutritional, organoleptic (e.g., appearance, odor, taste), biological, chemical, or other characteristics, material to consumers' purchasing and consumption decisions, vary between slaughtered meat or poultry products and those comprised of or containing cultured animal cells?

We anticipate that meat and poultry products composed of or containing cultured animal cells will be substantially equivalent to conventionally produced counterparts in terms of form, taste, texture, organoleptic properties, and nutritional and culinary attributes. It may be possible to produce cell-cultured products with improved nutritional profiles, fewer contaminants, longer shelf-life, or enhanced organoleptic properties compared with conventional products.

10. Should any of the definitions for "meat", "meat byproduct", or "meat food product" found in 9 CFR 301.2 be amended to specifically include or exclude foods comprised of or containing cultured animal cells?

No, cultured animal cells are muscle cells and therefore meet the definition of meat and meat food product found in 9 CFR 301.2. Because the cultured animal cells are only those found in meat, they are excluded from the definition of meat byproduct.

11. Should any of the definitions for "poultry product" or "poultry food product" found in 9 CFR 381.1 be amended to specifically include or exclude foods comprised of or containing cultured animal cells?

No, cell-cultured poultry products meet the current statutory definitions for poultry product and poultry food product. In accordance with the statute, a poultry product must be derived from a domesticated bird such as a chicken, turkey, duck, or goose, be wholly or in part from that bird, and be non-living at the point of consumption. Cell-cultured poultry is produced directly from cells that are isolated from domesticated birds, the cells are part of the bird, and they are non-viable prior to consumption.

12. Should FSIS-regulated broths, bases, and reaction flavors produced from cultured animal cells be required to declare the source material in the product name, ingredient sub-listing, or elsewhere on the label?

Yes, FSIS regulated broths, bases, and reaction flavors produced from cultured animal cells should be required to declare the source material in both the product name and in the ingredient sub-listing.

13. Should the presence of cultured animal cells in further processed products regulated by FSIS, such as a lasagna made with cell cultured beef cells as an ingredient, be qualified on the product label? If so, how should this be qualified?

Yes, the presence of cultured animal cells in further processed products regulated by FSIS, such as a lasagna made with cell-cultured beef cells as an ingredient, should be qualified on the product label in the product name and in the ingredient sub-listing and should meet the minimum required meat requirements as conventional products. For example, the FSIS Food Standards and Labeling Policy Book provides guidance on labeling for lasagna products made from conventional meat sources as follows:

- Lasagna with Meat Sauce: contains at least 6 percent meat in total product
- Meat Lasagna: contains at least 12 percent meat
- Poultry Lasagna: contains at least 8 percent poultry meat

When such products are prepared with *cell-cultured* meat or poultry, these products can be described as the following:

- Lasagna with Cell-Cultured Meat Sauce: contains at least 6 percent cell-cultured meat in total product
- Cell-Cultured Meat Lasagna: contains at least 12 percent cell-cultured meat
- Cell-Cultured Poultry Lasagna: contains at least 8 percent cell-cultured poultry meat

Alternatively, we believe USDA could also permit a qualifier after the product name identifying the cell-cultured content, such as Meat Lasagna, made with Cell-Cultured Beef.

14. What label claims are likely to appear on FSIS-regulated products comprised of or containing cultured animal cells? Should FSIS develop new regulations or guidance on such claims to ensure they are neither false nor misleading?

Because the products are not on the market, actual claims are not known, but many can be anticipated based on the production process and final product characteristics. Existing regulations and guidelines that require label review and approval are sufficient to ensure label claims are substantiated with data, truthful, not misleading, and not disparaging to conventional products. We encourage USDA to monitor claims and develop guidance as appropriate.

APPENDIX B

BlueNalu RFI Response (letter only)
Dated March 8, 2021



March 8, 2021

Submitted Electronically via regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information; Docket No. FDA-2020-N-1720

Dear FDA Officials:

BlueNalu appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA's) Request for Information on the Labeling of Foods Comprised of or Containing Cultured Seafood Cells (the RFI).¹ BlueNalu is the leader in developing cell-cultured seafood products, which we intend to bring to market. BlueNalu applauds FDA's leadership in beginning the discussion around the appropriate name for these products.

BlueNalu recognizes the importance for consumers—and industry—to have an accurate and consistent approach for naming seafood products produced using cell-culture methods. To that end, BlueNalu has sponsored one of the nation's leading experts on food safety communications to conduct independent empirical research to identify the best name for cell-cultured seafood products. Driven by that research, BlueNalu has reached three key conclusions about product naming for these products:

- First, cell-cultured seafood products should bear a common or usual name that clearly informs consumers that the product was produced using cell-culture technology while also reinforcing that the food remains a seafood product of a particular species.
- Second, the appropriate way to convey this information to consumers is to include the term "cell-cultured seafood" in the product name, coupled with the market name of the species (e.g., "Mahi-mahi, cell-cultured seafood").
- Third, it is essential that cell-cultured seafood products bear a common or usual name in a uniform manner, and BlueNalu encourages FDA to take steps as appropriate to ensure uniformity.

This approach ensures that consumers can readily identify these products as being a specific form of seafood produced in a particular way, which is essential for protecting consumer expectations as well

¹ 85 Fed. Reg. 63277 (Oct. 7, 2020).

as ensuring that food-allergic consumers are immediately made aware that these are fish or shellfish products that contain fish or shellfish allergens.

Furthermore, BlueNalu recognizes that a single term used across seafood, meat, and poultry product categories will reinforce and strengthen consumer understanding. As these products commercialize and reach the market in the United States, it is essential they are labeled clearly and uniformly within the seafood category, and consistently across meat and poultry product categories, to protect consumer expectations and build consumer familiarity with these products.

Driven by this research and in light of the best available evidence, to promote consumer understanding and expectations, BlueNalu intends to identify our cell-cultured seafood products using the format “market name, cell-cultured seafood” as the statement of identity.

In these comments, we first provide background on our company, then describe in depth the cutting-edge research on product naming for cell-cultured seafood, and finally respond to each question raised in the RFI.

I. The BlueNalu Approach

BlueNalu’s goal is to be the global leader in cell-cultured seafood production by providing consumers with safe, nutritious, and great-tasting cell-cultured seafood products. In pursuit of this goal, BlueNalu puts science, safety, and collaboration at the forefront of all we do. We are developing a “third option” for seafood that will complement the conventionally sourced wild-caught and farm-raised seafood available on the market today. Unlike its conventional counterparts, BlueNalu seafood is produced directly from the cells of fish using cutting-edge cell-culture food production methods. Although produced differently, our products will provide consumers with the safety, nutrition, and sensory experiences they expect from conventional seafood.

Our cell-cultured seafood will play a vital role in meeting the increasing demand for seafood and stabilizing the global seafood supply. According to the United Nations Food and Agriculture Organization, global per capita consumption of seafood has exceeded 20 kg/year and continues to reach all-time highs. Demand is projected only to increase as consumers continue to incorporate seafood into their diets due to its myriad of health benefits. However, as demand increases, the global seafood supply is threatened by increased overfishing, illegal fishing, ocean acidification, rising ocean temperatures, pollutants, and viruses, among other things. BlueNalu seeks to complement existing seafood production methods to help ensure a stable global supply of seafood that is as safe as seafood currently on the market and that will support the health, sustainability, and biodiversity of our oceans. BlueNalu has embraced a science-based, data-driven approach as we develop our cell-cultured seafood. We believe that evidence and science will drive the best decisions. Product naming is no different.

II. Dr. Hallman’s Cutting-Edge Empirical Research

As the leader in cell-cultured seafood, BlueNalu recognized the absence of empirical data and took seriously the need for greater independent research in the area of cell-cultured product naming. We commissioned a multi-phase empirical study by one of the nation’s leading expert in food technology

communications, Dr. Bill Hallman, Chair of the Department of Human Ecology at Rutgers University.² This is independent, rigorous, peer-reviewed research. Fundamentally, the multi-phase study sought to answer the same question FDA has posed through the RFI: What is the best way to name cell-cultured seafood in a manner that protects consumer expectations, avoids confusion, and aligns with FDA regulations? The research has resulted in a published peer-reviewed consumer study specifically designed to assess common or usual names that are consistent with FDA regulations³, and a second, confirmatory study currently under peer-review and available as a pre-print⁴ (see Attachments 1 and 2). The studies significantly advance scientific understanding of how to name these products.

The first study phase (Hallman I) was an experimental comparative study designed to evaluate how well seven leading potential product names performed against one another in conveying the basic nature of cell-cultured seafood to consumers, including how well a name described these new products and how well it differentiated these products from existing conventional counterparts without disparaging any products. Based on the results of the first phase, Dr. Hallman conducted a second phase study (Hallman II), in which he focused specifically on the two leading terms from the first study – “cell-cultured” and “cell-based” – using a large, nationally representative sample size to determine how the national population would be expected to understand the terms. The Hallman studies demonstrate that these terms performed measurably better than other names.

Based on the research and findings of the Hallman studies, BlueNalu determined that either the term “cell-cultured” or “cell-based” could appropriately identify these products to consumers. Uniformity, however, is also critical for reinforcing consumer understanding. We understand that the majority of the cell-cultured industry prefers the term “cell-cultured,” and therefore in the interest of driving uniformity, BlueNalu intends to use the phrase “market name, cell-cultured seafood” as the uniform common or usual name of all cell-cultured seafood.⁵

Because these studies represent the most robust and rigorous independent analysis of cell-cultured seafood naming—they truly are the state of the art—we describe them in detail at the outset and reference back to them throughout these comments.

² Dr. William K. Hallman, Rutgers University, <https://humanecology.rutgers.edu/faculty.asp?fid=28>. Dr. Hallman is a recognized leader in risk communications with decades of involvement in food policy, including as a former Chair of FDA’s Risk Communication Advisory Committee.

³ Hallman, W.K. and Hallman, W.K., II (2020). An empirical assessment of common or usual names to label cell-based seafood products. *Journal of Food Science*, 85, 2267-2277. <https://doi.org/10.1111/1750-3841.15351>.

⁴ Hallman, W.K. and Hallman, W.K., II (2021). A comparison of cell-based and cell-cultured as appropriate common or usual names to label products made from the cells of fish. (under review). bioRxiv preprint: <https://doi.org/10.1101/2021.02.26.433119>.

⁵ “Mahi-mahi, cell-cultured seafood” is used here as an example of how the naming convention would function as a standard of identity. This naming convention – market name, cell-cultured seafood – could be used with any seafood product. For example, “shrimp, cell-cultured seafood,” “herring, cell-cultured seafood,” or “squid, cell-cultured seafood.” Our use of various market names throughout is intended to show how the standard of identity would function and is not intended to favor any particular market name or species. This naming convention could also be applied to other cell-cultured products beyond the seafood category (e.g., “chicken breast, cell-cultured poultry).

A. The First Hallman Study (Hallman I)

1. Design

The first phase of Dr. Hallman’s research was published in the *Journal of Food Technology* as *An Empirical Assessment of Common or Usual Names To Label Cell-based Seafood Products* (“Hallman I”).⁶ The study is the only peer-reviewed, published study of its kind. Hallman I involved a detailed survey of 3,186 U.S. adults to test leading potential common or usual names using images of realistic packages that a consumer might encounter in a supermarket. Dr. Hallman identified five criteria to ensure that a common or usual name communicates needed information to consumers and complies with FDA regulations. Under Dr. Hallman’s criteria, the common or usual name for cell-cultured seafood must:

1. Enable consumers to distinguish cell-cultured seafood from wild and farmed fish.
2. Signal that those with allergies to other seafood products should not consume cell-cultured seafood products.
3. Be seen by consumers as an appropriate term to identify the product.
4. Not be disparaging to cell-cultured seafood products or to conventional products to which they might logically be compared.
5. Not evoke thoughts, images, or emotions that are inherently inconsistent with the idea that cell-cultured seafood products are safe, healthy, and nutritious.

To identify the terms for testing, Dr. Hallman first undertook a literature review to identify the scope of terms already in use regarding these types of products and conducted a Lexicon review using Google search analytics to identifying potential product descriptions already in use, which were then screened against the five criteria. Based on the search and criteria screening results, Dr. Hallman selected seven leading potential common or usual names for testing: “cell-cultured seafood,” “cultured seafood,” “cell-based seafood,” “cultivated seafood,” “produced using cellular aquaculture,” “cultivated from the cells of *species*,” and “grown directly from the cells of *species*.” The terms “wild caught,” “farm raised,” and a control condition with no common or usual name were also tested. Each term was tested in conjunction with salmon, tuna, and shrimp, the most commonly consumed seafood in the United States. High-resolution, realistic images of the front of packages consistent with those found in the marketplace were created for the experiment, as depicted below.



⁶ Hallman, W.K. and Hallman, W.K., II (2020). An empirical assessment of common or usual names to label cell-based seafood products. *Journal of Food Science*, 85, 2267-2277. <https://doi.org/10.1111/1750-3841.15351>.

For the first portion of the study, participants were provided a description of the term “seafood” but were not told about the concept of cell-cultured production methods. Participants were presented with the high-resolution image bearing the test name they had been randomly assigned then were asked to provide open-ended responses to questions including their overall reactions to the package, their interest in tasting the product, and how likely they would be to purchase the product in the next six months if it were sold in their grocery store. Next, participants had their attention focused on the product name and were asked a series of questions to determine how well the name identified the product, including questions to determine whether the name differentiated the cell-cultured product from conventional “wild-caught” and “farm-raised” products.

In the second portion of the study, participants were educated on the concept of “cell-cultured seafood.”⁷ With that information freshly in mind, participants were then asked a series of open-ended questions, including how familiar they were with the concept, how appropriate the proposed term was for describing the products, how clear the term was in communicating that the product was not caught in the ocean and that it was not farm-raised, and whether the product should be sold in the same section of the supermarket as wild-caught and farm-raised fish. Participants were also asked to rate how much they agreed or disagreed with the ideas that producing the product will benefit society, is wise, is ethical, and their openness to eating the product.

2. Results

Hallman I concluded that “cell-cultured seafood” and “cell-based seafood” stood out as the leading candidates for a product name because they distinguished conventionally sourced products, effectively signaled allergenicity, and performed as well as or better than other terms with respect to consumer perception and acceptance measures. As summarized below, all other terms failed to meet one or more of the Hallman criteria, making them inappropriate as product names.

In reaching this conclusion, Dr. Hallman analyzed how each term performed against his five criteria.

His key findings include:

- **Differentiates from wild caught and farm raised products.** “Cell-cultured” and “cell-based” performed particularly well in communicating to consumers that the product was “neither wild caught nor farm raised.” A majority of those viewing “cell-cultured” (55%) and “cell-based” (58%) were able to correctly identify the product as neither wild caught nor farm raised. Conversely, the terms without the word “cell” (*i.e.*, “cultivated,” “cultured,” and “produced using cellular aquaculture”) failed to adequately distinguish the products from conventionally sourced fish. Respondents not only struggled to identify the products as “neither wild caught nor farm

⁷ Specifically, the survey used the following description modified as appropriate with the name of the seafood and common or usual name to which they had been assigned:

The term Cell-cultured Seafood indicates that this salmon differs from both wild-caught and farmed salmon. It tastes, looks, and cooks the same and has the same nutritious qualities as Atlantic Salmon produced in traditional ways. Yet, it involves a new way of producing just the parts of Salmon that people eat, instead of catching or raising them whole. Cell-cultured Seafood means that a small number of cells from Atlantic Salmon were placed in a nutrient solution, where they grew and reproduced many times. The resulting meat was then formed into fillets that can be cooked or eaten raw.

raised,” but 40-50% of respondents viewing those terms mistakenly identified the products as farm raised.⁸

- **Allergenicity.** All terms adequately communicated that those allergic to fish/shrimp should not eat the product.
- **Appropriate way to identify the product.** Participants did not identify any of the names as an inappropriate term to communicate cell-cultured production methods. “Cell-cultured” and “cell-based” both performed well, with “cell-cultured” slightly outperforming “cell-based” in communicating these attributes.⁹ In contrast, the data also showed that names without the term “cell” performed poorly and were seen as less clear in communicating that the products were not caught in the ocean or farm raised.
- **Not disparaging.** None of the names were identified as disparaging of conventionally sourced seafood. However, some names performed better than others in terms of consumer acceptance.
- **Consistent with cell-cultured manufacturing.** “Cell-cultured” performed well in communicating that cell processed products are an equivalent third option to conventionally produced seafood. Meaning, respondents were “equally interested in tasting and purchasing” them and likely to perceive them as similarly nutritious as some conventionally sourced seafood.¹⁰

The table below summarizes how well each candidate term performed against Dr. Hallman’s key criteria:

Term	Differentiates wild caught and farmed	Communicates allergenicity	Appropriate	Not disparaging	Not inconsistent
Cell-cultured seafood	✓	✓	✓	✓	✓
Cell-based seafood	✓	✓	✓	✓	✓
Cultured seafood	Does not distinguish	✓	Least appropriate	Less likely to purchase	
Cultivated seafood	Does not distinguish	✓	✓	✓	✓
Produced using cellular aquaculture	Does not distinguish	✓	✓	✓	✓
Cultivated from the cells of <i>species</i>	✓	✓	✓	Less likely to purchase	Viewed as least positive.
Grown directly from the cells of <i>species</i>	✓	✓	✓	Less likely to purchase	Viewed as least positive.

⁸ Hallman I at 2272, Table 2.

⁹ Hallman I at 2276, Table 11.

¹⁰ Hallman I at 2274, Tables 7 and 8.

Overall, the terms “cell-cultured” and “cell-based” both performed measurably better among the seven leading terms tested in Hallman I because they met all or most of the measuring criteria suggesting that these terms would best communicate the nature of the products and best create an even playing field, facilitating consumer choice.

B. The Second Hallman Study (Hallman II)

1. Design

In the second phase of his research, Dr. Hallman tested the two leading terms from Hallman I — “cell-cultured” and “cell-based”—head-to-head using a large, nationally representative population sample of 1,200 participants. The names were tested on packages of frozen Atlantic salmon fillets.¹¹ As with the Hallman I study the stimulus labels were designed to mimic realistic conventional seafood packaging found in the marketplace.

Hallman II followed the same education and stimulus sequence of Hallman I, starting with open-ended questions before participants were provided any information on the concept and then moving onto more closed-ended questions. The questions in Hallman II were similar or the same as in Hallman I.

2. Results

Hallman II confirmed that both “cell-cultured” and “cell-based” perform well even when tested on a nationally representative population.

Hallman II reports that “both names do a good job” of distinguishing the product from conventionally sourced seafood, indicating that the product is ‘made from cells of Salmon,’ and communicating allergenicity. Nearly 80% of the participants indicated that were “not familiar at all” or only “slightly familiar,” “with the idea of producing just the parts of seafood that people eat, instead of catching or raising them whole.”¹² Yet, on their own, both “Cell-cultured Seafood” and “Cell-based Seafood” signaled to 60% of participants that the novel product is different from conventional “wild-caught” and “farm-raised” salmon. Additionally, without any explanation beyond the name, more than 40% correctly understood specifically that the products were made from the cells of salmon, as opposed to plants or something else entirely. Both terms performed equally well with respect to signaling allergenicity.¹³ Both are seen as equally safe and nutritious and both are imagined to taste equally as good.¹⁴

Key findings from Hallman II include:

- **Differentiates from wild caught and farm raised products.** Both “cell-cultured” and “cell-based” differentiated the product from conventionally sourced products and effectively

¹¹ Hallman I found that there were no species-specific effects. In other words, it did not matter whether participants were shown a package of salmon, tuna, or shrimp; the results were the same regardless. Therefore, the Hallman II study was able to simplify the experiment design to use only salmon labels.

¹² Hallman II at lines 482-484.

¹³ Hallman II at lines 488-491.

¹⁴ Hallman II at lines 492-493.

communicated the food is made from fish cells. Products identified as “cell-based” however were somewhat more likely to be confused with wild caught product than “cell-cultured” products, and products identified as “cell-cultured” were somewhat more likely to be confused with farm-raised product than “cell-based.” However, the rate of confusion overall was very low for both terms.¹⁵ Prior to receiving any priming information, for both terms, the majority of participants correctly identified the products as “neither wild-caught nor farm-raised.” These participants were then asked to indicate whether the salmon could best be described as “made from cells of Salmon,” “made from cells of Plants,” and “made from neither Salmon nor Plants.” For both terms, the largest percentage of participants indicated that “made from the cells of Salmon” was the best descriptor, with 43.9% of those viewing “cell-cultured” correctly identifying it as made from the cells of Salmon.¹⁶ After receiving information about the cell production process, participants who saw “cell-cultured” reported the term was slightly clearer in communicating that “the salmon was not caught in the ocean” and “was not farm-raised.”¹⁷

- **Allergenicity.** Both terms effectively communicated allergenicity.¹⁸
- **Appropriate way to identify the product.** Both of the names were seen as appropriate with no statistical differences between the two in ratings of appropriateness.¹⁹
- **Not disparaging.** Neither term was identified as disparaging of conventionally sourced seafood.
- **Consistent with cell-cultured manufacturing.** Neither term communicated any messages inconsistent with the product’s attributes. For example, very few consumers thought that the product was made from plant cells as opposed to salmon cells.

The chart below briefly summarizes the key results from Hallman II.

Term	Differentiates from wild caught and farm raised ²⁰	Communicates allergenicity	Appropriate	Not Disparaging	Not inconsistent
Cell-cultured seafood	Yes, slightly clearer after education.	Yes.	Yes.	Yes.	Yes
Cell-based seafood	Yes.	Yes.	Yes.	Yes.	Yes.

¹⁵ A greater proportion of those who saw the name “Cell-based” (15.0%) assumed that the product was wild-caught than those who saw the name “Cell-cultured” (11.1%). In contrast, a greater proportion of those who saw the name “Cell-Cultured” (30.1%) assumed that the product was farm-raised than those who saw the name “Cell-Based” (24.9%).

¹⁶ Hallman II at lines 601-603, Table 2.

¹⁷ Hallman II at lines 438-447.

¹⁸ Hallman II at lines 366-395, 488-491.

¹⁹ Hallman II at lines 434-437.

²⁰ For “cell-cultured,” 58.9% of participants identified the product as neither wild caught nor farm raised, 30% identified it as farm raised, and 11% identified it as wild caught. For “cell-based,” 60% of participants identified the product as neither wild caught nor farm raised, 25% identified it as farm raised, and 15% identified it as wild caught.

C. Key Takeaway for Statement of Identify

BlueNalu is committed to ensuring that consumers and regulators alike have full confidence in our cell-cultured seafood products. We recognize that consumers are increasingly asking for more information about the source and content of the foods they eat, and this information is especially important when introducing a new process that allows for a “third way” to produce seafood. We believe that consumers deserve to have a clear and consistent way to differentiate between wild-caught, farm-raised, and now cell-cultured seafood. The empirical evidence shows that the terms “cell-cultured” or “cell-based” are the best terms for informing consumers about the basic nature of these seafood products.

BlueNalu believes strongly that uniformity in the labeling of cell-cultured products is of paramount importance in building consumer understanding, trust, and acceptance. While the Hallman research concluded that “cell-based” in some measures slightly outperformed “cell-cultured” in overall consumer perception of the product, the differences were very slight. Further, we understand that other cell-cultured industry members in the seafood, poultry, and meat spaces prefer the term “cell-cultured” to “cell-based.” Therefore, to drive uniformity, BlueNalu supports the use of the term “cell-cultured” for all categories of products derived from cell-culture technology, and **intends to use the term “market name, cell-cultured seafood” as the uniform name of our cell-cultured seafood.** We believe, based on the best available evidence, that a single term that includes the word “cell” and is consistent across all categories of products derived from cell-culture technology will best promote consumer understanding. BlueNalu encourages FDA to ensure this term is used for all such products.

III. Responses to FDA’s Request for Information

Below we respond to each of the questions posed in the RFI. For ease of reference, for each question we have provided the full question in bold, followed by our response.

1. Should the name or statement of identity of foods comprised of or containing cultured seafood cells inform consumers about how the animal cells were produced? Please explain your reasoning.

Yes, the statement of identity should clearly indicate that the food was produced from animal cells, using the term “market name, cell-cultured seafood” for all cell-cultured seafood.²¹ First, FDA regulations require that products be named to disclose the basic nature of the food or its characterizing properties. Second, consumers increasingly expect to be provided information about the nature of their food, including whether it was produced using novel methods. Third, disclosing the production method is especially important for seafood given long-established consumer expectations that seafood sourcing be disclosed. Fourth, including the production method (i.e., “cell-cultured”) in the product name ensures a level playing field in the marketplace. Taken together, these legal and policy considerations strongly point to the need to clearly and succinctly identify the basic nature of cell-cultured foods. “Market name, cell-cultured seafood” is the best way to accomplish this.

First, the term “market name, cell-cultured seafood” satisfies FDA’s statutory and regulatory requirements because it provides a uniform name to communicate the basic nature of cell-cultured products and their characterizing properties in the simplest and most direct terms, providing

²¹ See supra Section II summarizing Hallman (2020) and Hallman (2021).

consumers with the information they need to make their own informed purchasing decisions.²² This is demonstrated by the Hallman research.

The Federal Food, Drug, and Cosmetic Act (FFDCA) deems a food misbranded if “its labeling is false or misleading in any particular,”²³ and a product cannot be offered for sale under the name of another food.²⁴ When there is an appropriate common or usual name for the product, the common or usual name must be used.²⁵ FDA regulations define the criteria for a common or usual name:

The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties... The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.²⁶

It is critical that cell-cultured seafood be labeled in a way that appropriately distinguishes it from conventional seafood.²⁷ Although cell-cultured seafood will be produced using genuine fish cells and will have the same nutritional and performance characteristics as conventional fish, it is produced very differently. Rather than catching or farming and then processing a whole fish, the parts of the fish that people eat are grown directly from the cells of that particular species. Therefore, cell-cultured seafood products must be named in a manner that makes clear they are fish of a certain species but that they were produced using cell-culture processes.²⁸ This approach aligns fully with FFDCA requirements and is consistent with FDA’s common or usual name regulations.

Further, these products should be named in a uniform manner. Uniformity is critical for promoting consumer understanding of these products, ensuring a level playing field in the marketplace, and allowing consumers to easily make informed purchase decisions and to readily distinguish cell-cultured seafood from conventional seafood.

²² FFDCA § 403(a); 21 C.F.R. § 102.5(a).

²³ FFDCA § 403(a).

²⁴ FFDCA § 403(b).

²⁵ FFDCA § 403(i)(1).

²⁶ 21 C.F.R. § 102.5(a).

²⁷ See FFDCA §§ 403(a), (b).

²⁸ Importantly, cell-culture production processes are different than bioengineering processes and should be approached differently through labeling. FDA historically has not required that bioengineered foods be labeled to disclose the bioengineering production method. FDA has reasoned that disclosure is not required for bioengineered foods because the final product is materially the same and because the bioengineering techniques are simply extensions at the molecular level of traditional breeding methods. FDA Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992); *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000). Here, by contrast, although our cell-cultured seafood products truly are fish, the production method is quite different. Cell processing techniques are not an extension of traditional methods and do not seek to achieve the same goals as traditional fish harvesting, which is centered on the growth, capture, harvest, and processing of whole fish. In this instance, unlike with bioengineered plant varietal cultivation, the new methods do “differ from other foods in [a] meaningful . . . way.” 57 Fed. Reg. at 22991.

Additionally, incorporating the “cell-cultured” statement directly into the product name, as opposed to including it as an on-label qualifier, ensures that cell-cultured seafood is disclosed as such when it is included as an ingredient in a multi-ingredient food.²⁹ For example, if “cell-cultured seafood” is part of the common or usual name of the food, an ingredient statement for a breaded fish product made using cell-cultured seafood might look like the following example:

<p>INGREDIENTS: Minced Pollock (Cell-cultured Seafood), Bread Crumbs (Unbleached Wheat Flour, Sugar, Salt And Yeast), Water, Sunflower Oil, Wheat Flour.</p> <p>CONTAINS: Fish (Pollock)</p>
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As explained further below in response to Question 2, “*Market name*, cell-cultured seafood” best satisfies this requirement. The term accurately identifies the basic nature and characterizing properties of the food: it is a particular species of fish that has been produced using cell-culture production methods, as opposed to having been caught or raised whole. The term “cell-cultured” is “simple and direct.” The format “*market name*, cell-cultured seafood” is also easily applied uniformly across all cell-cultured products, and the term “cell-cultured” distinguishes the cell-cultured product from conventional products. This approach facilitates ready comparison between production methods for the same species (e.g., “Mahi-mahi, cell-cultured seafood” compared to seafood that is wild caught Mahi-mahi or farm raised Mahi-mahi) and between different species within a production method (e.g., “Mahi-mahi, cell-cultured seafood” compared to “Tuna, cell-cultured seafood”).

Second, the production method for these products should be part of the product name because consumers have increasingly expressed interest in understanding how their foods are produced. BlueNalu is committed to putting transparency at the forefront. Clearly identifying the nature of cell-cultured products is essential for building consumer familiarity with and confidence in this new way of producing seafood. Because the vast majority of consumers will at least initially be unfamiliar with the concept of cell-cultured foods, the common or usual name of these seafood products must inform consumers about how the cell-cultured seafood was produced because it is the essential differentiating characteristic of the product.

Third, there is already a consumer expectation specific to seafood that the method of production be disclosed. Already, consumers are accustomed to seeing seafood sold at retail being marketed as either “wild caught” or “farm raised.”³⁰ This has established a consumer expectation for the disclosure of the production method. Without identifying the product as cell-cultured, consumers may either falsely believe the product is conventional fish (wild caught or farm raised), or they may mistakenly identify the product as an alternative to fish, which among other problems could pose serious allergen issues. Consumers might also assign value for other reasons to cell-cultured or conventional seafood and may prefer to purchase one over the other. In any case, labeling is essential.

²⁹ 21 C.F.R. § 101.4(a)(1) (“Ingredients . . . shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel . . .”).

³⁰ 7 CFR § 60.200(d). Although these method of production disclosures are required by Agricultural Marketing Service (AMS) regulations, they have helped to establish and reinforce the expectation that consumers be informed about the source of their seafood.

Fourth, calling the food “*market name*, cell-cultured seafood” would ensure a level playing field among producers and marketers of the different seafood options. As noted above, consumers are used to seeing production methods disclosed on seafood labels. Both Hallman studies found that respondents thought it would be appropriate for cell-cultured products to be sold in the same area of the supermarket as their conventional counterparts.³¹ Unlike plant-based meat alternatives, which are sometimes found grouped in vegan or vegetarian sections of a store, it would be appropriate and reasonable to expect that cell-cultured seafood would be offered for sale alongside their conventionally sourced counterparts because the products are genetically the same and differ only on the basis of method production. Assuming the products are grouped this way and that consumers expect to see and rely upon seafood production methods to make purchasing decisions, it would be necessary to include the production method of cell-cultured products so that consumers could make informed choices and best understand their options.

2. What terms should be in the name or statement of identity of a food comprised of or containing cultured seafood cells to convey the nature or source of the food to consumers? (For example, possible terms could be “cell cultured” or “cell based” or “cell cultivated.”) Please explain your reasoning and provide any studies or data about consumer understanding of such terms.

BlueNalu supports the establishment and use of uniform labeling for these novel fish products. Uniform naming will be critical in introducing consumers to and educating consumers about the products. Uniform naming will also be important for protecting consumer expectations, as multiple names for the same product will cause confusion and undermine confidence in the marketplace. Although we defer to FDA on the best mechanism for establishing uniform labeling, BlueNalu recommends using the term “*market name*, cell-cultured seafood” as the common or usual name for these products, based on both the results of Dr. Hallman’s empirical research and the importance of uniformity in product naming across the entire cell-culture industry.

As discussed in response to Question 1 above, FDA’s statutory and regulatory requirements for the naming of foods require that the name of a food not be false or misleading in any particular and that the common or usual name of a food “accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties.” The common or usual name must be “uniform among all identical or similar products and may not be confusingly similar to the name of any other food.”³² The term “cell-cultured” is simple and direct. In two words, it conveys the basic nature and characterizing properties of the food, which is that the seafood was produced using cell-culture processes rather than conventionally caught or farmed. Likewise, including the name of the species conveys that the product in fact is made of genuine fish cells, which also conveys that fish-allergic consumers should not eat it. The “*market name*, cell-cultured seafood” framework can be readily applied to all cell-cultured seafood, and naming consistency will reinforce consumer understanding and expectations for these products. Moreover, the term “*market name*, cell-cultured seafood” avoids confusion by differentiating the cell-cultured products from their conventional counterparts.

³¹ In both studies, across all terms, respondents on average stated that they neither agreed nor disagreed with the products sharing shelf space.

³² FFDC § 403(a); 21 C.F.R. § 102.5(a).

Additionally, the term “cell-cultured” is similar to the established practice in the marketplace for using modifiers in product names to distinguish a new product from a conventional counterpart (e.g., “plant-based”). For meat alternative products, for example, consumers widely accept that the term “plant-based” signals that the product is different than its conventional counterpart. Here, the term “market name, cell-cultured seafood” would signal to consumers that the cell-cultured seafoods (i) are comparable to conventional seafood, and (ii) differ in a meaningful way from their conventional counterparts. This will provide consumers the necessary information to make informed purchasing decisions.

These conclusions are reinforced by the Hallman studies³³, described in detail above and attached for review. The Hallman criteria show that “cell-cultured” not only meets the regulatory criteria but performs measurably better than many other potential names.³⁴ While “cell-based” may measure slightly better in an overall impression score, the terms are essentially equal in head-to-head testing on key criteria such as signaling allergenicity, being seen as an appropriate name, being seen as safe and nutritious.³⁵

The criteria tested a variety of points of potential confusion to identify a term that would be accurate and non-misleading. First, “cell-cultured” is accurate and non-misleading because it is effective in differentiating between cell-cultured products and conventional seafood. Second, “cell-cultured” effectively communicates allergenicity. Third, respondents considered “cell-cultured” to be an appropriate name. Finally, “cell-cultured” is a non-disparaging term that is well-accepted by respondents and perceived consistently with the fact that cell-cultured seafood on the market will be as safe and nutritious as conventionally raised seafood.

While “cell-cultured” and “cell-based” both tested well, we believe that uniform labeling will be critical for promoting consumer awareness of these products, for protecting consumer expectations, and for ensuring fairness in the marketplace. Importantly, using different statements of identity for the same type of products risks giving consumers the mistaken impression that the cell-cultured products are materially different from one another and would make it more difficult for consumers to readily differentiate between cell-cultured and conventional seafood. Recognizing that the majority of the cell-cultured companies across the seafood, meat, and poultry sectors are amenable to using the term “cell-cultured,” we recommend that term be used uniformly for these products. Should FDA instead conclude that a different term containing the word “cell” be used³⁶—in particular, “cell-based”—we would encourage FDA to follow the rest of our recommendations presented in these comments and drawn from the Hallman research, and we would urge FDA to take steps to clearly communicate its expectations to the industry and general public and take appropriate steps to ensure uniformity. Analyzing “market name, cell-cultured seafood” in light of Dr. Hallman’s key criteria reinforces this conclusion that “market name, cell-cultured seafood” should be the uniform statement of identity for these products.

³³ See supra Section II summarizing Hallman (2020) and Hallman (2021).

³⁴ See, supra Section II.A.2.

³⁵ Hallman II at lines 504-513.

³⁶ The Hallman studies provide strong empirical evidence that the term “cell” needs to be included in the statement of identity. The leading terms tested that did not use the word “cell” performed poorly in one or more categories and presented a higher likelihood of consumer confusion.

“Cell-cultured” distinguishes from conventionally sourced seafood

First, “market name, cell-cultured seafood” is accurate and non-misleading because it effectively distinguishes the product from conventionally sourced counterparts, and it performs well against these criteria. “Cell-cultured” generates very little consumer confusion about the essential characteristics of the food.

In Hallman I, participants viewing the four terms incorporating the word “cell” were more likely to correctly identify the product as “neither wild caught nor farm raised.” 55% of those viewing “cell-cultured” were able to correctly identify the product as neither wild caught nor farm raised. Names without the word “cell” failed to do so. Hallman II confirmed that “cell-cultured” performed well on a nationally representative population, finding that the term signaled to 58.9% of participants that the fish was neither wild caught nor farm raised, even when many of the study participants were not familiar with cell-cultured production methods.³⁷ In other words, the term was effective at informing consumers that the products represented a third seafood option, even when consumers didn’t know a third option existed.

“Cell-cultured” communicates allergenicity

Second, the Hallman studies showed that “market name, cell-cultured seafood” clearly and accurately communicates to the consumers that someone with an allergy to fish should not consume the product. The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires products that are or that contain fish (as with other major food allergens) to disclose the presence of the fish allergen, including the specific species of fish.³⁸ As Hallman I and II show, the term “market name, cell-cultured seafood” is effective at communicating both that the product is fish and which particular species.

“Cell-cultured” perceived as appropriate name

In both studies, respondents stated that “cell-cultured” was not an inappropriate term.

“Cell-cultured” is not disparaging and is consistent with characteristics of the product

Finally, taken together, Hallman criteria 4 and 5, show that “cell-cultured” does not communicate misleading, false, or disparaging messages about the product. The term is perceived as similarly safe and nutritious as conventionally raised seafood, which is truthful and accurate. Neither “cell-cultured” nor “cell-based” communicated any messages inconsistent with the product’s safety or nutritional attributes.

2a. How do these terms inform consumers of the nature or source of the food?

As explained above, the Hallman studies³⁹ showed that “cell-cultured” was effective³⁹ in communicating to the consumer that the fish was neither wild caught nor farm raised, that it was derived from cell-cultured seafood, and that it has the same allergenicity as conventionally sourced seafood. Hallman

³⁷ Hallman II at lines 342-351, 601-603 Table 2. Participants were more likely to misidentify product labeled “cell-based” as wild caught (15% versus 11%). Conversely, participants were more likely to misidentify a product labeled as “cell-cultured” as farm-raised (30% to 24.9%).

³⁸ FFDC § 403(w)(2).

³⁹ See supra Section II summarizing Hallman (2020) and Hallman (2021).

It confirms Hallman I's conclusions. As noted, the Hallman studies showed that about 58% of consumers were able to determine from the term alone that the product was neither wild-caught nor farm raised, and even without any prior explanation of the production process, 43.9% of consumers were able to determine that the products were made directly from the cells of fish. As consumers become increasingly familiar with this new way to produce seafood, hopefully reinforced by a uniform naming approach, these percentages are likely to further increase.

2b. If foods comprised of or containing cultured seafood cells were to be labeled with the term “culture” or “cultured” in their names or statements of identity (e.g., “cell culture[d]”), would labeling differentiation be necessary to distinguish these products from other types of foods where the term “culture” or “cultured” is used (such as “aquaculture”)? Please explain your reasoning and provide any studies or data about consumer understanding of such terms.

The Hallman research shows that when used with the term “cell” these terms effectively communicate the basic characteristics of the food (e.g., “cell-cultured *species*”). The Hallman research shows that use of the terms “culture” or “cultured” on their own are inadequate to effectively differentiate cell-cultured products from conventional farm-raised or wild-caught products.⁴⁰ These terms, if used, would require additional labeling to differentiate them from conventional counterparts.

The Hallman I study showed that the terms “cultured” and “cultivated” did not perform as well as the term “cell-cultured,” in part because participants struggled to differentiate “cultured” products from “aquaculture.”⁴¹ The terms “cultivated,” “cultured,” and “produced using cellular aquaculture” failed to adequately distinguish the products from conventionally sourced fish. These terms performed least well in signaling that the product was neither wild caught nor farm raised. Further, 40-50% of respondents viewing those terms mistakenly thought they were farm raised. For the terms “cultured” and “produced using cellular aquaculture,” respondents struggled to identify these products as “neither wild caught nor farm raised,” with only 40% of respondents able to do so. Additionally, and perhaps more importantly, 41% mistakenly assumed that the seafood was farm raised.⁴²

Comparatively, the term “cell-cultured” performs substantially better than the single word terms “cultured” or “cultivated.” For example, where 41% of respondents seeing “cultured” misidentified it as “farm raised,” only 29% seeing “cell-cultured” thought it was “farm raised,”⁴³ a difference of more than 10%. As the term “cell-cultured” becomes more familiar to consumers through exposure in the marketplace, there will be even less likelihood of confusion.

Given the likelihood that many consumers will remain unfamiliar with cell-cultured foods for a period of time, it is important that the product name put consumers on notice that the food is not a conventional seafood product, even if the consumer might not know what specific alternatives exist. This approach best protects consumer expectations, and “market name, cell-cultured seafood” achieves this goal.

⁴⁰ See supra Section II summarizing Hallman (2020) and Hallman (2021).

⁴¹ Hallman I at 2271.

⁴² The term “cultivated” performed even more poorly than “cultured.” Less than 30% of respondents identified “cultivated” products as “neither wild caught nor farm raised” and over half (53.8%) mistakenly identified them as “farm raised.”

⁴³ Hallman I at 2272, Table 2.

- 3. The names of many conventionally produced seafood products have been established by common usage or by statute or regulation. Names are also recommended for seafood species in *The Seafood List*. In FDA's view, foods comprised of or containing cultured seafood cells are not yet in the marketplace and, therefore, do not have common or usual names established by common usage.**

As explained below in response to this question's sub-parts, BlueNalu believes that the common or usual name framework is the appropriate way to identify the product name for cell-cultured seafood, even though these products have not yet entered the marketplace. However, even if FDA were to determine that there is no common or usual name established by common usage, "market name, cell-cultured seafood" is also the most appropriate descriptive term for these products for the same reasons identified in the Hallman research, and uniform use of the term would best protect consumer expectations.

- 3a. If you disagree with FDA's view, what are these names and what evidence demonstrates that the names are commonly used and understood by the American public for foods derived from cultured animal cells?**

Although we recognize the difficulty of aligning on an approach to product naming before a product has entered the marketplace, neither the FFDCa nor FDA regulations limits common or usual names to only products that already exist in the marketplace. Indeed, were that the case, no new product would ever have a common or usual name. Rather, it is appropriate to look to the motivating principles behind the common or usual name regulation to identify a common or usual name for a product entering the marketplace. This approach drives uniformity and increases the likelihood of consumers understanding the new products. Moreover, FDA can facilitate this process by taking steps as appropriate to ensure alignment around a particular name, in this instance, "market name, cell-cultured seafood".

FDA's detailed regulation defining common or usual names drives home this point. That regulation provides a detailed description of the criteria for a common or usual name: it must "accurately identify" the "basic nature" of the food or its "characterizing properties or ingredients" "in as simple and direct terms as possible"; it must be uniform among all identical or similar products; it cannot be "confusingly similar" to the name of a different food; and it must be different for each class or subclass of foods.⁴⁴ Nowhere does this regulation require that the name be used by or be familiar to a specific threshold of consumers.

It is true that a common or usual name "may be established by common usage,"⁴⁵ or through regulation. But FDA regulations do not require that the "common usage" be limited only to foods already in the marketplace, nor do regulations limit the development of common or usual names to only these mechanisms. Had that been the case, the regulation would have said that common or usual names "may *only* be established" in the manner listed. The regulation is permissive, not exclusive. And in any event, the FFDCa imposes no such limitations, noting only that a common or usual name should be used, "if any there be."⁴⁶

⁴⁴ 21 C.F.R. § 102.5(a).

⁴⁵ 21 C.F.R. § 102.5(d).

⁴⁶ FFDCa § 403(i)(1).

In fact, there is evidence of enough use of the term “cell-cultured” and enough familiarity with the concept of cell-cultured seafood to have confidence that the term “market name, cell-cultured seafood” will be meaningful to consumers. Dr. Hallman’s literature review and Lexicon searches establish that the concept of cell-cultured foods has been in use since at least 2014.⁴⁷ Further, Hallman I found that at least 19% of respondents already were either “very” or “extremely familiar” with the concept.⁴⁸ The Hallman I survey was administered nearly a year ago, and consumer familiarity has likely increased since then. And of the participants in the Hallman II study, 58.9% understood the term “cell-cultured” to differentiate the products from conventional seafood, and 43% understood the term to specifically describe cell-cultured production processes (i.e., that the product is “made from the cells of salmon”). These data provide direct evidence that consumers are able to use and understand this term. Thus, the Hallman studies reflect consumer usage and understanding appropriate to support a common or usual name under 21 C.F.R. § 102.5(a).

However, even if FDA were to conclude that the common or usual name framework is not the appropriate one for naming cell-cultured seafood, “market name, cell-cultured seafood” is also the best “appropriately descriptive term” for these products. Under FDA regulations, if a food lacks a standardized name and a common or usual name, the food is to be named using an “appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.”⁴⁹ The nature of cell-cultured seafood is not obvious by looking at it, so cell-cultured seafood would have to be named using an appropriately descriptive term. Fortunately, the factors evaluated in the Hallman studies provide ample evidence that “market name, cell-cultured seafood” would be an “appropriately descriptive term.” Indeed, the studies showed it was effective at describing the cell-cultured products and differentiating them from conventional seafood products, and study participants specifically found it to be “appropriate.” Therefore, although BlueNalu believes that the common or usual name framework is the most appropriate way to align on the product name for cell-cultured seafood, the “appropriately descriptive term” framework leads to the same conclusion: “market name, cell-cultured seafood” is the appropriate name for these products.

Were FDA to follow the “appropriately descriptive term” framework, however, it is critical that FDA ensure that a uniform term be used. Uniformity is essential to promote consumer awareness, protect consumer expectations, and foster fair competition in the marketplace.

3b. Should names for conventionally produced seafood products established by common usage, statute, or regulation be included in the names or statements of identity of food derived from cultured seafood cells? Please explain your reasoning.

Yes, the common or usual name of the food should be “market name, cell-cultured seafood” (e.g., Mahi-mahi, cell-cultured seafood). The Hallman studies identified “market name, cell-cultured seafood” as one of the clearest ways to communicate the material characteristics of these novel products to consumers, including their allergenicity.⁵⁰ As discussed above in response to question 2, FALCPA requires the particular species of fish be declared to aid food-allergic consumers. BlueNalu understands the seriousness and critical importance of accurate allergen labeling.

⁴⁷ Hallman I at 2268 (surveying earlier consumer perception studies related to cell-cultured food production). See *generally* supra Section II summarizing Hallman (2020) and Hallman (2021).

⁴⁸ Hallman I at 2275.

⁴⁹ 21 C.F.R. § 101.3(b)(3).

⁵⁰ See supra Section II summarizing Hallman (2020) and Hallman (2021).

Including the name of the species in the common or usual name will communicate the most complete information to consumers. This will be especially important when cell-cultured seafoods are used as ingredients in other foods such as a fish stick or seafood salad. The inconsistency of including the species name only in the allergen statement (and not in the name of the ingredient itself) could generate unnecessary confusion among consumers.

Moreover, as FDA emphasizes in The Seafood List, it is important to “unambiguously identify a species in the marketplace.”⁵¹ The fish cells used in our cell-cultured seafood are real fish cells from a specific species. They are genetically indistinguishable from cells taken from a conventionally caught or farmed fish of that species; DNA barcoding would identify them as the same species. Declaring the species in the product name is therefore consistent with FDA policy.

Including the species name is also critically important for protecting consumer expectations and preventing the passing off of a less valuable species as a higher-value one. Consumers will seek out specific fish species for various reasons, including taste, nutrition, cost, and specific cooking applications. Consumers need to be provided with market name information to make these purchase decisions.

3c. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate? Please explain your reasoning.

The market name of the product should be qualified with the phrase “cell-cultured seafood” so that the common or usual name of the food communicates its basic nature and characterizing properties.⁵² With this qualification included in the common or usual name itself, no further qualifiers are necessary absent some other material difference between the foods. As discussed above, the method of production should be disclosed in the common or usual name of the food. “Cell-cultured seafood” accomplishes this in clear, direct terms.⁵³ Dr. Hallman’s research establishes “*market name*, cell-cultured seafood” is appropriate without additional qualifying language.⁵⁴ The term succinctly informs consumers of the market name of fish from which the cells were obtained (important for allergen concerns, consumer preference, and economic value) and that the product was produced using cell-culture processes rather than caught or farmed conventionally. This is consistent with other naming approaches, such as the naming of nutritionally modified foods and other instances where a food with an established name is in some way different than its conventional counterpart.

Beyond the use of “cell-cultured seafood,” no additional qualifying language is needed. In fact, further language could confuse consumers and impede innovation. As discussed in response to Question 5, if the cell-cultured product differs from its conventional counterpart in other material ways (e.g., it has a materially different nutritional profile), then that information may require disclosure on a case-by-case basis.

⁵¹ FDA Guidance for Industry: The Seafood List (July 2012), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list>.

⁵² See 21 C.F.R. § 102.5(a).

⁵³ 21 C.F.R. § 102.5(a).

⁵⁴ See supra Section II summarizing Hallman (2020) and Hallman (2021).

3d. Do these names, with or without qualifying language, clearly distinguish foods derived from seafood cell culture from conventionally produced seafood? Please explain your reasoning.

The name “*market name*, cell-cultured seafood” sufficiently differentiates the product from its conventional counterparts without additional qualifying language. Hallman I demonstrated that 55% of those viewing “cell-cultured” were able to correctly identify the product as neither wild caught nor farm raised.⁵⁵ However, three of the other names studied (“cultivated,” “cultured,” and “produced using cellular aquaculture”) did not sufficiently distinguish cell-cultured products from wild caught or farm raised fish. In fact, 40-50% of respondents viewing those terms mistakenly thought the products were farm raised.

3e. Should FDA update *The Seafood List* to include foods comprised of or containing cultured seafood cells? Please explain your reasoning.

FDA should not update The Seafood List to include foods comprised of or containing cell-cultured seafood as separate entries in the list. The Seafood List identifies what FDA considers to be acceptable market names for seafood that “allow[] consumers to unambiguously identify a *species* in the marketplace.” (emphasis added). Cell-cultured seafood is produced using the cells of a particular fish species (e.g., cell-cultured Mahi-mahi is produced using the cells of *Coryphaena hippurus*, the scientific name for Mahi-mahi). Cell-cultured seafoods are not separate species of fish. Rather, the cells are genetically identical, meaning they have the same DNA sequences. Therefore, it would be misleading (and potentially dangerous) to modify The Seafood List in a way that could confuse consumers about what species of fish they are eating. However, FDA may want to consider adding an explanation to FDA’s Guidance for Industry on The Seafood List⁵⁶ and/or FDA Compliance Policy Guide 540.750⁵⁷ to clarify that the use of the term “cell-cultured” is appropriate to combine with the species-specific name and would not render the product misbranded.

4. Should terms that specify a certain type of seafood (such as “fillet” or “steak”) be included in or accompany the name or statement of identity of foods comprised of or containing cultured animal cells?

Yes. Terms such as “fillet” or “steak” have established meaning to consumers, identifying the different forms in which the fish is presented. In particular, consumer understanding of these terms is rooted in the shape of the piece of fish (e.g., thickness and shape) and corresponding cooking attributes. Consumers expect a fillet, for example, to be of a certain general shape, to be practically free of bones, and to be ready to cook. Consumers often seek out a specific cut based on the cooking application. While the product known as a “fillet” is described in some reference documents based on how it is cut from the whole fish, these descriptions are not intended to limit a “fillet” or a “steak” to only tissue cut

⁵⁵ “Cell-based” also performed well, with 58% of respondents accurately identifying it as “neither wild caught nor farm raised.” See *generally*, supra Section II summarizing Hallman (2020) and Hallman (2021).

⁵⁶ FDA, Guidance for Industry: The Seafood List (July 2012), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list>.

⁵⁷ FDA, CPG Sec 540.750 - Use of The Seafood List to Determine Acceptable Seafood Names (July 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540750-use-seafood-list-determine-acceptable-seafood-names>.

from a whole fish or that has been cut away from bone. Rather, those definitions, which long predate cell-culture technology, are merely using the way the cuts are removed from a whole fish as a point of reference that the reader will readily understand when picturing the product. To the consumer, the important issue is not how specifically the tissue was removed from the fish at the processing facility, but rather what shape, appearance, and cooking attributes the product possesses.⁵⁸

Simply put, cell-cultured seafood presented in a form comparable to an existing cut such as a fillet or steak should be identified accordingly to facilitate consumer selection. On the other hand, cell-cultured seafood presented in a manner that does not replicate the existing cut should not bear that term. FDA's existing authority to take action against labels that are false or misleading under FFDCA § 403(a) would allow FDA to take action should a term be misapplied.

4a. Under what circumstances should these terms be used? What information would they convey to consumers? For example, would such terms convey the physical form or appearance of the food? Please explain your reasoning. Additionally, please provide any studies or data about consumer understanding of such terms when used to describe foods comprised of or containing cultured seafood cells.

Consumers have an established understanding for how various cuts of fish look and function when cooking. When a cell-cultured seafood product is processed in the same form as an established cut, such as a fillet, and the product looks and functions accordingly, it is appropriate to use the same term (e.g., "fillet") to communicate that to the consumer. These terms are important for consumer expectations. For example, if a consumer wants to purchase a cut of fish to pan-fry, the consumer might look for frozen fish fillets. A product labeled as a "Salmon fillet, cell-cultured seafood" would immediately and succinctly tell the consumer that the product is a form of salmon, that it is in fillet form, and that it was produced using cell-cultured processes (rather than being wild caught or farmed). With those four words, the consumer would have all the information necessary to make a purchase decision.

4b. Would these terms be misleading to consumers? Please explain your reasoning and provide any supporting studies or data.

BlueNalu has no reason to believe that use of the terms "fillet" or "steak" would be misleading to consumers. Importantly, BlueNalu believes that terms such as "fillet" or "steak" should be used only when they accurately describe the form in which the seafood product is produced. Use of the terms "fillet" or "steak" would not be misleading or confusing on cell-cultured fish because the consumer is adequately put on notice by the product name that the product meets the characteristics of a fillet or steak but is produced using cell culture methods rather than cut from a whole fish. For conventional products, references to how the fillet or steak is cut from the whole fish provide an anatomical point of reference to describe the resulting fish tissue, but both conventional and cell-cultured cuts would otherwise have all the same characteristics. Meaning, consumers would receive the product they would expect, a piece of fish in a certain shape with no bones.

⁵⁸ Should a consumer want a "fillet" or a "steak" specifically from a conventionally produced fish, the consumer would immediately be informed through the product name whether the product was produced using cell-culture processes.

5. When comparing conventionally produced seafood to foods comprised of or containing cultured seafood cells, what attributes (such as nutrition, taste, texture, or aroma) vary between the foods and should FDA consider to be material to consumers' purchasing and consumption decisions? Please explain your reasoning.

BlueNalu believes that comparability should drive whether any additional labeling information is needed. Consumers are likely to assume that the cell-cultured product is comparable to its conventional counterpart unless otherwise disclosed. If a seafood product produced using cell-culture processes is comparable to conventional products in all material ways, then no additional labeling should be needed (other than using "market name, cell-cultured seafood" in the product name). We believe that nutrition, taste, texture (or mouthfeel), and cooking performance are the key product attributes that consumers seek out in seafood. BlueNalu intends to market a product that is comparable to conventional counterparts in these areas and therefore would not require ingredient or other disclosures.

Cell-culture processes also provide the opportunity to prepare seafood products in a way that achieves changes to targeted nutritional attributes. For example, a cell-cultured fish product could be produced in a manner that presents a modified fatty acid profile. In such a case, we believe the label should include a qualifier informing consumers of the material nutritional change from the conventional counterpart. FDA's Seafood Nutrition Facts⁵⁹ and USDA FoodData Central⁶⁰ database could provide useful points of reference for evaluating nutritional variance.

5a. Are there other characteristics beyond nutritional attributes or organoleptic properties that may be material differences? These could relate either to cellular constituents or characteristics influenced by the cell culture production process. Please be specific in your response and explain your reasoning.

BlueNalu's first products will be genetically identical to conventional counterparts and therefore would not require disclosures. Cell-cultured seafood is produced using the cells of a particular fish species (e.g., *Coryphaena hippurus*). Meaning, they have the same DNA sequences and are not materially different from a genetic standpoint. In keeping with FDA and USDA's joint framework for regulating cell-cultured products, we anticipate that a thorough FDA premarket consultation process will ensure that cell-cultured products are as safe as their conventional counterparts and, in the process, identify any other material differences through the cell-culture processing steps that would require disclosure. Because cell-culture processes vary, we believe that these issues are best handled on a case-by-case basis.

III. Conclusion

Based on FDA's longstanding product naming approach and the research and findings the Hallman studies, BlueNalu recommends using "market name, cell-cultured seafood" as the common or usual name of all cell-cultured seafood.

The Hallman studies establish that "market name, cell-cultured seafood" is an appropriate common or usual name for cell-cultured seafood products. The Hallman criteria show that "market name, cell-

⁵⁹ Seafood Nutrition Facts (Jan. 2008), available here <https://www.fda.gov/media/76889/download>.

⁶⁰ USDA FoodData Central, available here <https://fdc.nal.usda.gov/>.

cultured seafood” not only meets the regulatory criteria in 21 C.F.R. § 102.5(a), but also performs measurably better on a variety of consumer acceptance metrics than other potential names. The Hallman criteria tested a variety of points of consumer understanding to identify a term that would be accurate and non-misleading. First, “cell-cultured” is accurate and non-misleading because it is effective in differentiating between cell-cultured products and conventional seafood. Second, “cell-cultured” effectively communicates allergenicity. Third, respondents considered “cell-cultured” to be an appropriate name. Fourth, “cell-cultured” is a non-disparaging term that is well-accepted by respondents and perceived as similarly safe and nutritious as conventionally raised seafood. Finally, although “cell-based” also performed well in the Hallman studies, industry acceptance of the term “cell-cultured” would allow for uniformity in product naming across all cell-cultured products, which is essential to establishing trust and confidence among consumers.

Therefore, “cell-cultured” would be the most appropriate term to promote consumer awareness, protect consumer understanding, and ensure the most objective and level playing field. BlueNalu intends to use the name “*market name*, cell-cultured seafood” for our cell-cultured seafood products, and we encourage FDA to ensure the uniform use of this term for all cell-cultured seafood products.

* * *

BlueNalu is pleased to provide responses to this Request for Information and appreciates FDA’s consideration of our responses and the attached empirical research. If I can be of additional assistance, please do not hesitate to contact me at cooperhouse@bluenalu.com.

Sincerely,



Lou Cooperhouse
President and CEO
BlueNalu

Enclosures

APPENDIX C

Hallman, W.K. and Hallman, W.K., II (2020). An empirical assessment of common or usual names to label cell-based seafood products. *Journal of Food Science*, 85, 2267-2277.

An empirical assessment of common or usual names to label cell-based seafood products

William K. Hallman  and William K. Hallman II 

Abstract: An important consideration in the commercialization of cell-based meat, poultry, and seafood is what common or usual name to use on package labels to meet U.S. Food and Drug Administration (FDA) regulations. However, naming these products has been the subject of considerable debate. This study used a 3×10 between-subjects online experiment involving a quota sample of 3,186 U.S. adult panel participants to test common or usual names using images of realistic packages of three types of seafood that a consumer might encounter in a supermarket. The terms tested were, “cell-based seafood,” “cell-cultured seafood,” “cultivated seafood,” and “cultured seafood” and the phrases, “produced using cellular aquaculture,” “cultivated from the cells of _____,” and “grown directly from the cells of _____,” where the blanks are filled by the name of the seafood product. Five criteria were used for evaluation, including each term’s ability to: enable consumers to distinguish cell-based seafood from wild and farmed fish, to signal potential allergenicity, be seen by consumers as an appropriate term to identify the product, not disparage either cell-based or conventional products, and not evoke thoughts, images, or emotions that are inconsistent with the idea that the products are safe, healthy, and nutritious. The results showed that “cell-based seafood” outperforms the other names tested. It enables consumers to recognize that the products are neither wild caught nor farm raised, signals potential allergenicity, is seen as an appropriate name for describing the technology/process, and it performs well with respect to measures of consumer acceptance, particularly in comparison to conventional products.

Keywords: Cell-Based, Cell-Cultured, Common or Usual Name, Nomenclature, Seafood

Practical Application: Creating consensus around a single common or usual name for cell-based meat, poultry, and seafood products is clearly important both for regulatory reasons and for shaping public perceptions and understanding of the products that are labeled with it. Our findings suggest that “cell-based” is the best common or usual name for seafood products that both meets FDA regulatory requirements and performs well with respect to potential consumer acceptance. Consistent use of this term by industry, advocates, and regulators would help orient consumers to what is likely to be a transformational food technology.

1. INTRODUCTION

The production of cell-based meats, poultry, and seafood involves new technologies that directly produce only the parts of animals that people prefer to eat, rather than deriving these from whole animals. Through *in vitro* production of specific muscle, fat, and connective tissues, producers are able to create food products that duplicate the taste, texture, nutritional, and culinary attributes of their conventional counterparts (Stephens et al., 2018).

Investment, research, and development in the technology are proceeding rapidly. Although no products have yet been approved for sale in any country, several companies have held events exhibiting various prototypes, and others are at various stages of planning and scaling up production (Kateman, 2020).

An important consideration in the pathway to commercialization is what to call the products derived from this technology. U.S. Food and Drug Administration (FDA) regulations (21CFR101.3) require that all foods that do not have defined *standards of identity*

(21CFR130.8) be labeled with a “common or usual name” as a *statement of identity* so that consumers can make informed choices about the products they buy. Similarly, the U.S. Dept. of Agriculture (USDA) requires that common or usual names be used to label meat (9CFR317.2) and poultry products (9CFR381.117). Under 21CFR102.5, which is most prescriptive, the general principles for establishing the common or usual name of a food include:

The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

Assuming that meat, poultry, and seafood products produced through *in vitro* tissue production are nutritionally equivalent to their conventionally produced counterparts, and are similar in form, taste, texture, and in nutritional and culinary attributes, the obvious dissimilarity that needs to be clearly communicated to consumers is that the product did not involve the growing or

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harvesting of whole animals. However, there is little consensus about what name to use to refer to either the technology or its products.

In part, this lack of consensus is because choosing what common or usual name to use on product labels goes beyond regulatory issues. There is power inherent in labeling a concept, because the name given to it can evoke images, emotions, metaphors, and meanings that profoundly shape public perceptions and acceptance (Broad, 2020). What to call these products have unsurprisingly been the subject of considerable debate among consumers, advocates, regulators, and the producers of both cell-based and conventional meat products, with various stakeholders proposing terms likely to elicit very different reactions from consumers (Ong, Choudhury, & Naing, 2020).

Skeptics of the products, as well as some consumer organizations, have proposed the adoption of terms that they argue is necessary to clearly distinguish these products from conventional meat (Hansen, 2018). These terms include, “lab-grown meat,” “synthetic meat,” “artificial meat,” “fake meat,” and “schmeat.” Each of these names has been rejected by the producers of cell-based products as scientifically inaccurate and as calculated to portray their foods as unnatural and unappetizing (AMPS Innovation, 2020).

In contrast, advocates of the rights and humane treatment of animals and some companies have referred to the products as “clean meat,” “animal-free meat,” “slaughter-free meat,” and “cruelty-free meat.” However, these terms have been rejected by traditional meat producers as derogatory to conventional products (Greene & Angadjivand, 2018). In response, some advocates have proposed using the term “cultivated” (Friedrich, 2019), suggesting that a more appealing name is necessary to encourage consumers to purchase meat products that do not require the slaughter of animals. However, this term has not been embraced by manufacturers (Siegener, 2019).

Producers of cell-based products would prefer to call these foods “cell-based,” “cell-cultured,” or “cultured,” or to refer to them as the products of “cellular agriculture” or “cellular aquaculture.” They argue that these names are scientifically accurate and can differentiate their products from conventional meat without denigrating either (Corbyn, 2020).

Creating consensus around a single common or usual name is clearly important both for regulatory reasons and for shaping public perceptions and understanding of the products that are labeled with it. The production of these meat, poultry, and seafood products entails the use of a new process with which most Americans are likely to be unfamiliar. Although consumer knowledge and awareness will evolve over time and with the approval and introduction of the products into the marketplace, many consumers will likely first encounter them by seeing a packaged product in a store. Therefore, there is an opportunity to help familiarize consumers with what is likely to be a transformational technology through the selection and consistent use of a descriptive term that transparently references how these products are made and thus, how they are different from conventional products.

There have been multiple efforts to evaluate consumer perceptions, acceptance, and potential purchase of meat products produced through the technology (Bryant & Barnett, 2018). These include qualitative studies involving focus group participants responding to various terms, including reactions to “lab grown meat” in Manchester, UK (O’Keef, McLachlan, Gough, Mander, & Bows-Larkin, 2016); New Zealander’s reactions to “*in vitro* meat” (Tucker, 2014); and responses to “synthetic meat” in the

United Kingdom, Belgium, and Portugal (Verbeke, et al., 2015). They also include analyses of comments posted to U.S. news stories about “*in vitro* meat” (Laestadius, 2015; Laestadius & Caldwell 2015), and word association tasks involving small numbers of graduate students from the Netherlands, Ethiopia, and China responding to “cultured meat” (Bekker, Tobi, & Fischer, 2017).

Online surveys have also been conducted to gauge consumer perceptions and acceptance of “clean meat” in the United States, China, and India (Bryant, Szejda, Deshpande, Parekh, & Tse, 2019), and “cultured meat” in France (Hocquette et al., 2015). Wilks and Phillips (2017) recruited mTurk participants to respond to “*in vitro* meat,” though also informing participants that, “*in vitro* meat is also referred to as cultured meat, schmeat, or synthetic meat.” Valente, Fiedler, Sucha Heidemann, & Molento (2019) also conducted an online survey of reactions to “*in vitro* meat,” among highly educated participants from two large cities in Brazil, recruited using a snowball sampling technique.

Several experiments have also been conducted to compare proposed terms with respect to consumer perceptions of, and willingness to purchase cell-based products bearing different names. In a nonpeer-reviewed study, The Good Food Institute (2017) reported that they used mTurk participants to test the terms “clean meat,” “meat 2.0,” “pure meat,” “safe meat,” and “cultured meat.” Consistent with its recommendation that “clean meat” be adopted by the industry (Friedrich, 2016), the experimental data suggested that “clean meat” should be the preferred term because it outperformed the others with respect to participant’s stated willingness to purchase products bearing that name. Grieg (2017) attempted to replicate the Good Food Institute study, again using mTurk participants. The results, reported in an online blog, suggested that “clean meat” outperformed “cultured” with respect to self-reported purchase preferences.

Focused on “optimizing consumer acceptance,” the Good Food Institute worked with food product consulting firm Mattson to generate a list of 74 names provided by stakeholders, ultimately testing the performance of the terms, “clean meat,” “cultured meat,” “craft meat,” “cell-based meat,” and “slaughter-free meat” (Szejda, 2018). Participants were asked to rate how appealing the name is, how accurately it describes the product, and how well it differentiates from conventional meat. The results suggested that “slaughter-free,” “craft,” “clean,” and “cultured” performed best in name appeal, “slaughter-free” and “cell-based” performed best in descriptiveness and differentiation from conventional meat, and “slaughter-free” and “craft” performed best in likelihood of trying and of purchasing the product (Szejda & Urbanovich, 2019).

Finally, in a peer-reviewed study using 185 mTurk participants, Bryant and Barnett (2019) concluded that “clean meat” and “animal-free” meat performed better than “lab-grown meat” and “cultured meat” with respect to positive participant attitudes and behavioral intentions.

Unfortunately, none of these studies were designed to evaluate the terms for use as common or usual names on product labels. In particular, none of the studies examined the ability of the terms to help consumers distinguish cell-based products from conventional products, which is key from a regulatory perspective. Instead, they focused mainly on measuring perceptions of the technology, or on ways to frame that technology to improve public acceptance.

Most of the studies also used sampling methods likely to result in highly unrepresentative samples, making it difficult to generalize the results. These methods included snowball sampling, data collected from convenience samples of students, and the use of

crowdsourced convenience samples consisting of mTurk respondents, which have been shown to differ from the population as a whole in several important ways (Chandler & Shapiro, 2016).

All of the studies also described the technology to participants using text, graphics, or videos *before* they answered questions measuring the key dependent variables. This is problematic with respect to evaluating the effectiveness of a common or usual name, because the name needs to communicate the “characterizing properties” of a food, and what distinguishes it from other foods, *on its own*; that is, without the benefit of additional explanatory text or other supporting materials.

To address this gap in the literature, the goal of this research is to assess the performance of proposed common or usual names to best meet the regulatory criteria established in 21CFR102.5, and are also likely to be acceptable to the relevant stakeholders. The study uses a between-subjects experimental design to test proposed common or usual names using images of realistic packages of three types of seafood that a consumer might encounter in a supermarket. Seafood is used as the basis for the stimulus materials because all of the previous peer-reviewed studies examining public perceptions of the various names proposed for cell-based products have focused on meat. However, the development of cell-based seafood products is also well underway (Krueger, Rubio, Datar, & Stachura, 2019), with at least six companies actively working to bring cell-based seafood products to market (Leschin-Hoar, 2019).

Moreover, while the best performing common or usual name should ideally be applied to cell-based meat, poultry and seafood products alike, cell-based seafood products must contend with additional regulatory issues not faced by cell-based meat products, which adds complexity to the choice of an appropriate name. For example, while meat and poultry products require a common or usual name that will distinguish them from conventional products, those conventional products are generally derived from domesticated animals. Yet, many cell-based seafood products must distinguish themselves from *both* wild caught and farm raised varieties of the same species. In addition, most consumers are very familiar with the limited variety of conventional meat and poultry products available in supermarkets. However, recent FMI (2019, 2020) surveys have found that less than a third of seafood consumers consider themselves “very knowledgeable” about how to purchase or prepare seafood, its nutritional benefits, how to recognize the freshness or quality of seafood products, or even about the different types of seafood available, potentially creating additional challenges in distinguishing cell-based seafood products from conventional products.

Certain combinations of proposed terms with the word seafood may also be problematic. For example, the term “cultured fish” already has a meaning associated with aquaculture (Watson, 2018), and “cultivated” is already associated with the production of farmed mussels.

Similarly, the term “cultured seafood” might be mistakenly interpreted by consumers as one of the existing kinds of “fermented seafood” products already available for purchase, and “clean fish” may be mistaken for conventional fish that have been gutted or free from contaminants.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (Public Law 108-282) also requires that the label of a food with an ingredient that contains protein from a “major food allergen” declare the presence of that allergen. Because cell-based seafood products will involve the propagation of muscle, fat, and connective tissues from conventional fish, they will likely contain the same level of allergenic proteins as conven-

tional seafood products. Therefore, the labels of cell-based fish will also need to appropriately signal to consumers that those allergic to fish should not eat the product. In addition, FALCPA requires that the type of fish or shellfish be declared on product labels.

Therefore, to meet FDA regulatory requirements, the best performing terms should, at minimum:

- A. Enable consumers to distinguish cell-based seafood from wild and farmed fish.
- B. Signal that those with allergies to other seafood products should not consume cell-based seafood products.

In addition to these FDA regulatory requirements, to meet the needs of the various stakeholders expected to use them, the best performing terms should:

- C. Be seen by consumers as an appropriate term to identify the product.
- D. Not be disparaging to cell-based seafood products or to the conventional products to which they might logically be compared.
- E. Not evoke thoughts, images, or emotions that are inherently inconsistent with the idea that the cell-based food products are safe, healthy, and nutritious.

In addition to these five criteria, the terms should ideally be able to be used as modifiers of “meat,” “poultry,” and “seafood,” or be a phrase that accurately describes the technology that could be used after a product name. They should anchor consumer perceptions within a network of associations that are not inherently negative. They have to be available for use by any producer, so terms that are already trademarked or copyrighted are unusable. They should not be perceived as oxymoronic (for example, animal-free meat). Finally, they should not have existing meanings not associated with the technology or its products (for example, sustainable seafood, clean fish, and cultured fish) that might be confusing or misleading to consumers.

The terms chosen to test are currently attached to “meat” but also appear in articles and blogs about seafood. These are: “cultured seafood,” which is used by the companies Wild Type, Mosa Meat, Just, and Integriculture; “cell-based seafood” which is used by the companies BlueNalu and Shiok meats, “cell-cultured seafood,” which is used by USDA/FDA in their joint press releases regarding joint regulatory oversight of these products; “cultivated seafood,” the term currently being used and recommended by the Good Food Institute; the phrase “produced using cellular aquaculture,” used by BlueNalu to describe the process, as well as the phrases “cultivated from the cells of ____” and “grown directly from the cells of ____,” where the blanks are filled by the name of the fish.

2. MATERIALS AND METHODS

2.1 Experimental design

The seven proposed common or usual names described in the introduction were tested, along with terms “wild caught,” “farm raised,” and a control condition that had no common or usual name. Each of the 10 resulting terms was tested in association with three types of seafood (salmon, tuna, and shrimp), which account for 55% of all of the seafood consumed in the United States (Seafoodhealthfacts.org, 2018) increasing the likelihood of participant familiarity with the products that were labeled. To eliminate potential priming effects, each participant was randomly

assigned to consider only one of the 30 packages created in this 3 × 10 between-subjects design.

2.2 Materials

High-resolution images of the front of packages of Atlantic Salmon, Ahi Tuna, and Shrimp were created for this experiment (see Figure 1). The top one-third of each package showed the image of the cooked seafood product, noted as a “serving suggestion,” which is typical of conventional seafood packages already in the marketplace. The middle third contained the product title, as well as the common or usual name to be tested, printed in a font size half that of the product title. The bottom third of each package contained a clearly visible, and accurate Nutrition Facts Label (NFL), reflecting the values equivalent to conventional products, as well as the net weight of the package contents, and statements indicating that the product “Contains salmon/tuna/shrimp,” and is “Perishable,” and to “Keep Frozen” and “Cook Thoroughly.” Just above the NFL, the packages of shrimp had a statement indicating that they were “Large, 31–40 Shrimp Per Pound.”

2.3 Participants

Study participants were recruited from a web-based consumer panel with more than 3.2 million active members enrolled in the United States. The experiment was administered during an 18-day period in February and March 2020. A total of 8,485 randomly selected E-rewards panel members were sent an e-mail invitation to participate in the study. Demographic information (education level, year of birth, ethnicity, race, and gender) was used to produce a sample balanced to 2010 U.S. Census data. A total of 5,527 panelists clicked on the link in the e-mail invitation and 3,644 individuals completed the questionnaire, for a completion rate of 42.9%. Of these, 3,186 participants completed one of the 30 experimental conditions reported here. The remaining participants were assigned to complete a different task that will be reported in a separate article.

2.4 Procedure

After providing informed consent and confirming that they were aged 18 or older, the participants read a description of the term “seafood”:

“The term *Seafood* refers to both Fish (like salmon, tuna, tilapia, flounder, catfish, cod, sardines, herring, and other species) and Shellfish, including Mollusks (like oysters, clams, mussels, scallops, octopus, squid) and Crustaceans (like shrimp, crabs, lobsters, crayfish). Seafood is eaten raw, baked, broiled, grilled, poached, breaded, and fried. It is also an ingredient in many dishes, including stews, gumbos, dips, and spreads.”

With this in mind, they were then asked how often they had consumed seafood in the previous year. They were then shown a high-resolution image of the package associated with the condition to which they had been randomly assigned and asked to provide the “first thought, image, or feeling that comes to mind when seeing this package.” These open-ended responses were recorded as text and later coded into relevant categories by two independent coders. To ensure that each participant actively examined and thought about the package and its contents, the participants repeated this exercise twice more; looking at the package and providing a reaction to it using an open-ended response box. They then were shown the same package a fourth time, and asked for their overall reactions, their interest in tasting it, and how likely they would be to purchase the product in the next six months if it were sold in their grocery store.

The participants were then shown an enlarged picture of the cooked product on the package and asked about their familiarity with the seafood depicted *in general*, whether it is a good source of Omega 3 fatty acids and whether pregnant women should limit consumption of that seafood. They were then asked if they had ever tasted salmon/tuna/shrimp, whether they liked the taste, had ever ordered it in a restaurant, purchased it in a store, cooked it, and if they or anyone in their households were allergic to it, or to any type of seafood.

An enlarged image of the name of the seafood and the common or usual name was then displayed. While still in view, the participants were asked, “Which of the following best describes this salmon/tuna/shrimp?” The response categories were “Wild Caught,” “Farm Raised,” and “Neither Wild Caught nor Farm Raised.” They then were asked whether it would be safe to eat the product if one were allergic to fish/shrimp, and how safe it would be to eat if one were not allergic. They were then asked to indicate how natural they thought the product is, and how likely it is that the product is genetically modified (GM), made from plants, fermented, or contains “an unhealthy amount of mercury.”

An enlarged, high-resolution image of the NFL was then shown, and while still in view, the participants were asked how nutritious they believed the product is. They were then asked whether pregnant women should eat it, whether children should eat it and to compare the product to wild-caught and farm-raised salmon/tuna/shrimp.

Up to this point, the participants were not provided with any additional information about the meaning of the common or usual names that they viewed on the packages. So, in the final part of the experiment, those randomly assigned to view one of the seven common or usual names tested were shown the following description (modified as appropriate with the name of the seafood and common or usual name to which they had been assigned).

“The term Cell-based Seafood indicates that this salmon differs from both wild-caught and farmed salmon. It tastes, looks, and cooks the same and has the same nutritious qualities as Atlantic Salmon produced in traditional ways. Yet, it involves a new way of producing just the parts of Salmon that people eat, instead of catching or raising them whole. Cell-based Seafood means that a small number of cells from Atlantic Salmon were placed in a nutrient solution, where they grew and reproduced many times. The resulting meat was then formed into fillets that can be cooked or eaten raw.”

The participants were asked how familiar they were with “the *idea* of producing just the parts of salmon/tuna/shrimp that people eat, instead of catching or raising them whole,” and, how appropriate the term was “for describing this new way of producing just the parts of salmon/tuna/shrimp that people eat, instead of catching or raising them whole?” They indicated how clear the term was in communicating that the product was not caught in the ocean and that it was not farm-raised. They reported how much they agreed or disagreed with the ideas that producing the product will have benefits for society, is wise, is ethical, and that the idea of eating it is disgusting. Finally, they responded as to whether the product should be sold in the same section of the supermarket as wild-caught and farm-raised fish and then answered a series of sociodemographic questions.

2.5 Statistical analyses

The experimental data were analyzed using IBM SPSS Statistics for Windows (version 25; IBM Corp., Armonk, NY, USA). Differences in means were analyzed using Analysis of Variance,



Figure 1—Examples of package images.

with *post hoc* comparisons made using the Tukey’s HSD test. Differences in proportions were analyzed using z -tests of column proportions with Bonferroni correction. In all statistical tests, a significance level of 0.05 was established to distinguish significant differences.

3. RESULTS AND DISCUSSION

The median length of the completed survey was 11.2 minutes. Of the 3,186 participants, 51% were male. Mean age was 49.66, $SD = 15.85$, 27.9% reported children under 18 in the household. An overview of the sociodemographic characteristics of the sample is shown in Table 1.

The majority (91.7%) of the participants reported eating at least some seafood in the prior 12 months, with 62.0% reporting they had eaten at least one meal a month containing seafood, 32.4% at least one meal a week, and 1.9% one or more meal per day. The majority of the participants had eaten shrimp (72.7%), tuna (64.9%), and salmon (58.4%) in the prior year. In addition, the participants reported having consumed crab (42.3%), cod (40.1%), tilapia (36.1%), and lobster (30.7%). The participants also indicated they were moderately to very familiar with the general type of seafood they viewed; shrimp ($M = 3.66$, $SD = 1.20$), salmon ($M = 3.49$, $SD = 1.24$), tuna ($M = 3.33$, $SD = 1.24$) $F(2, 3,185) = 18.96$, $P < 0.001$, $\eta^2 = 0.012$) (scale: 1 (*not familiar at all*), 2 (*slightly*), 3 (*moderately*), 4 (*very*), 5 (*extremely familiar*)).

The remainder of the results is organized to address the regulatory and other criteria discussed in the introduction. There were no statistically significant interaction effects at the $P < 0.05$ level between the type of seafood and the common or usual name seen on the package with respect to any of the dependent measures discussed below. Therefore, only the main effects of the common or usual name are presented.

3.1 Criterion A: Distinguish from conventional products

A key criterion for establishing a common or usual name is the ability of consumers to distinguish the products labeled with it

from the traditional products with which they are already familiar. After seeing the product packages and asked to provide reactions to them four times, the participants were asked, “Which of the following best describes this salmon/tuna/shrimp?” The response categories were “wild caught,” “farm raised,” and “neither wild caught nor farm raised.” The proportion of participants placing the products in each response category differed by product name tested, $X^2(18, N = 3,186) = 1,474.57$, $P < 0.001$.

As shown in Table 2, 92.6% of those who saw packages labeled as wild caught and 89.4% of those who saw packages labeled as farm raised correctly identified them as such. This was as expected, as the task only required participants in these conditions to match the response category with what they had seen on the label.

Of those in the control condition (with no common or usual name displayed), 52.8% responded that the seafood was “neither wild caught nor farm raised.” However, nearly a third (31.6%) reported that it was “wild caught” and 15.5% responded that it was “farm raised.”

Of the common or usual names seen by the participants, the four names incorporating the word “cell” (“Cultivated from the Cells of,” “Cell-Based,” “Cell-Cultured,” and “Grown Directly from the Cells of”) resulted in the largest percentage of participants (60.9%, 58.4%, 55.0%, 53.7%, respectively) correctly identifying the seafood as “neither wild caught nor farm raised.” A z -test of column proportions with Bonferroni correction indicated that there were no statistically significant differences in these percentages.

The terms “cultured” (40.8%) and “produced using cellular aquaculture” (40.3%) were less successful in signaling that the seafood was “neither wild caught nor farm raised.” Moreover, nearly equal percentages (41.1% and 39.3%, respectively) mistakenly assumed that the seafood was “farm raised.”

Finally, the term “cultivated” performed most poorly in distinguishing the seafood from conventional products. Only 29.9% of the participants correctly identified it as “neither wild caught nor farm raised,” and more than half (53.8%) misidentified it as “farm raised.”

Table 1—Sociodemographic characteristics of the sample, (N) = 3,186.

Sociodemographic characteristic	% of total
Gender	
Male	51.0%
Female	49.0%
Marital status	
Married	46.1%
Single, never married	28.8%
Divorced or separated	13.6%
Living with partner	5.8%
Widowed	5.4%
Educational level	
Less than high school	2.2%
High school/GED	20.7%
Some college	20.1%
Two-year college degree (Associate)	10.9%
Four-year college degree (BA, BS)	27.7%
Master's degree	14.2%
Doctoral degree	1.8%
Professional degree (MD, JD)	2.4%
Ethnicity ^a	
Caucasian	76.1%
African American	16.2%
Hispanic/Latino	11.0%
Asian	5.5%
Native American	2.2%
Other	3.1%
Household income	
Less than \$10,000	9.6%
\$10,000 to \$19,999	12.1%
\$20,000 to \$29,999	10.9%
\$30,000 to \$39,999	7.6%
\$40,000 to \$49,999	7.1%
\$50,000 to \$59,999	7.4%
\$60,000 to \$69,999	5.7%
\$70,000 to \$79,999	6.7%
\$80,000 to \$89,999	5.1%
\$90,000 to \$99,999	5.3%
\$100,000 to \$149,999	12.9%
\$150,000 or more	9.7%
Shopping for household	
I do all of it	60.9%
I do most of it	17.0%
I do about half of it	15.7%
Someone else does most of it	5.2%
Someone else does all of it	1.3%

^aParticipants could indicate multiple categories.

3.2 Criterion B: Signal potential allergens

Because products produced from the cells of live fish contain proteins that can cause an allergic response among some individuals, it is important that the label enable fish or shellfish-allergic consumers to identify these products as potential allergens. After viewing the product title and common or usual name, the participants were asked, “If you are allergic to fish/shrimp, is it safe for you to eat this salmon/tuna/shrimp? The response options were, 1 (*definitely not*), 2 (*probably not*), 3 (*probably yes*), 4 (*definitely yes*). On average, participants believed that those allergic fish/shrimp should not eat the product (*Mdn* = 2.0). A Kruskal–Wallis test indicated that there are no statistically significant differences among the common/usual names in signaling allergenicity ($H(9) = 15.317, P = 0.083$).

3.3 Criteria C and D: Not be disparaging

After indicating how often they ate seafood, the participants were shown the package of seafood and asked to respond to the open-ended question, “What is the first thought, image, or

Table 2—Percent describing the product as wild caught, farm raised, or neither, by common or usual name.

	Common name									
	Cultivated from the cells of	Cell-based	Cell-cultured	Grown directly from the cells of	Cultured	Produced using cellular aquaculture	Cultivated	Wild caught	Farm raised	Control
Neither wild caught nor farm raised	60.9% _a	58.4% _a	55.0% _a	53.7% _a	40.8% _{b,c}	40.3% _{b,c}	29.9% _c	4.6% _d	4.7% _d	52.8% _{b,b}
Farm raised	22.1% _{b,b}	21.9% _{b,b}	29.1% _{b,c}	29.0% _{b,c}	41.1% _{c,d}	39.3% _c	53.8% _d	2.8% _e	89.4% _f	15.5% _a
Wild caught	16.9% _a	19.7% _a	16.0% _a	17.4% _b	18.1% _a	20.4% _{b,b}	16.4% _a	92.6% _c	5.9% _d	31.6% _b
N	318	320	313	328	326	313	318	323	322	316

Note: Each subscript letter within a row denotes a subset of Common Name categories whose proportions do not differ significantly from each other at the .05 level using the Z-test of column proportions with a Bonferroni correction determining the critical value.

Table 3—Ratings of first thought or image and overall reactions by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P-value</i>	η^2
Rating of First thought or image				9.514	<0.001	0.026
Wild caught	5.56 ^a	1.58	323			
Produced using cellular aquaculture	5.32 ^{ab}	1.69	313			
Cultivated	5.25 ^{ab}	1.76	318			
Farm raised	5.25 ^{ab}	1.73	322			
Control	5.24 ^{ab}	1.77	316			
Cell-based	5.16 ^{abc}	1.74	320			
Cultured	5.09 ^{bc}	1.74	326			
Cell-cultured	4.99 ^{bc}	1.92	313			
Grown directly from the cells of	4.75 ^{cd}	1.90	328			
Cultivated from the cells of	4.47 ^d	1.98	307			
Overall reactions				11.18	<0.001	0.031
Wild caught	5.53 ^a	1.58	323			
Control	5.27 ^{ab}	1.76	316			
Farm raised	5.26 ^{ab}	1.75	322			
Cultivated	5.20 ^{ab}	1.80	318			
Produced using cellular aquaculture	5.18 ^{bc}	1.67	313			
Cell-based	5.00 ^{bc}	1.81	320			
Cultured	4.99 ^{bc}	1.76	326			
Cell-cultured	4.85 ^{bcd}	1.96	313			
Grown directly from the cells of	4.55 ^{cd}	1.99	328			
Cultivated from the cells of	4.43 ^d	1.99	307			

Notes: Scale: 1 (*extremely negative*), 2 (*moderately negative*), 3 (*slightly negative*), 4 (*neither positive nor negative*), 5 (*slightly positive*), 6 (*moderately positive*), 7 (*extremely positive*). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using the Tukey HSD *post hoc* test.

feeling that comes to mind when seeing this package? For ease of coding, the participants were informed that they should list only one response, as they would have the chance to record to additional responses in subsequent questions. Each of the 3,168 first responses was coded into one of 28 categories developed using a grounded theory approach (see Table S1 in the supplemental materials). Two trained researchers independently coded each response and these were compared. Any discrepancies were resolved by consensus. The terms, “grown directly from the cells of salmon/tuna/shrimp,” and “cultivated from the cells of salmon/tuna/shrimp” evoked the smallest percentages of initial open-ended responses suggesting that the product was appetizing (18.3% and 16.9%). On average, 26.0% of the participants who saw the other five common or usual names wrote responses clearly indicating that the product was appetizing.

The participants were also asked to rate how positive or negative their first thought, image, or feeling was, using a scale ranging from 1 (*extremely negative*) to 7 (*extremely positive*) (Table 3). While all of initial reactions to the packages were in the positive range (that is, above 4.0), “wild caught” was rated most positively, “grown directly from the cells of” and “cultivated from the cells of” received the least positive ratings. A similar pattern was observed with respect to the overall ratings given after having seen the package four times (Table 3). The correlation between the initial and the overall rating was 0.78.

Asked how safe it would be to eat the seafood if not allergic to it, all of the products (including wild caught and farm raised) were rated as “somewhat” to “moderately” safe to eat

Table 4—How safe is it for you to eat this if you are not allergic to seafood by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P-value</i>	η^2
Safe to eat				5.63	<0.001	0.016
Wild caught	6.13 ^a	1.36	323			
Farm raised	5.97 ^{ab}	1.59	322			
Control	5.93 ^{ab}	1.51	316			
Cultivated	5.90 ^{ab}	1.60	318			
Cultured	5.90 ^{ab}	1.42	326			
Produced using cellular aquaculture	5.86 ^{abc}	1.43	313			
Cell-based	5.73 ^{bc}	1.56	320			
Grown directly from the cells of	5.60 ^{bc}	1.64	328			
Cell-cultured	5.58 ^{bc}	1.67	313			
Cultivated from the cells of	5.47 ^c	1.74	307			

Notes: Scale: 1 (*very unsafe*), 2 (*moderately unsafe*), 3 (*somewhat unsafe*), 4 (*neither safe nor unsafe*), 5 (*somewhat safe*), 6 (*moderately safe*), 7 (*very safe*). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using the Tukey HSD *post hoc* test.

Table 5—How nutritious by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P-value</i>	η^2
Nutritious				5.63	< 0.001	0.016
Farm raised	3.80 ^a	1.05	322			
Wild caught	3.80 ^a	0.99	323			
Produced using cellular aquaculture	3.74 ^{ab}	1.06	313			
Cultivated	3.70 ^{abc}	1.09	318			
Control	3.67 ^{abc}	1.07	316			
Cell-based	3.65 ^{abc}	1.07	320			
Cultured	3.62 ^{abc}	1.01	326			
Grown directly from the cells of	3.56 ^{abc}	1.04	328			
Cell-cultured	3.53 ^{bc}	1.08	313			
Cultivated from the cells of	3.45 ^c	1.12	307			

Notes: Scale: 1 (*not at all nutritious*), 2 (*slightly nutritious*), 3 (*moderately nutritious*), 4 (*very nutritious*), 5 (*extremely nutritious*). Means with the same superscript letter are not significantly different from each other at $P < 0.05$.

(Table 4). They were also rated as “moderately” nutritious, with products labeled as “produced using cellular aquaculture,” “cultivated,” “cell-based,” “cultured,” and “grown directly from the cells of,” and the Control product rated as equally nutritious as the conventional “wild caught” and “farm raised” products (Table 5). However, the seafood with the names “cell-cultured” and “cultivated from the cells of” were judged to be slightly less nutritious than the conventional products.

Each of the products was also imagined to taste “slightly” to “moderately” good (Table 6). Products labeled as “cultivated,” “produced using cellular aquaculture,” “cell-based,” and “cultured” were thought to be as good tasting as “wild caught” and “farm raised,” while those labeled as “cell-cultured,” “grown directly from the cells of,” and “cultivated from the cells of” were imagined to taste less good than wild caught and farm raised seafood.

The participants indicated that they were “moderately” interested in tasting all of the products (Table 7), expressing equal interest in tasting the products labeled as “wild caught,” “produced using cellular aquaculture,” “farm raised,” “cell based,” and the control product. They were least interested in tasting products labeled with the phrases, “cultivated from the cells of” and “grown directly from the cells of.” However, they were equally as

Table 6—Imagined taste by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P</i> -value	η^2
Taste				16.49	< 0.001	0.018
Wild caught	5.67 ^a	1.53	323			
Farm raised	5.58 ^a	1.57	322			
Cultivated	5.48 ^{ab}	1.62	318			
Produced using cellular aquaculture	5.47 ^{ab}	1.48	313			
Control	5.38 ^{abc}	1.73	316			
Cell-based	5.35 ^{abc}	1.57	320			
Cultured	5.34 ^{abc}	1.50	326			
Cell-cultured	5.15 ^{bc}	1.61	313			
Grown directly from the cells of	5.01 ^c	1.62	328			
Cultivated from the cells of	5.00 ^c	1.65	307			

Notes: Scale: 1 (extremely bad), 2 (moderately bad), 3 (slightly bad), 4 (neither good nor bad), 5 (slightly good), 6 (moderately good), 7 (extremely good). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using the Tukey HSD *post hoc* test.

Table 7—Interest in tasting by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P</i> -value	η^2
Taste				6.41	<0.001	0.018
Wild caught	3.68 ^a	1.36	323			
Produced using cellular aquaculture	3.45 ^{ab}	1.40	313			
Farm raised	3.44 ^{ab}	1.43	322			
Control	3.41 ^{ab}	1.46	316			
Cell-based	3.35 ^{abc}	1.48	320			
Cultivated	3.34 ^{bc}	1.51	318			
Cultured	3.29 ^{bc}	1.45	326			
Cell-cultured	3.21 ^{bc}	1.49	313			
Cultivated from the cells of	3.01 ^c	1.49	307			
Grown directly from the cells of	3.00 ^c	1.51	328			

Notes: Scale: 1 (not at all interested), 2 (slightly interested), 3 (moderately interested), 4 (very interested), 5 (extremely interested). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using Tukey HSD *post hoc* test.

interested in tasting the seafood with the other proposed common or usual names as they were in tasting the “farm raised” product.

Similarly, they indicated that they were equally likely to purchase the seafood labeled as “wild caught,” “farm raised,” “produced using cellular aquaculture,” “cultivated,” “cell-based,” and “cultured,” and the control products. However, they were less likely to purchase products labeled as “cell-cultured” than the “wild caught” product and less likely to purchase products with the phrases “grown directly from the cells of,” or “cultivated from the cells of” (Table 8) than both the conventional “wild caught” and “farm raised” products.

Perceptions of the products’ naturalness fell into five slightly overlapping groups, with the “wild caught” seafood viewed as most natural (Table 9). The control product, and the products labeled as “farm raised” and as “cultivated” are seen as less natural than “wild caught.” Those labeled as “cultured,” “produced using cellular aquaculture,” and “cell-based” form the middle group and are seen as equally natural. “Cell-cultured” overlaps with those in the middle group, but also with those labeled with the phrases “grown directly from the cells of” and “cultivated from the cells of” which were seen as the least natural of all of the products tested.

Judgments of the likelihood that the products were GM followed a similar pattern (Table 10). The “wild caught” product,

Table 8—Likelihood to purchase in next six months by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P</i> -value	η^2
Likelihood to purchase				6.86	<0.001	0.019
Wild caught	5.04 ^a	2.02	323			
Farm raised	4.85 ^{ab}	2.13	322			
Control	4.80 ^{ab}	2.14	316			
Produced using cellular aquaculture	4.79 ^{ab}	2.07	313			
Cultivated	4.71 ^{ab}	2.19	318			
Cell-based	4.64 ^{abc}	2.16	320			
Cultured	4.56 ^{abcd}	2.12	326			
Cell-cultured	4.41 ^{bcd}	2.23	313			
Grown directly from the cells of	4.12 ^{cd}	2.29	328			
Cultivated from the cells of	4.07 ^d	2.24	307			

Notes: Scale: 1 (extremely unlikely), 2 (moderately unlikely), 3 (slightly unlikely), 4 (neither likely nor unlikely), 5 (slightly likely), 6 (moderately likely), 7 (extremely likely). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using the Tukey HSD *post hoc* test.

Table 9—Rating of “How Natural” by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P</i> -value	η^2
How natural				49.57	<0.001	0.123
Wild caught	6.30 ^a	1.18	322			
Control	5.62 ^b	1.38	316			
Farm raised	5.53 ^b	1.66	320			
Cultivated	5.29 ^{bc}	1.66	318			
Cultured	4.91 ^{cd}	1.67	324			
Produced using cellular aquaculture	4.91 ^{cd}	1.72	311			
Cell-based	4.87 ^{cd}	1.85	319			
Cell-cultured	4.54 ^{de}	1.99	312			
Grown directly from the cells of	4.09 ^e	2.12	327			
Cultivated from the cells of	4.09 ^e	2.16	307			

Notes: Scale: 1 (very unnatural), 2 (moderately unnatural), 3 (somewhat unnatural), 4 (neither natural nor unnatural), 5 (somewhat natural), 6 (moderately natural), 7 (very natural). Means with the same superscript letter are not significantly different from each other at $P < 0.05$ using the Tukey HSD *post hoc* test.

rated as “slightly unlikely” was viewed as least likely to be GM. The control and “farm raised” products were seen as “neither likely nor unlikely” to be GM, as were the “cultivated” and “cultured” products, while products labeled as “cell-based,” “produced using cellular aquaculture,” and “cell-cultured” were seen as “slightly likely” to be GM. Finally, those labeled with the phrases “grown directly from the cells of” and “cultivated from the cells of” were seen as the most likely to have been GM. Thus, the terms containing the word “cell” were perceived (in general) as more likely to be GM than those without it. However, while some companies may ultimately use genetic modification in the production of their cell-based foods, others will not.

All of the seafood products were seen as unlikely to have been made from plants. Products labeled as “cell-cultured” and “cell-based” products were seen as “slightly unlikely” to have been made from plants, followed by the phrases, “produced using cellular aquaculture,” “cultivated from the cells of,” and “grown directly from the cells of.” The products labeled as “cultivated” and “cultured” were rated as “moderately unlikely” to have been made from plants, followed by the control product. The “wild caught” and “farm raised” products, with which consumers are

Table 10—Ratings of likelihood that the seafood is genetically modified, made from plants, and “Contains an Unhealthy Amount of Mercury” by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P</i> -value	η^2
How likely it is genetically modified				196.41	<0.001	0.156
Cultivated from the cells of	5.62 ^a	1.63	307			
Grown directly from the cells of	5.48 ^{ab}	1.69	328			
Cell-cultured	5.18 ^{bc}	1.64	313			
Produced using cellular aquaculture	4.94 ^{cd}	1.71	313			
Cell-based	4.94 ^{cd}	1.75	320			
Cultured	4.60 ^{de}	1.68	326			
Cultivated	4.49 ^e	1.77	318			
Farm raised	4.24 ^{ef}	1.85	322			
Control	4.03 ^f	1.66	316			
Wild caught	2.95 ^g	1.93	323			
How likely it is made from plants				25.52	<0.001	0.067
Cell-based	3.73 ^a	1.95	320			
Cell-cultured	3.39 ^{ab}	1.91	313			
Produced using cellular aquaculture	3.06 ^{bc}	1.92	313			
Cultivated from the cells of	3.04 ^{bc}	1.88	307			
Grown directly from the cells of	2.98 ^{bc}	1.97	328			
Cultivated	2.73 ^{cd}	1.97	318			
Cultured	2.71 ^{cd}	1.83	326			
Control	2.44 ^{de}	1.81	316			
Farm raised	2.14 ^e	1.77	322			
Wild caught	2.03 ^e	1.74	323			
Contains unhealthy amount of mercury				6.39	<0.001	0.018
Wild caught	4.14 ^a	1.66	323			
Control	4.08 ^{ab}	1.61	316			
Cultivated	3.92 ^{abc}	1.71	318			
Cell-based	3.78 ^{bcd}	1.72	320			
Cell-cultured	3.66 ^{bcd}	1.72	313			
Grown directly from the cells of	3.61 ^{cd}	1.77	328			
Cultured	3.60 ^{cd}	1.58	326			
Produced using cellular aquaculture	3.57 ^{cd}	1.81	313			
Farm raised	3.47 ^d	1.80	322			
Cultivated from the cells of	3.47 ^d	1.75	307			

Notes: Scale: 1 (*extremely unlikely*), 2 (*moderately unlikely*), 3 (*slightly unlikely*), 4 (*neither likely nor unlikely*), 5 (*slightly likely*), 6 (*moderately likely*), 7 (*extremely likely*). Means with the same superscript letter are not significantly different from each other at $P < .05$ using the Tukey HSD *post hoc* test.

already familiar, were seen as the least likely to have been made from plants.

None of the products were viewed as likely to be fermented (See Table in S2). The products labeled as “wild caught” and “farm raised” were seen as least likely to have been fermented. However, there were no statistically significant differences among the terms tested as common or usual names.

None of the products were thought likely to “contain an unhealthy amount of mercury (Table 10). The “wild caught,” control, and “cultivated” products, which were judged as “neither likely nor unlikely” were seen as the most likely to contain an unhealthy amount of mercury. The remaining names were judged to be “slightly unlikely” to “neither likely nor unlikely” and were not significantly different from each other.

The participants were divided as to whether pregnant women should eat any of the seafood products, (including both “wild caught” and “farm raised” products). Coded as 1 (*definitely not*), 2 (*probably not*), 3 (*probably yes*), and 4 (*definitely yes*), the overall median was 2.00. A Kruskal–Wallis test indicated that there were no statistically significant differences among the common or usual names. There was a small negative Spearman’s rank-order correlation between the likelihood that the product contains an unhealthy amount of mercury and whether pregnant women should eat it $r_s(3,186) = -0.129$, $P < 0.001$.

In contrast, using the same scale, the majority indicated that children *should* eat each of the products ($Mdn = 3.00$). A Kruskal–Wallis test indicated that the participants thought that children should eat some products with common or usual names more than others, $H(9) = 40.497$, $P < 0.001$. Pairwise comparisons with adjusted P -values indicated that the participants were less likely to believe that children should eat “cell-cultured seafood” than “cultivated” ($P = 0.028$), “wild caught” ($P = 0.012$), or “farm raised” products ($p < 0.001$). They were also less likely to believe that children should eat seafood “cultivated from the cells of” than “wild caught” ($P = 0.036$), or “farm raised” products ($P = 0.004$). Similarly, they were less likely to believe that children should eat “cultured seafood” ($P = 0.037$) or products “grown directly from the cells of” than “farm raised” ($P = 0.036$). There was a small negative Spearman’s rank-order correlation between the likelihood that the product contains an unhealthy amount of mercury and whether children women should eat it $r_s(3,186) = -0.158$, $P < 0.001$. There was also a positive Spearman’s rank-order correlation between whether the participants thought that pregnant women should eat any of the seafood and whether children should eat it ($r_s(3,186) = 0.555$, $P < 0.001$).

The participants were asked to compare the product with the proposed common or usual name to the properties of farm raised and wild caught varieties. They were asked, in a randomized order, whether the product had more, less, or the same amount of “heart-healthy omega 3s,” protein, microplastics, mercury, antibiotics, bacteria, artificial colors, growth hormones, pesticides, and “other environmental contaminants.” They were also asked whether the product was better, the same, or worse with respect to taste, texture, nutrition, cost, the environment, and “the sustainability of ocean fish.” Using a Bonferroni corrected P value of $P < 0.001$ to account for multiple tests using the same dependent measure, only the comparisons of the amount of pesticides in the products with the common or usual names to their wild caught counterparts were significant $F_{(6,2224)} = 5.44$, $P < 0.001$, $\eta^2 = 0.015$ (see Table S3).

3.4 Criterion E: Be seen as an appropriate term

After reading the description of the proposed common or usual name to which they had been assigned, the majority of the participants (61%) indicated that they were “not familiar at all” “with the *idea* of producing just the parts of seafood that people eat, instead of catching or raising them whole.” The remainder reported that they were “slightly” (9%), “Moderately” (13%), “very” (10%), or “extremely familiar” (9%) with the concept. Coded on a corresponding scale of 1 to 5, there were no statistically significant differences among the common or usual names with respect to familiarity with the concept.

The participants were then asked to indicate how appropriate the common or usual name they viewed is “for describing this new way of producing just the parts of salmon/tuna/shrimp that people eat, instead of catching or raising them whole.” Using a

Table 11—Rating of clarity in communicating that the product was not “Caught in the Ocean” or “Farm Raised” by common or usual name.

	<i>M</i>	<i>SD</i>	<i>N</i>	<i>F</i>	<i>P-value</i>	η^2
Not caught in the ocean				17.22	<0.001	0.045
Grown directly from the cells of	5.50 ^a	1.85	328			
Cultivated from the cells of	5.25 ^{ab}	1.82	307			
Cell-cultured	4.89 ^{bc}	1.92	313			
Cultivated	4.59 ^{cd}	2.08	318			
Produced using cellular aquaculture	4.54 ^{cd}	2.06	313			
Cell-based	4.46 ^{cd}	2.17	320			
Cultured	4.21 ^d	2.00	326			
Not farm raised				18.54	<0.001	0.048
Grown directly from the cells of	5.30 ^a	1.87	328			
Cultivated from the cells of	5.18 ^{ab}	1.77	307			
Cell-cultured	4.80 ^{bc}	1.90	313			
Cell-based	4.49 ^{cd}	2.13	320			
Produced using cellular aquaculture	4.46 ^{cd}	2.01	313			
Cultivated	4.18 ^d	2.14	318			
Cultured	4.06 ^d	2.06	326			

Notes: Scale: 1 (extremely unclear), 2 (moderately unclear), 3 (slightly unclear), 4 (neither clear nor unclear), 5 (slightly clear), 6 (moderately clear), 7 (extremely clear). *N* = 2,225. Means with the same superscript letter are not significantly different from each other at *P* < 0.05 using the Tukey HSD *post hoc* test.

scale of 1 (extremely inappropriate) to 7 (extremely appropriate), none of the names proposed was judged to be “inappropriate” (*M* = 4.97, *SD* = 1.81) and there were no statistically significant differences in ratings of appropriateness among the names.

The participants were also asked how clear the term is “in communicating that the salmon/tuna/shrimp was not caught in the ocean” and in communicating that it was not “farm raised.” As shown in Table 11, none of the proposed common or usual names was judged as “unclear” in communicating either of these concepts. The phrases “grown directly from the cells of” and “cultivated from the cells of” rated as “slightly clear” were perceived to be clearest and “cultured” was perceived to be least clear in communicating that the products were not caught in the ocean and were not farm raised.

Using a set of agree–disagree questions coded as: 1 (*strongly disagree*) and 7 (*strongly agree*), the participants indicated no differences between the names in the level of agreement that producing the seafood product will have benefits for society (*M* = 4.69, *SD* = 1.59, *N* = 2,225), that producing it is wise (*M* = 4.49, *SD* = 1.70, *N* = 2,223), and is ethical (*M* = 4.58, *SD* = 1.67, *N* = 2,221). Moreover, there were no differences between the names in the level of agreement that the idea of eating the product is disgusting (*M* = 4.35, *SD* = 1.84, *N* = 2,222). Finally, there were no differences between the names as to whether each seafood product should be sold in the same section of the supermarket as wild caught and farm raised seafood (*M* = 4.47, *SD* = 1.83, *N* = 2,223).

3.5 Determining the best performing common or usual name

Assessments of each of the five criteria were used to establish which of the seven candidate names performed best in meeting both the regulatory requirements and the needs of stakeholders.

The terms performed equally well with respect to criterion B (signaling allergenicity) and E (seen as an appropriate name). Unfortunately, the terms “cultivated,” “cultured,” and “produced using cellular aquaculture” performed least well in signaling that the product is neither “wild caught” nor “farm raised.” In fact, more than half of those viewing “Cultivated” and more than 40% of those who saw “cultured” and “produced using cellular aquaculture” mistakenly thought these terms meant “Farm Raised.” Because these terms failed to meet the key regulatory criterion (A) the ability of the common or usual name to distinguish the product from its conventional counterparts, they were removed from further consideration.

The phrases “cultivated from the cells of” and “grown directly from the cells of” were also removed from further consideration. They performed well in distinguishing the labeled product from those that are wild caught and farm raised. However, they received among the least positive overall reactions and were seen as most likely to be GM. Compared to the conventional “wild caught” and “farm raised” products with which they must compete, they are also consistently in the bottom tier with respect to perceptions of safety, nutrition, taste, naturalness, interest in tasting, and likelihood to purchase.

The remaining two names, “cell-based” and “cell-cultured” both did a good job at signaling that the product is different from both “wild caught” and “farm raised” seafood (meeting criterion A). In direct comparisons between the two, the terms “cell-based” and “cell-cultured” are also not significantly different from each other on most of the other key dependent measures.

However, “cell-based” outperforms “cell-cultured” when comparing the pattern of results for each term to those associated with the conventional “wild caught” and “farm raised” seafood products with which consumers are already familiar. In contrast to “cell-cultured” products, the participant’s initial reactions to “cell-based” were as positive as they were to “wild caught” and “farm raised” and overall reactions were as positive as “farm raised.” They judged “cell-based” as nutritious as both “wild caught” and “farm raised” seafood, while “cell-cultured” products were not. Unlike “cell-cultured” seafood, “cell-based seafood” was imagined to taste as good as both “wild caught” and “farm raised” seafood and the participants indicated that they were equally interested in tasting and in purchasing “cell-based seafood” as they were “wild caught” and “farm raised” seafood. In contrast, they were only equally interested in tasting and purchasing “cell-cultured” seafood as they were in tasting and purchasing “farm raised” seafood products. Finally, the participants were less likely to indicate that children should eat “cell-cultured seafood” than both “wild caught” and “farm raised” products, while they were equally likely to indicate that children should eat “cell-based seafood” as “wild caught” and “farm raised.” Thus, the overall pattern of results suggests that the term “cell-based” is the better of the two names with respect to likely consumer acceptance and purchase of these novel products.

4. CONCLUSION

“Cell-based seafood” appears to be the best candidate name considered in this study. It meets the regulatory requirements to distinguish products from those already known to consumers and to signal allergenicity. It is seen as an appropriate name for describing the technology/process and it performs as well or better than other terms with respect to key measures related to consumer perceptions and acceptance. As such, the term “cell-based seafood”

should be considered the best common or usual name to be used to label seafood products produced using the technology.

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AUTHOR CONTRIBUTIONS

W. Hallman is responsible for all aspects of the study design, data analysis, and production of the manuscript. W. Hallman II assisted with the review of the literature, coding of open-ended responses, preparation of tables, and review and editing of the manuscript.

CONFLICTS OF INTEREST

None to declare.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. First Thought, Image, Or Feeling Categorized.


Table S2. Rating of the Likelihood that the Seafood is Fermented By Common or Usual Name.

Table S3. Compared to Wild Caught ___ Does This ___ Have More, Less, or the Same Amount of.

APPENDIX D

Hallman, W. K., & Hallman, W. K. (2021). A comparison of cell-based and cell-cultured as appropriate common or usual names to label products made from the cells of fish. *Journal of Food Science*, 86(9), 3798-3809.

A comparison of cell-based and cell-cultured as appropriate common or usual names to label products made from the cells of fish

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Abstract: Using an online experiment with a nationally representative sample of 1200 adult American consumers, two “common or usual names,” “Cell-Based Seafood” and “Cell-Cultured Seafood,” were assessed using five criteria. Displayed on packages of frozen Atlantic Salmon, both “Cell-Based” (60.1%) and “Cell-Cultured” (58.9%) enabled participants to differentiate the novel products from “Farm-Raised” and “Wild-Caught” fish and 74% also recognized that those allergic to fish should not consume the product. Thus, both names met key regulatory criteria. Both names were seen as appropriate terms for describing the process for creating the product, meeting the criteria for transparency. There were no significant differences in the perceived safety, naturalness, taste, or nutritiousness of the products bearing the two names. However, participants’ overall impressions associated with “Cell-Based” were rated as more positive than those associated with “Cell-Cultured” ($P < 0.001$, $\eta^2 = 0.010$), as were their initial thoughts, images, and feelings ($P < 0.001$, $\eta^2 = 0.008$). The participants were also slightly more interested in tasting ($P < 0.05$, $\eta^2 = 0.004$) and in purchasing ($P < 0.01$, $\eta^2 = 0.006$) “Cell-Based” than “Cell-Cultured” seafood. After learning the meaning of the terms, participants’ overall impressions of “Cell-Based” remained higher than “Cell-Cultured” ($P < 0.05$, $\eta^2 = 0.003$) and they remained slightly more interested in tasting ($P < 0.05$, $\eta^2 = 0.004$) and in purchasing ($P < 0.05$, $\eta^2 = 0.005$) “Cell-Based” than “Cell-Cultured” seafood. Therefore, “Cell-Based Seafood” should be adopted as the best common or usual name for seafood made from the cells of fish.

Practical Application: Widespread adoption and consistent use of a single “common or usual name” for “Cell-Based” seafood, meat, poultry, and other products by the food industry, regulators, journalists, marketers, environmental, consumer, and animal rights advocates, and other key stakeholders would help shape public perceptions and understanding of this rapidly advancing technol-

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ogy and its products. This study confirms that “Cell-Based Seafood” is the best performing term to label seafood products made from the cells of fish. It meets relevant FDA regulatory requirements and slightly outperforms “Cell-Cultured Seafood” with regard to positive consumer perceptions, interest in tasting, and likelihood of purchasing these novel products.

1 | INTRODUCTION

Development of the technology to bring cell-based meats, poultry, and seafood to market at an affordable price is moving at a rapid pace (Dolgin, 2020; Miller, 2020). Stakeholder adoption and consistent use of a single term to refer to and to label cell-based protein products would help settle regulatory issues, shape public perceptions, and promote a clearer understanding of cell-based products (Hallman & Hallman, 2020). Yet, consensus regarding what to call these products remains elusive, with different stakeholders favoring different terms (Ong et al., 2020).

Balancing both marketing and regulatory considerations, Hallman and Hallman (2020) proposed five criteria for choosing a common or usual name that could be used to appropriately label products made from the cells of fish, shellfish, and crustaceans, and by extension, other cell-based meat, poultry, and game products. In their criterion A, they argued that to meet FDA and USDA regulatory requirements, a common or usual name should enable consumers to distinguish cell-based products from conventionally produced products. For seafood, this means that the common or usual name should signal to consumers that the cell-based seafood is neither wild-caught nor the product of aquaculture (i.e., farm-raised).

Although Hallman and Hallman's criterion A is that the common or usual name convey that there are important differences between cell-based and conventional products, their criterion B is that the common or usual name should also signal important similarities. FALCPA, the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282), requires that foods that consist of, or that contain, protein from a “major food allergen” bear a label that declares that allergen's presence. Because cell-based seafood products will necessarily be produced using the cells of fish, shellfish, or crustaceans, the common or usual name should not suggest that the products are safe to eat by those who are allergic to other seafood products.

Although meeting FDA regulatory requirements is a necessary prerequisite, the common or usual name must also meet the needs of consumers and the companies

making these products. Therefore, Hallman and Hallman (2020) also argued that a common or usual name should be chosen that is seen by consumers as neither “disparaging” of existing conventional products nor of cell-based products (Criterion C). Similarly, they proposed that an effective common or usual name should not elicit consumer reactions that suggest that the cell-based food products are unsafe, unhealthy, or less than nutritious (Criterion D). These latter criteria recognize that if the common or usual name is expected to be adopted voluntarily by producers, it cannot work against efforts to sell either cell-based or conventional products. Although perhaps implicit in the FDA requirements for common or usual names, they set as their Criterion E that consumers view the name as appropriate to identify the product.

Hallman and Hallman (2020) used these five criteria as the basis for testing seven potential common or usual names for cell-based seafood. The names they tested included, “Cultivated Seafood,” “Cultured Seafood,” “Cell-Based Seafood,” and “Cell-Cultured Seafood.” They also tested the phrase “Produced using Cellular Aquaculture” and the phrases “Cultivated from the Cells of ____” and “Grown directly from the Cells of ____,” filling in the blanks with the name of the packaged seafood product. Three controls (wild-caught, farm-raised, and no common or usual name) were also tested as comparisons. To test these names and phrases, they used a 3 × 10 between-subjects experimental design, collecting data online from a quota sample of 3186 U.S. adults drawn from opt-in panels. These common or usual names tested were shown as labels on realistic packages of frozen seafood (salmon, shrimp, and tuna).

The results showed that all of the common or usual names performed equally well in signaling that those allergic to seafood should not eat the products (Criterion B). Each was also seen as an appropriate name to identify the product (Criterion E). However, the majority of the participants were unable to differentiate seafood products labeled with the terms “Cultivated,” “Cultured,” and the phrase “Produced using Cellular Aquaculture” from conventional “Wild-Caught” or “Farm-Raised” seafood. Therefore, none of these terms meet the essential regulatory criterion (A) for common or usual names. Only the

four terms incorporating the word “cell” (“Cell-Based,” “Cell-Cultured,” “Cultivated from the Cells of ___,” and “Grown directly from the Cells of ___”) cued more than half of the participants that the products were neither “Wild-Caught” nor “Farm-Raised.”

Yet, the phrases “Cultivated from the Cells of ___” and “Grown directly from the Cells of ___” performed poorly with respect to the consumer perception/marketing criteria (C and D). Consumers rated products with those terms the least positively and they were seen as most likely to be genetically modified. Importantly, they also performed relatively poorly regarding consumer perceptions of the associated product’s taste, safety, nutrition, and naturalness, particularly in comparison to conventional “Wild-Caught” and “Farm-Raised” products. Consumers also expressed the least interest in tasting, and were least likely to purchase the products with these terms.

Both of the names, “Cell-Based” and “Cell-Cultured,” met the key regulatory criteria and in direct comparisons, the terms “Cell-Based” and “Cell-Cultured” were not significantly different from each other on most of the consumer perception and marketing-related measures tested. Nevertheless, “Cell-Based” was found to outperform “Cell-Cultured” when comparing the pattern of results for each term to those of the conventional “Wild-Caught” and “Farm-Raised” seafood products, with which these novel products would compete in the marketplace.

Although Hallman and Hallman (2020) recommended “Cell-Based” as the best performing term of the seven tested, “Cell-Based” and “Cell-Cultured” generated similar results. The study also had some limitations. It was designed as an initial evaluation of seven potential common or usual names (and three comparisons) and tested these using three different seafood products. The resulting 3×10 experimental design randomly assigned ~100 participants per condition. Because of the large number of statistical tests performed, conservative *P*-values needed to be adopted to reduce experiment-wise error. In addition, the opt-in quota sample was inadequate to project the results to the U.S. population with a reasonable margin of sampling error.

To overcome these limitations, this study examines the two best performing names identified by Hallman and Hallman (2020), “Cell-Based” and “Cell-Cultured,” using a nationally representative sample of 1200 participants, permitting projections of the results to the U.S. population. It also adds measures to better assess the ability of the two names to distinguish the novel seafood product from its conventional counterparts, and measures to further explore consumer perceptions of the products after learning the meaning of the common or usual names.

2 | MATERIALS AND METHODS

2.1 | Experimental design

Two proposed common or usual names, “Cell-Based Seafood” and “Cell-Cultured Seafood,” were tested using a two-group between-subjects design. Group assignment was random and each participant viewed only one of the names tested.

2.2 | Materials

Each name was tested on the label of packages of frozen Atlantic Salmon Fillets. Salmon was chosen because it is one of the most commonly consumed seafood products in the United States (Seafoodhealthfacts.org, 2018), so participants were expected to be familiar with it. Salmon is also high in Omega 3 fatty acids and low in methylmercury, so it is recommended by the FDA and EPA as a “best choice” for consumption by women who are (or might become) pregnant, breastfeeding mothers, and young children (U.S. Food & Drug Administration, 2019).

High-resolution pictures of the front of packages containing frozen Atlantic Salmon were created for this experiment, identical to those used in Hallman and Hallman (2020) (see Figure 1). These were designed to mimic conventional seafood packages currently available in the supermarket. As is typical of such packages, the top one-third depicted a cooked salmon fillet, presented as a “serving suggestion.” The middle third displayed the product title, “Atlantic Salmon Fillets.” The common or usual name to be tested was printed directly below the product title. A Nutrition Facts Label (NFL) with accurate values corresponding to those of conventional Atlantic Salmon Fillets appeared on the bottom third of the package. The net weight was printed at the bottom of the package along with declarations that the product “CONTAINS SALMON,” and is “PERISHABLE,” and advising consumer to “KEEP FROZEN” and to “COOK THOROUGHLY.”

2.3 | Participants

Data were collected between October 6 and October 13, 2020. The study participants consisted of adult American consumers (18 and older) recruited from the YouGov.com web-based consumer panel. YouGov initially interviewed 1780 respondents from whom, a sample of 1600 participants were selected to produce the final dataset, matching a sampling frame derived from the 2018 American



FIGURE 1 Package images

Community Survey (ACS). Of these 1600 participants, 1200 were randomly assigned to complete one of the two experimental conditions reported in this study. A total of 591 participants viewed packages displaying the common or usual name, “Cell-Based Seafood,” whereas 609 viewed packages displaying the common or usual name, “Cell-Cultured Seafood.” Sampling error associated with $N = 600$ is $\pm 4\%$ when projected to the population.

The median length of the experiment was approximately 11.8 min. Consistent with census data, 51.3% of the 1200 participants were female. Mean age was 47.41, $SD = 17.69$; 10.8% reported children under age 5 in the household. When asked “who does the grocery shopping for the household,” 55.4% reported doing “all of it,” 17.7% “most of it,” 15.5% “about half of it,” 8.5% “some of it,” and 2.9% “someone else does all of it.” About nine-in-10 (90.5%) of the participants reported having eaten one or more meals containing seafood in the 12 months prior to the survey. Moreover, 63.6% reported they had eaten at least one seafood meal a month, 31.4% reported that they had eaten at least one seafood meal a week, and 1.2% indicated that they had consumed one or more meal containing seafood

per day. About four-in-10 (42.9%) reported having eaten a salmon fillet in the previous 12 months. Only 8.1% reported that they were “not familiar at all” with salmon in general. Consistent with this, 70.0% reported that they had previously purchased uncooked salmon fillets in a store, online, or at a fish market, 69.5% reported that they had cooked salmon fillets, and 42.0% reported that they had ordered a salmon fillet in a restaurant. The majority (58.6%) reported having previously tasted Atlantic Salmon specifically, with 83.5% of these indicating that they liked its taste. Additional sociodemographic characteristics of the sample provided by YouGov as part of its panel recruitment are shown in Table 1.

2.4 | Procedure

The procedures used were adapted from those reported in Hallman and Hallman (2020). The participants provided informed consent and confirmed that they were 18 years of age or older and so eligible to participate. They then read an inclusive description of the term “seafood” and were asked

TABLE 1 Sociodemographic characteristics of the sample ($N = 1200$)

Sociodemographic characteristic ^a	% of total
Gender	
Male	48.7%
Female	51.3%
Marital status	
Married	44.7%
Single, never married	33.2%
Divorced or separated	14.2%
Living with partner	6.2%
Widowed	5.8%
Educational level	
Less than high school	4.7%
High school/GED	33.8%
Some college	23.0%
2-year college degree (Associate)	8.7%
4-year college degree (BA, BS)	18.4%
Postgraduate	11.5%
Race/Ethnicity	
White	63.1%
Black/African-American	12.1%
Hispanic/Latino	16.2%
Asian	3.5%
Native American	1.3%
Two or more races	2.1%
Other	1.6%
Middle Eastern	0.2%
Household income	
<\$10,000	6.8%
\$10,000–\$19,999	8.5%
\$20,000–\$29,999	12.9%
\$30,000–\$39,999	11.1%
\$40,000–\$49,999	7.7%
\$50,000–\$59,999	6.9%
\$60,000–\$69,999	6.0%
\$70,000–\$79,999	8.3%
\$80,000–\$119,999	4.2%
\$120,000–\$249,999	1.8%
\$250,000–\$349,999	1.7%
\$350,000–\$499,999	0.6%
≥\$500,000	0.4%
Prefer not to say	7.9%

^aCategories and data provided by YouGov, collected as part of their panel recruitment.

how often they had eaten a meal containing seafood in the previous 12 months, and if they had not eaten any seafood, to indicate why. Those who had consumed seafood were then shown a list of seafood and asked to indicate which

they had eaten. The participants were also asked about their familiarity with dietary guidelines for eating seafood, and how many 4-ounce portions of seafood they had eaten in the prior week.

The participants were then shown the image of the package bearing the common or usual name to which they had been randomly assigned. The participants were asked to look at the package carefully, to record (in free text) the “first thought, image, or feeling that comes to mind when seeing this package.” After recording their open-ended responses, each participant rated how positive or negative their thought, image, or feeling was, using a scale ranging from 1 (*extremely negative*) to 7 (*extremely positive*).

To ensure that each participant actively considered the package and its label, the participants saw the package a second time and were asked to repeat the same exercise. Finally, they were presented with the package a third time and asked how positive or negative their overall reactions to the salmon product were, how interested they would be in tasting the salmon, and if it were sold in their grocery store, how likely they would be to purchase it in the next 6 months.

The participants then viewed an enlarged version of the picture of the cooked salmon fillet that appeared on the package. They were asked how familiar they are with salmon overall, whether they had ever tasted Atlantic Salmon, and if so, how much they liked or disliked the taste. Those who indicated that they had previously eaten salmon were asked if they had ever ordered a salmon fillet in a restaurant or purchased it in a store, online, or at a fish market. They were also asked about their likelihood of purchasing uncooked and fully cooked salmon fillets in a store in the next 6 months, whether they have ever cooked salmon fillets, whether it is true or false that salmon is a good source of “heart-healthy” Omega 3s, and if they or anyone who lives in their households is allergic to salmon or to any other seafood.

The participants were then shown an enlarged image of the product name “Atlantic Salmon Fillets” along with the common or usual name to be tested printed below it. While viewing the image, the participants were asked, “Which of the following best describes this salmon?” The response categories were “Wild-Caught,” “Farm-Raised,” and “Neither Wild-Caught nor Farm-Raised.” Those who indicated that it was “Neither Wild-Caught nor Farm-Raised” were then asked a follow-up question, “Which of the following best describes this salmon?” The response categories were “Made from the cells of Salmon,” “Made from the cells of Plants,” and “Made from neither Salmon nor Plant cells.”

The proteins in the cells of fish can cause allergic responses in some individuals. Therefore, it is important that consumers recognize that cell-based seafood products

will also contain potential allergens and avoid eating them. To test this, participants were shown the product title and common or usual name, and were asked, "If you are allergic to fish, is it safe for you to eat this salmon?" They then rated the product's naturalness and how likely they thought that it had been genetically modified.

The NFL was then shown, enlarged so that it could be easily read. While the NFL was still on screen, the participants indicated how nutritious the salmon is, and how good or bad they thought the salmon tastes. Finally, they were asked whether pregnant women should eat the salmon and separately, whether children should consume it.

Because a common or usual name must convey appropriate meaning on its own, no definition of either "Cell-Based" or "Cell-Cultured" Seafood was provided to the participants prior to the final part of the experiment. Participants then read the following description ("Cell-Cultured Seafood" was substituted for those randomly assigned to that condition).

"The term Cell-Based Seafood indicates that this salmon differs from both wild-caught and farmed salmon. It tastes, looks, and cooks the same and has the same nutritious qualities as Atlantic Salmon produced in traditional ways. Yet, it involves a new way of producing just the parts of salmon that people eat, instead of catching or raising them whole. Cell-Based Seafood means that a small number of cells from Atlantic Salmon were placed in a nutrient solution, where they grew and reproduced many times. The resulting meat was then formed into fillets that can be cooked or eaten raw."

After reading this definition, the participants were asked to indicate their existing familiarity with "the *idea* of producing just the parts of salmon that people eat, instead of catching or raising them whole." They were asked to indicate how appropriate the term was "for describing this new way of producing just the parts of salmon that people eat, instead of catching or raising them whole?" They then rated the clarity of the term in communicating that the product "was not caught in the ocean," how clear it communicated that the product was not farm-raised, and whether they agreed or disagreed that Atlantic Salmon that is "Cell-Based" (or "Cell-Cultured") should be "sold in the same section of the supermarket as wild-caught and farm-raised fish."

After having read the description of "Cell-Based" (or "Cell-Cultured") Seafood, the participants were prompted to take a final look at the package of Atlantic Salmon. They were then asked how positive or negative their overall reactions to the salmon were, how interested they would be in tasting it, how likely they would be to buy the product in the next 6 months if it were sold in their grocery store, and how likely they would be to recommend that preg-

nant women buy the salmon. They then answered questions related to a second experiment, the results of which will be summarized in a subsequent article. The participants finished by reporting whether they have any children under the age of 5 living in the household and whether they are the primary shopper in their household.

2.5 | Statistical analyses

Analyses were conducted using IBM SPSS Statistics for Windows (version 27; IBM Corp., Armonk, New York). Differences in means were analyzed using analysis of variance to produce effect sizes using partial eta-squared (η_p^2). Z-tests of column proportions with Bonferroni correction were used to analyze differences in proportions. A *P*-value of 0.05 was used to distinguish significant differences within statistical tests. Where appropriate, weighted data are reported in the tables reporting percentages projected to the U.S. population. To avoid potential distortions in the variance associated with key variables, sample weights were not used when reporting means, standard deviations, the results of ANOVAs, effect sizes, and correlations.

3 | RESULTS AND DISCUSSION

3.1 | Criterion A: Ability to distinguish from conventional products

As shown in Table 2, the majority of those who viewed the name "Cell-Based" (60.1%) and those who saw "Cell-Cultured" (58.9%) on the package label correctly identified the salmon as "neither wild-caught nor farm-raised." There were no statistically significant differences in these percentages, projected to the population. Thus, even in the absence of additional labeling information describing their meaning, both names do a good job of indicating to American consumers that the products are different from conventional wild-caught and farm-raised fish. However, a greater proportion of those who saw the name "Cell-Cultured" (30.1%) assumed that the product was farm-raised than those who saw the name "Cell-Based" (24.9%). In contrast, a greater proportion of those who saw the name "Cell-Based" (15.0%) assumed that the product was wild-caught than those who saw the name "Cell-Cultured" (11.1%).

As shown in Table 2, the largest percentage of those who viewed "Cell-Cultured" (43.9%) and of those who viewed "Cell-Based" (40.8%) indicated that "Made from the cells of Salmon" was the best descriptor for the product. There are no statistically significant differences in these percentages,

TABLE 2 Common or usual name

	Cell-based		Cell-cultured		Total	
	N	%	N	%	N	%
Wild-Caught	88 _a	15.0%	68 _b	11.1%	156	13.0%
Farm-Raised	146 _a	24.9%	185 _b	30.1%	331	27.6%
Neither Wild-Caught nor Farm-Raised	352 _a	60.1%	362 _a	58.9%	714	59.5%
Made from the Cells of Salmon	239 _a	40.8%	270 _a	43.9%	509	42.4%
Made from Neither Salmon nor Plants	66 _a	11.3%	74 _a	12.0%	140	11.7%
Made from the Cells of Plants	47 _a	8.0%	18 _b	2.9%	65	5.4%

Note: $N = 1201$ (weighted data to project to the U.S. population, rounded to whole numbers). Each subscript letter within a row denotes a subset of Common Name categories whose proportions do not differ significantly from each other at the 0.05 level using the Z-test of column proportions with a Bonferroni correction determining the critical value. Only those indicating that the Salmon was Neither Wild-Caught nor Farm-Raised were asked the follow-up question asking whether the product was made from the cells of Salmon, Plants, or Neither, so these answers are shown as a subset of "Neither Wild-Caught nor Farm-Raised."

TABLE 3 Ratings of thoughts, images, or feelings and overall reactions by common or usual name

	M	SD	N	F	P-value	η^2
Rating of first thought, image, or feeling				10.267	<0.001	0.022
Cell-Based	4.84	1.78	591			
Cell-Cultured	4.49	1.94	609			
Rating of second thought, image, or feeling				7.633	<0.01	0.018
Cell-Based	4.69	1.73	591			
Cell-Cultured	4.40	1.91	609			
Overall reactions				11.514	<0.001	0.023
Cell-Based	4.82	1.72	591			
Cell-Cultured	4.46	1.93	591			

Scale: 1 = extremely negative; 2 = moderately negative; 3 = slightly negative; 4 = neither positive nor negative; 5 = slightly positive; 6 = moderately positive; 7 = extremely positive.

projected to the population. Thus, even in the absence of additional labeling, both names do a good job of indicating to American consumers that the products are made from the cells of fish. The smallest percentage (8.0%) of those who saw "Cell-Based" and "Cell-Cultured" (2.9%) thought that the product was "made from the cells of plants." A z-test of column proportions indicated that these proportions are statistically different. A similar proportion (11.3%) of those who viewed "Cell-Based" and 12.0% of those who viewed "Cell-Cultured" thought that the product was made from "neither plant nor salmon cells."

3.2 | Criterion B: Signal the presence of potential allergens

"Cell-Based" and "Cell-Cultured" were equally competent in signaling allergenicity ($H(1) = 1.687$, $P = 0.194$). Overall, participants understood that those with allergies to fish should "not" eat the product ($Mdn = 2.0$), scale: 1 (definitely not), 2 (probably not), 3 (probably yes), and 4 (definitely yes).

3.3 | Criteria C and D: Not be viewed as disparaging of cell-based or conventional products

Each of the open-ended responses to the question, "What is the first thought, image, or feeling that comes to mind when seeing this package?" was coded using one of the 28 categories developed by Hallman and Hallman (2020) (see Table S1). Each response was independently coded by two trained researchers, with any discrepancies resolved by consensus. As shown in Table 3, the thoughts, images, and feelings associated with "Cell-Based" were rated by the participants as more positive than those associated with "Cell-Cultured." Similarly, the participants' overall reaction to "Cell-Based" was also rated more positively than their overall reaction to "Cell-Cultured."

The participants were asked how safe it would be to eat the salmon if one is not allergic to fish, responding using the scale: 1 (very unsafe), 2 (moderately unsafe), 3 (somewhat unsafe), 4 (neither safe nor unsafe), 5 (somewhat safe), 6 (moderately safe), and 7 (very safe). Both the "Cell-Based" ($M = 5.58$, $SD = 1.64$) and "Cell-Cultured" Salmon

($M = 5.54$, $SD = 1.65$) were equally rated as “somewhat” to “moderately” safe to eat ($F(1, 1198) = 0.178$, $P = 0.673$, $\eta_p^2 = 0.000$). They were also equally rated as “moderately” nutritious; “Cell-Based” ($M = 3.55$, $SD = 0.95$), “Cell-Cultured” ($M = 3.55$, $SD = 0.98$) ($F(1, 1197) = 0.002$, $P = 0.97$, $\eta_p^2 = 0.000$) (scale: 1 = [not at all nutritious], 2 [slightly nutritious], 3 [moderately nutritious], 4 [very nutritious], and 5 [extremely nutritious]).

Both products were also equally imagined to taste “slightly” good; “Cell-Based” ($M = 5.09$, $SD = 1.59$), “Cell-Cultured” ($M = 4.99$, $SD = 1.64$) ($F(1, 1198) = 1.337$, $P = 0.25$, $\eta_p^2 = 0.001$) (scale: 1 [extremely bad], 2 [moderately bad], 3 [slightly bad], 4 [neither good nor bad], 5 [slightly good], 6 [moderately good], and 7 [extremely good]). The participants also reported that they were “moderately” interested in tasting both products, though they were slightly more interested in tasting “Cell-Based” ($M = 3.12$, $SD = 1.49$) than “Cell-Cultured” Atlantic Salmon ($M = 2.94$, $SD = 1.52$) ($F(1, 1198) = 4.499$, $P = 0.034$, $\eta_p^2 = 0.004$) (scale: 1 [not at all interested], 2 [slightly interested], 3 [moderately interested], 4 [very interested], and 5 [extremely interested]).

Both products were equally rated as “neither natural nor unnatural”; “Cell-Based” ($M = 4.22$, $SD = 1.87$) and “Cell-Cultured” Salmon ($M = 4.07$, $SD = 1.96$) ($F(1, 1197) = 2.033$, $P = 0.154$, $\eta_p^2 = 0.002$) (scale: 1 [very unnatural], 2 [moderately unnatural], 3 [somewhat unnatural], 4 [neither natural nor unnatural], 5 [somewhat natural], 6 [moderately natural], 7 [very natural]). However, “Cell-Cultured” Salmon ($M = 5.62$, $SD = 1.43$) was seen as slightly more likely to have been genetically modified than “Cell-Based” Salmon ($M = 5.42$, $SD = 1.52$) ($F(1, 1198) = 5.395$, $P = 0.02$, $\eta_p^2 = 0.004$) (1 [extremely unlikely], 2 [moderately unlikely], 3 [slightly unlikely], 4 [neither likely nor unlikely], 5 [slightly likely], 6 [moderately likely], and 7 [extremely likely]).

Overall, the participants believed that pregnant women should probably not consume “either” of the salmon products. Using weighted data, 53.6% of the participants seeing either name indicated that pregnant women should probably or definitely not eat this salmon. Coded as 1 (definitely not), 2 (probably not), 3 (probably yes), and 4 (definitely yes), the median for both “Cell-Based” and “Cell-Cultured” was 2.00. By contrast, the majority in both conditions indicated that children “should” eat the salmon depicted using the same scale. The median for both “Cell-Based” and “Cell-Cultured” was 3.00. About seven-in-10 of those who saw “Cell-Based” (70.6%) and “Cell-Cultured” (69.1%) indicated that children should probably or definitely eat the salmon. Kruskal–Wallis tests indicated no statistically significant differences between the two names with respect to either dependent measure.

3.4 | Criterion E: Be seen as an appropriate term

After viewing the description of the meaning behind “Cell-Based” or “Cell-Cultured,” two thirds of the participants (68%) reported that they were “not familiar at all” “with the idea of producing just the parts of seafood that people eat, instead of catching or raising them whole.” The remaining participants indicated that they were “slightly” (10.7%), “moderately” (11.1%), “very” (6.5%) or “extremely familiar” (3.5%) with the idea (all percentages reported using weighted data). Coded on a scale of 1 (not at all familiar) to 5 (extremely familiar), there were no statistically significant differences between the two names with regard to participant familiarity with the concept ($M = 1.68$, $SD = 1.12$). Similarly, using a scale of 1 (extremely inappropriate) to 7 (extremely appropriate), both of the names were seen identically as “slightly appropriate” ($M = 4.97$, $SD = 1.81$) “for describing this new way of producing just the parts of salmon that people eat, instead of catching or raising them whole.”

Participants were also asked how clear the term they viewed is, “in communicating that the salmon was not caught in the ocean,” and in communicating that it was not “Farm-Raised,” responding using the scale: 1 (extremely unclear), 2 (moderately unclear), 3 (slightly unclear), 4 (neither clear nor unclear), 5 (slightly clear), 6 (moderately clear), and 7 (extremely clear). The participants who saw “cell-cultured” indicated that the term was slightly clearer in communicating that, “the salmon was not caught in the ocean” ($M = 4.52$, $SD = 2.07$), than those who saw “Cell-Based” ($M = 4.12$, $SD = 2.18$) ($F(1, 1198) = 10.48$, $P = 0.001$, $\eta_p^2 = 0.009$). Similarly, “Cell-Cultured” was seen as slightly clearer in communicating that “the salmon was not farm-raised” ($M = 4.38$, $SD = 2.09$), than “Cell-Based” ($M = 4.09$, $SD = 2.16$) ($F(1, 1198) = 5.315$, $P = 0.021$, $\eta_p^2 = 0.004$).

It should be noted that these responses were given “after” reading the explanation of the meaning of the terms. Yet, when seeing the terms “Cell-Based” and “Cell-Cultured” on the packages at the beginning of the experiment (prior to explaining their meaning), both were seen equally as “Neither Wild Caught nor Farm Raised.” Moreover, a greater proportion of those who saw the name “Cell-Cultured” assumed that the product was farm-raised than those who saw the name “Cell-Based,” whereas a greater proportion of those who saw the name “Cell-Based” thought that the product was “Wild-Caught.” On its own (without explanation), therefore, “Cell-Cultured” does not appear to be clearer than “Cell-Based” in demonstrating that the salmon was not produced using traditional methods.

The participants were asked to indicate their level of agreement that the “Cell-Based” and “Cell-Cultured” salmon they viewed should be sold in the same section of the supermarket as “Wild-Caught” and “Farm-Raised” seafood, using a scale of 1 (*strongly disagree*) to 7 (*strongly agree*). The mean responses for both terms were identical ($M = 4.31$, $SD = 1.90$) (4 = *neither agree nor disagree*).

3.5 | Consumer perceptions post-explanation of the meaning of the term

The participants who saw packages labeled as “Cell-Based” had slightly more positive overall reactions ($M = 4.24$, $SD = 1.93$) than those who saw packages labeled as “Cell-Cultured” ($M = 4.01$, $SD = 1.93$) ($F(1, 1198) = 4.164$, $P = 0.042$, $\eta_p^2 = 0.003$) (scale: 1 [*extremely negative*] to 7 [*extremely positive*]). Those who saw “Cell-Based” also expressed slightly more interest in tasting the salmon ($M = 2.83$, $SD = 1.47$) than those who saw “Cell-Cultured” ($M = 2.65$, $SD = 1.51$) ($F(1, 1198) = 4.397$, $P = 0.036$, $\eta_p^2 = 0.004$) (scale: 1 [*not interested at all*] to 5 [*extremely interested*]). Those who saw “Cell-Based” also indicated greater likelihood of purchasing the salmon in the next 6 months ($M = 3.77$, $SD = 2.22$) than those who saw “Cell-Cultured” ($M = 3.45$, $SD = 2.26$) ($F(1, 1198) = 6.308$, $P = 0.012$, $\eta_p^2 = 0.005$) (scale: 1 [*extremely unlikely*] to 7 [*extremely likely*]). However, they were equally unlikely to recommend that pregnant women buy the salmon; “Cell-Based” ($M = 3.34$, $SD = 1.97$), “Cell-Cultured” ($M = 3.26$, $SD = 2.03$) ($F(1, 1198) = 0.488$, $P = 0.485$, $\eta_p^2 = 0.000$) (scale: 1 [*extremely unlikely*] to 7 [*extremely likely*]).

3.6 | Discussion: Determining the best performing common or usual name

It should be noted that a common or usual name is required by U.S. law as a “statement of identity,” and must communicate “on its own” (i.e., free from other supporting statements) that the product is different in some substantial way from the existing products with which it might be confused. It must also communicate this to all shoppers who read the label, and not just to those who regularly shop for seafood or to consumers who are already inclined to purchase cell-based seafood. It must also appropriately communicate the identity of the product to those who would wish to avoid it. Therefore, this study employed a representative sample of adult American consumers, rather than targeted samples of likely seafood consumers only. The logic of the study design also assumes

that although most consumers are likely already familiar with both “wild-caught” and “farm-raised” seafood products, initially, most will be unfamiliar with cell-based products prior to encountering them in the supermarket. That nearly 80% of the participants said they were unfamiliar with the “idea” of producing just the parts of Salmon that people eat instead of catching or raising them whole suggests that this is currently the case. Given this, seeing a seafood product with an unfamiliar common or usual name will not automatically cue the fact that there is a new “third-way” of producing seafood that is neither “wild-caught” nor “farm-raised.”

Much of the prior research designed to address the issue of appropriate nomenclature for these products has focused mainly on issues of consumer acceptance (Bryant & Barnett, 2018, 2020). This approach makes sense from a marketing perspective because the promised benefits of cell-based meats, poultry, and seafood (Stephens et al., 2018; Tomiyama et al., 2020) can only be realized if consumers are willing to purchase them. However, the term ultimately used to label cell-based products must meet regulatory criteria as well as marketing criteria. Names chosen solely to maximize potential consumer acceptance (Szejda, 2018) may fall short of regulatory requirements or may be viewed as false or misleading by regulators or as lacking transparency by consumers. Therefore, the study assessed five criteria to determine the name that best meets the requirements of producers, consumers, and regulatory agencies.

The results of this study confirm the findings in Hallman and Hallman (2020). On their own, both “Cell-Based Seafood” and “Cell-Cultured Seafood” signaled to 60% of consumers that the novel product differs from conventional “wild-caught” and “farm-raised” salmon (meeting criterion A). Without any additional explanation, more than 40% also directly understood that the products were made from the cells of salmon. Both terms were equally able to signal potential allergenicity, with 72.6% of those who saw “Cell-Based Seafood” and 75.4% of those who saw “Cell-Cultured Seafood” indicating that those allergic to seafood should “probably” or “definitely not” consume the product (meeting criterion B). Therefore, both terms tested meet the key regulatory criteria.

Both terms are also seen as appropriately descriptive “for describing this new way of producing just the parts of Salmon that people eat, instead of catching or raising them whole” (meeting criterion E). This should be of importance to producers. Because of the purported environmental, ethical, health, and other benefits associated with cell-based meat, poultry, and seafood, companies should want to transparently differentiate their cell-based products from their conventional counterparts. They may also find such differentiation necessary to justify the price

premium likely needed to be charged when cell-based products initially make it to market.

Producers of cell-based meat will also want to avoid repeating the errors made in introducing GM (genetically modified) foods to consumers (Hallman, 2018). One of the mistakes made by producers of GM foods was to send unlabeled GM products into Europe and other markets where they faced significant resistance. The resulting backlash created longstanding consumer mistrust of producers of GM products and of Genetically Modified Organisms (GMOs) in general (Mohorčič & Reese, 2019). In choosing to voluntarily differentiate their products using a transparent common or usual name, producers of cell-based meat, poultry, and seafood would also likely preempt efforts to mandate labeling of their products using terms they may find limiting or pejorative.

Products labeled with either term are seen as equally safe and nutritious and are presumed to taste equally as good. Neither is seen as unnatural, although the products labeled as “Cell-Cultured” were seen as slightly more likely to have been genetically modified.

From a marketing perspective, packages of Atlantic Salmon Fillets with the common or usual name “Cell-Based Seafood” were rated by participants as slightly more positive than those with the common or usual name “Cell-Cultured Seafood.” Both before and after reading the description of the meaning of the terms, participants reported slightly more positive overall impressions, slightly greater interest in tasting, and slightly greater likelihood of purchasing the products labeled as “Cell-Based Seafood” than those labeled as “Cell-Cultured Seafood.”

Although the mean differences and associated effect sizes in these measures are small, the pattern of those differences is consistent. They also add to those of Hallman and Hallman (2020), who found that the pattern of results associated with “Cell-Based” was similar to those of “Wild-Caught” and “Farm-Raised” seafood products, whereas the pattern of those associated with “Cell-Cultured” was dissimilar. In that study, initial reactions to “Cell-Based Seafood” were as positive as they were to both “Wild-Caught Seafood” and “Farm-Raised Seafood.” The products labeled as “Cell-Based Seafood” were also judged to be as nutritious as both “Wild-Caught” and “Farm-Raised” seafood, whereas “Cell-Cultured” products were not. Participants imagined that “Cell-Based Seafood” tasted as good as both “Wild-Caught” and “Farm-Raised” seafood. They were also equally interested in tasting and likely to purchase “Cell-Based Seafood” as they were seafood that was either “Wild-Caught” or “Farm-Raised.” In contrast, those who saw “Cell-Cultured Seafood” products were only as interested in tasting and purchasing them as they were in tasting and purchasing “Farm-Raised” seafood products. Thus, the overall pattern of results from

this study combined with those of Hallman and Hallman (2020) suggests that “Cell-Based” is currently the better choice for a common or usual name for seafood made from the cells of fish, based on measures of likely consumer acceptance and purchase of these innovative products.

4 | CONCLUSION

This study confirms that “Cell-Based Seafood” is the best candidate for a common or usual name for seafood made from the cells of fish. It meets the regulatory requirements to signal (on its own) that the novel products are not the same as conventional wild-caught and farm-raised seafood. At the same time, combined with the product name, “Atlantic Salmon Fillets,” it indicates to consumers that the products are made from the cells of fish, and therefore, those who are allergic to fish should not eat them. From a marketing perspective, “Cell-Based” is viewed as an appropriate term for describing the process for producing the products, meeting the need for transparency in labeling. Additionally, consumers indicate that they perceive “Cell-Based Seafood” products more positively than “Cell-Cultured” and are slightly more inclined to want to taste and purchase “Cell-Based” products. Therefore, the term “Cell-Based Seafood” should be considered the best common or usual name to be used to label seafood products produced from the cells of fish.

4.1 | Limitations

As with any online experiment, there are limitations to this study. This study only examines the terms “Cell-Based” and “Cell-Cultured” with respect to seafood. Although it builds on an earlier study testing seven potential common or usual names, it provides a comparison of only the two best names derived from that study within a representative sample of American consumers. Other names have been suggested by various stakeholders that might be tested in future research. Additional studies are also needed to assess these terms with respect to cell-based meat, poultry, and other products that also require a similar statement of identity.

The study represents a current snapshot of consumer beliefs, attitudes, and intentions with respect to potential statements of identity for a novel product with which most are unfamiliar. However, common or usual names are established by common use. As consensus is developed with respect to an optimal common or usual name and it is used with greater frequency by companies, regulators, journalists, advocates, critics, and others, consumers will become much more familiar with its connection to

the novel products for which it serves as a statement of identity. Thus, the results of this study serve as a baseline. Future studies may be needed to assess consumer perceptions, particularly as cell-based products enter the marketplace.

The common or usual name is intended to appropriately identify the product as a particular type of food, distinguishable from others. It is not intended to communicate all of the benefits or advantages of the product. Marketers using the common or usual name are able to add truthful but not misleading statements to the label, including claims related to health, sustainability, and the environment, free from claims, and any others that they think may help to sell the product. The testing of such claims on labels bearing the terms “Cell-Based” or “Cell-Cultured” will no doubt be undertaken in future marketing studies.

The ultimate goal of many cell-based seafood companies is to create novel products that will look, taste, cook, and have the same form, texture, and nutritional values as their conventional counterparts. These products are still in their developmental stages, and none have been approved for sale in the United States or elsewhere. Therefore, the image of the cooked salmon fillet presented on the package in this study is aspirational and does not represent a currently available cell-based seafood product. Yet, showing an example of a cooked cell-based salmon product in its future idealized form (matching the essential characteristics of conventional salmon fillets) represents the most difficult test of key regulatory criterion (A). That is, the ability of the common or usual name “by itself” to help consumers distinguish the novel product from the “wild-caught” and “farm-raised” products with which consumers are already familiar. Because the image on the package looks like conventional salmon, consumers had only the common or usual name being tested to distinguish it from conventional salmon.

However, because cell-based seafood products do not yet exist in the marketplace, no consumer has had any experience with such products. Thus, the participants were asked to consider a hypothetical product, with which none could have any real familiarity. The participants viewed an image of a conventional salmon fillet on the package as a stand-in for the hypothetical cell-based product, which likely influenced their perceptions of it. Real cell-based seafood products that finally reach the market may look different, so consumer reactions to those images, and the product packages bearing them may also be different. Future research designed to measure consumer reactions to various forms of cell-based seafood may help marketers better gauge potential receptivity for their products.

Finally, the packaging shown in the experiment was specifically designed as a vehicle for comparing the suitability of common or usual names as a statement of prod-

uct identity. It was not created to test consumer reactions to the packaging design itself, or to test the acceptability of the package for retail purposes in the United States or any other market. Future studies intended to test optimal design elements for packages marketing “Cell-Based” or “Cell-Cultured” seafood products may fill this gap.

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Data collection and analysis was supported by BlueNalu through a contract providing full-academic freedom to the authors, including the right to choose the terms to be tested, identify and apply the appropriate evaluation criteria, design the study evaluating the terms, select appropriate measures, collect and analyze the data, and publish the results in a peer-reviewed journal, without the direction or interference of the company. A preprint version of this paper was published at <https://doi.org/10.1101/2021.02.26.433119>

AUTHOR CONTRIBUTIONS

William K. Hallman—Conceptualization; formal analysis; funding acquisition; investigation; methodology; project administration; supervision; writing original draft; writing review editing. William K. Hallman II—Data curation; formal analysis; investigation; validation; visualization; writing original draft; writing review editing.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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APPENDIX E

AMPS Innovation and NFI Joint Letter in Response to FDA's RFI

Dated March 8, 2021



March 8, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Request for Information: Labeling of Foods Comprised of or Containing Cultured Seafood Cells,
Docket No. FDA-2020-N-1720

Together, as representatives of the leading conventional seafood and cell-cultured meat, poultry and seafood companies, the National Fisheries Institute (NFI) and the Alliance for Meat, Poultry and Seafood Innovation (AMPS Innovation) write to express our support for a labeling framework for cell-cultured seafood that fosters transparency, consumer confidence, and a level playing field across FDA regulated products, conventional and cell-cultured alike, that also aligns with longstanding law and policy.

Background:

As the global demand for seafood increases, the need for expanded production, increased accessibility, and a more diversified supply is greater than ever before. Meeting these needs will require innovative solutions and a clear, science-based regulatory system that supports these new production methods while also ensuring robust food safety standards, consumer confidence, and consumer choice. These innovative solutions are intended to complement the current supply of conventionally harvested wild-caught and farm-raised seafood products, as a third source of seafood and thereby strengthening the overall seafood system. One such innovative solution involves cell-cultured processes that are used to produce an additional source of real, healthy, and trusted seafood for consumers to enjoy.

Although cell-cultured seafood products are not yet on the market, in the U.S. or globally, these products are rapidly approaching commercialization. To continue to stand as a leader at the forefront of food innovation, the United States should continue the work done thus far to foster a regulatory pathway for cell-cultured products in the U.S. A critical component of this is ensuring a labeling framework that ensures consumer transparency, supports consumer choice, and creates a fair, non-disparaging playing field across products.

On March 7, 2019, FDA and USDA signed a joint agreement outlining each agency's intended roles with respect to the oversight of human food produced using animal cell culture technology. In implementing this joint agreement, the agencies have committed to developing 'joint principles for product labeling and claims to ensure that products are labeled consistently and transparently.' Subsequently, in October 2020, the FDA issued this Request for Information and USDA also indicated that it would issue an Advanced Notice of Proposed Rulemaking, both intended to seek feedback regarding labeling for these products.

Our Position:

As representatives of the farmed, wild-caught, and cell-cultured seafood industries, we appreciate this opportunity to share our collective views with the FDA on the key issue of labeling for seafood produced using cell cultured technology. Our priority is for products made through this new production method to be labeled descriptively, accurately, and consistently to represent what the products actually are, how they are made, and ensure robust consumer transparency. Accordingly, we believe that labeling of seafood products produced using cell cultured technology should be thoughtfully based on the following key criteria:

1. Truthful, non-misleading, descriptive, and clear, communicating to the consumer what the product is and how it is produced, in line with FDA's regulatory requirements.

We believe that seafood products produced using cell culture technology should be labeled in a way that is truthful, non-misleading, descriptive, and clear so as to inform consumers of what the products are and how they are produced. To do so, it is critical that these products are differentiated from and are clearly identifiable in comparison to their conventional counterparts through an accurate and descriptive qualifier or modifier. In addition, labeling should not be misleading in describing characteristics about the product, or its conventional counterparts in comparison.

2. Signal potential allergenicity and nutrition for consumer safety and transparency.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (Public Law 108-282) requires that foods containing protein from a "major food allergen" declare the presence of that allergen on the label. Since seafood produced using cell culture technology is real seafood, it also will contain allergenic proteins similar to that in conventional seafood. In order to ensure consumer health and safety, the labels on these innovative seafood products will need to clearly signal this similarity to consumers to put those with seafood allergies on notice that the same risks apply as with conventional seafood. As required by FALCPA, the specific the type of finfish or crustacean shellfish would need to be declared.

3. Non-disparaging to either cell-cultured or conventional seafood products.

The label should not be disparaging or elicit negative connotations for either cell-cultured products or their conventional counterparts but create a fair marketplace for all seafood products alike. In specific, the label should not evoke thoughts, images, or emotions that create questions or concerns regarding the safety or nutritional quality of the seafood product, whether conventional or cell-cultured.

4. Differentiated from conventionally produced wild or farmed seafood products through a qualifier that modifies the conventional name of the product.

In order to clearly differentiate from conventionally produced wild or farmed seafood products, an appropriate qualifier should be used to denote seafood products that are produced using the method of cell cultured technology. The qualifier should be science-based, accurate, and informed by peer-reviewed, published consumer studies. In addition, the qualifier should modify the conventionally used

acceptable market name/common name¹ of the product, for example ‘bluefin tuna’, to ensure consumer understanding of what the product is in terms of taste, texture, and nutritional composition.

Thus far, only Rutgers Professor Dr. William Hallman has published a peer-reviewed consumer study specifically designed to assess common or usual names that are consistent with FDA regulation², and has conducted a second, confirmatory study currently under peer-review and available as a pre-print³.

Dr. Hallman, Chair of the Department of Human Ecology at Rutgers University and a former Chair of FDA’s Risk Communications Advisory Committee, designed both research studies to determine the most appropriate nomenclature, and hence labeling, that protects consumer expectations and transparency, avoids consumer confusion, and aligns with the relevant FDA regulations on labeling.

In July 2020, the first of Dr. Hallman’s peer-reviewed studies was published in the Journal of Food Science. This study examined the potential nomenclature for seafood products produced using cell cultured technology by evaluating consumer understanding of various terms and consumer ability to differentiate these innovative products from their conventional counterparts. The terms tested were: “cell-based,” “cell-cultured,” “cultivated,” and “cultured;” and the phrases, “produced using cellular aquaculture,” “cultivated from the cells of _____,” and “grown directly from the cells of _____,” (with the blanks representing the commonly referenced seafood product (e.g. bluefin tuna, etc.)).

As the basis for this research, Dr. Hallman developed and utilized five criteria to evaluate each term, including their ability to:

1. Enable consumers to distinguish cell-cultured seafood from wild and farmed seafood;
2. Signal potential allergenicity of consuming seafood made from cells;
3. Be seen by consumers as an appropriate term to identify the product;
4. Not disparage either cell-cultured or conventional seafood products; and
5. Not evoke thoughts, images, or emotions that are inconsistent with the idea that the products are safe, healthy, and nutritious.

In the study, encompassing a nationally representative sample of adults, Dr. Hallman found that consumers most clearly understood the nature and production process of these innovative products when denoted by the qualifier “cell-based” or “cell-cultured.” (Hallman, 2020). Subsequently, Dr. Hallman conducted a second study to further evaluate the terms ‘cell-based’ and ‘cell-cultured,’ using a large, nationally representative sample of 1,200 participants. This study also will be published in the near future.

Once again, the study’s findings demonstrated that the qualifiers “cell-based” and “cell-cultured” best inform consumers about the nature of these seafood products. Further, Dr. Hallman’s research clearly identifies that terms not containing the word “cell,” such as “cultured” and “cultivated,” underperform

¹ As recommended in FDA’s Seafood List

² Hallman, W.K. and Hallman, W.K., II (2020), An empirical assessment of common or usual names to label cell-based seafood products. Journal of Food Science, 85: 2267-2277. <https://doi.org/10.1111/1750-3841.15351>

³ Hallman, W.K. and Hallman, W.K., II (2021), A comparison of cell-based and cell-cultured as appropriate common or usual names to label products made from the cells of fish (under review). bioRxiv preprint: <https://doi.org/10.1101/2021.02.26.433119>

based on the criteria of differentiating these products from conventional seafood, relative to terms that include the word cell.

5. Reference the appropriate market or species name as outlined in the Seafood List and the Regulatory Fish Encyclopedia

In addition to the requisite qualifier that signals the cell culture production method, these seafood products should include the same market or species names as their conventional counterparts (e.g., “tuna” or “salmon”), as memorialized in FDA’s Seafood List and the Regulatory Fish Encyclopedia. Not only does this accurately describe the product and what it is, including its taste/texture and nutritional attributes, but more so it ensures consistency with the current labeling paradigm across seafood products, thereby ensuring consumer understanding and transparency.

6. Uniform within the cell-cultured seafood categories, and consistent with the meat and poultry categories.

As these products commercialize and reach the market in the United States, it is essential they are labeled clearly and uniformly within the seafood category, and consistently across meat and poultry product categories, in order to minimize consumer confusion and maximize consumer understanding, transparency, and reception.

We note the following:

- First, that Dr. Hallman concluded that the terms “cell-based” and “cell-cultured” performed best on the five criteria he set forth.
- Second, that cell-cultured meat and poultry companies prefer the term “cell-cultured” to “cell-based,” and so for the sake of achieving consistency across all product categories, we support the term “cell-cultured.”

With respect to this RFI, and per the USDA/FDA Formal Agreement to “develop joint principles for product labeling and claims to ensure that products are labeled consistently and transparently,” **NFI and the super-majority of AMPS Innovation, including all of the cell-cultured seafood companies, urge the FDA to adopt and memorialize the sole use of the term “cell-cultured”** to support uniform labeling within the seafood category. Although we defer to FDA on the most appropriate method for doing so, we believe that issuing a Compliance Policy Guide (CPG) and letter to industry would provide appropriate guidance.

Summary:

In sum, as representatives of the leading conventional seafood and cell-cultured meat, poultry and seafood companies, it is our combined priority for products made through this new production method of cell cultured technology to be labeled descriptively, accurately, and consistently in order to represent what the products actually are, how they are made, and ensure robust consumer transparency. We think that it is significant that the National Fisheries Institute and the Alliance for Meat, Poultry and Seafood Innovation came together to support a single term, one that the evidence demonstrates consumers will understand. We thank the FDA for this opportunity to share our collective views on this very important topic and look forward to continuing to support the agency as it pioneers and fosters a

regulatory pathway to market, including a labeling framework, for cell-cultured seafood products, and this evolving industry, in the U.S.

Sincerely,

The Alliance for Meat, Poultry and Seafood Innovation (AMPS Innovation)
The National Fisheries Institute (NFI)