CENTER FOR
Science IN THE
Public Interest
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Nutrition Action Healthletter

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By Electronic Submission
Docket No. FDA-2020-N-1720
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Comments to Request for Information on Labeling of Foods Comprised of or Containing Cultured Seafood Cells

The Center for Science in the Public Interest (CSPI)[1] appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on how foods comprised of, or containing, cultured seafood cells should be labeled.

Importantly, FDA has an opportunity to establish naming conventions for a new category of products with which consumers are not yet familiar. Choosing the terms that should be included in the name or standard of identity of products from animal cell culture technology is crucial to the successful adoption of these novel food products. FDA's leadership in this arena can influence marketplace success, consumer confidence, and even naming conventions for cell-cultured seafood in other countries.

While CSPI does not propose a particular phrase for identifying those foods for consumers as FDA requests, we believe FDA should select a phrase that is accurate, neutral, and informative to consumers. Below, we set forth issues, principles, and criteria that FDA should consider when deciding what term or phrase will identify foods with cultured seafood cells.[2]

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[1] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by 400,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry and no grants from the federal government.

[2] The FDA Request for Comment refers to "cultured animal cells" for the food products which they are considering how to label. For the remainder of this comment, CSPI refers to these food products as "cell cultured." While CSPI believes FDA should consider "cell-cultured" as a one possible term to label these foods, it is not endorsing that terminology as the best or only phrase that would satisfy the criteria CSPI sets forth in the comment and meet FDA regulatory obligations.

I. The Labeling for Cell-Cultured Seafood Products Should Identify Any Safety Concerns and Nutritional Differences [Question 5]

There are no cell-cultured seafood products available on the market and little, if any, public information about the production process that will be used to produce those final products at scale (including the constitution of the final product and the inputs used to produce the products). Therefore, it is impossible to know whether the final products will pose safety concerns or nutritional differences that should be specified on the product's label.

However, since these products will be considered "substitutes" and/or "functional equivalents" for similar traditionally produced seafood products, any relevant safety concerns or nutritional differences should be reflected on the label.

When cell-cultured seafood products are ready for their food safety assessment at FDA, the agency, with stakeholder input, should identify material differences from traditional products and then make consumers aware of those differences on the product label. The following are some examples of possible safety concerns and/or nutritional differences that FDA should ensure are identified on product labels, if applicable:

- **Allergens.** Some consumers are allergic to certain seafood species. If a product contains cells from a species that can invoke an allergic reaction, the name of that species should be include in the common name and the product should contain a warning statement about the potential allergen.

- **Food Safety Handling Differences.** Cell-cultured seafood will be produced in large fermentation tanks instead of from live animals. Once processed, those products may require different handling or cooking instructions to be safely consumed. FDA should require that information be included on the label. This information is important to educate consumers about how to handle these new products and to identify any differences in handling and cooking from the traditional seafood product it mimics. For example, if cell-cultured seafood can be eaten raw and at room temperature due to its production in a sterile process, we do not want consumers mistaking traditional seafood for cell-cultured seafood and consuming it without appropriate preparation, thereby introducing risk of foodborne illness.

- **Nutritional Differences.** Consumers expect certain nutritional components in a seafood product, such as omega three fatty acids from some fish species. If the cell-cultured product has a significantly greater or lesser amount of a nutrient compared to its traditional counterpart, FDA should ensure those differences are

identified on the label. Labels should identify all nutritional differences that individual consumers might consider material to their purchase or consumption of the product.

II. FDA Should Ensure that Labels for Cell-Cultured Seafood Products are Non-Misleading and Inform Consumers of all Material Facts. The "Common Name" Should Distinguish the Products from Traditional Seafood. [Questions 1 and 3]

Today's consumers care about knowing where their food comes from. Any information provided to consumers should be accurate, non-misleading, informative, accessible, and not result in consumer confusion. Cell-cultured seafood products should have labels with a standardized term that conveys to consumers the difference between the product and seafood produced using traditional methods (*e.g.*, wild-caught, farm-raised). It also should inform consumers about any potential allergens. FDA's task is to find a term or phrase that satisfies these criteria.

A. The Name Should be the Acceptable Market Name of the Seafood Species with an Appropriate Qualifier Phrase that is Consistent across all Cell-Cultured Products.

Consumers are used to identifying seafood products by the common market species name, as found in the FDA Seafood List. CSPI believes that the best way to label cell-cultured seafood products is to use the common name of the comparable traditional product but qualify that name with words that signal to the consumer that the product is one made with cell-culture technology. It is critical that the accompanying qualifiers distinguish for the consumer the differences in production processes with clarity and transparency.

The chosen accompanying qualifier language should be required for all cell-cultured seafood products, as the method of production does not vary significantly enough between seafood species at this time to justify establishing different qualifiers for different species or products. Use of the same term will enhance consumer recognition and understanding of the new products as consumers learn to identify a specific, standardized term with the new technology. If non-standardized qualifying terms are used for different species, consumers could be misled into thinking that the cell-cultured salmon and shrimp are not produced using the same general production methods.

Also, it is critically important to include the specific species name on the label so that consumers who have seafood allergies will be able to identify products they should avoid.

Consumers with seafood allergies have learned to read labels to identify seafood species they should avoid.

B. Misleading and Inaccurate Terms Should Not Be Permitted

Stakeholders who support and oppose cell-cultured animal products have proposed different terms to identify these products. Many of the proposed terms are misleading and some may not be accurate (*e.g.*, if they do not convey to the consumer how the product was produced and is different from the traditional product).

Some terms suggested by opponents of the technology to stigmatize these products, Those terms, such as "synthetic" and "artificial," may not be clear to consumers and FDA should eliminate them from consideration. Such terms, which are already in use on foods (particularly "artificial"), likely fail to adequately convey the distinctions related to production methods that characterize these foods.

Similarly, FDA should eliminate some terminology which has been proposed by product developers to make implicit claims of superiority. Those terms could be perceived by consumers as creating the perception of product benefits not rooted in facts. For example, labeling cell-cultured seafood "clean" is not sufficiently descriptive and does not communicate factually about the nature of the food: "clean seafood" does not tell the consumer what technology was used to create the cell-based product. Similarly, terms such as "humane" or "cruelty-free" fail to inform the consumer about how cell-based production differs from traditional seafood.

In its request for comments, FDA specifically mentions "cultivated" and "cultured" as possibilities terms they could require on seafood labels. Without further qualification of those terms, we note that they are not appropriate for labeling because they do not appropriately convey for consumers how the products were produced.

"Cultivated" terminology has been embraced by proponents of the cell-cultured protein products and stems from the use of meat *cultivators* (bioreactors) in the production process of cell-based foods.[3] While those versed in the science and business of cellular agriculture may recognize that a "cultivated" product refers to seafood produced using cultivators, average consumers are unlikely to understand the reference. Consumers will likely not understand how a cultivated seafood product is distinct from a traditional seafood product, nor would it be conveyed by the term.

[3] Friedrich, Bruce. "Cultivated meat: Why GFI is embracing new language," Good Food Institute, Sept. 13, 2019. At https://gfi.org/blog/cultivatedmeat/

Additionally, the term "cultured seafood," while factually correct (since the cells are grown in a cell culture medium during the production process), does not accurately communicate to consumers how the product is different from traditional seafood. The term "cultured," when used alone, is confusing because it does not include *what* was cultured to produce the seafood and could not reasonably be inferred to refer to cell culture technology (especially by consumers who are not even aware that this new technology exists). "Cultured" also has a recognized meaning as fermented, *e.g.*, cultured dairy products like cheese, yogurt, and kefir, which may confuse consumers into thinking they are purchasing a fermented product.

C. FDA Should Conduct Consumer Studies and Consider the Results of Peer-Reviewed Studies to Help Determine the Best Common Name for Cell-Cultured Seafood.

To date, no consumer in the U.S.? has ever purchased cell-cultured seafood, which provides the FDA with an opportunity to introduce a name that will be accurate and informative to consumers from the inception of the technology. To inform FDA about which possible terms would meet its regulatory obligations, FDA should conduct consumer research, such as surveys and/or focus groups. In addition, FDA should consult peer-reviewed studies that have examined possible nomenclature for cell-cultured products. Objective data and analysis on consumer perceptions of different terms will help FDA make an informed and reasoned decision on the best label statement.

To help with the design of its own studies, we encourage FDA to review the work of William K. Hallman and William K. Hallman II.[4] Those studies are noteworthy because they explicitly focus on the terminology for seafood products and were conducted with an eye towards regulatory considerations. One of the most useful aspects of those studies is the analysis of potential labeling terms based on five regulatory and market criteria the chosen term should satisfy. Those five criteria are that the term: (1) allow the consumer to differentiate the product from conventionally produced product; (2) identify potential allergenicity; (3) is seen by the consumer as an appropriate term to identify the product; (4) is not disparaging to the cell-cultured products nor the traditional products; and (5) does not elicit responses that the products are not nutritious, healthy, or safe. CSPI recommends that FDA use similar criteria in its own research when deciding on what label information to provide consumers.

[4] See William K. Hallman and William K. Hallman II. "An empirical assessment of common or usual names to label cell-based seafood products," *Journal of Food Science*, vol. 85:8 (2020) doi: 10.1111/1750-3841.15351; William K. Hallman and William K. Hallman II, "A Comparison of Cell-Based and Cell-Cultured as Appropriate Common or Usual Names to Label Products Made from the Cells of Fish." 2021, *Journal of Food Science*, https://doi.org/10.1101/2021.02.26.433119.

FDA should also take into consideration the results of the two Hallman and Hallman empirical studies. In the first study, Hallman and Hallman randomly surveyed over 5,000 participants and tested perceptions of seven names for cell-cultured seafood products, and the terms "wild-caught" and "farm-raised," using commonly consumed seafood varieties in the United States.[5] Participants were shown sample packaging, asked questions about their perceptions on allergens in cell-cultured products, whether cell-cultured products should be sold alongside conventional seafood products, and about their familiarity with "the idea of producing just the parts of salmon/tuna/shrimp that people eat, instead of catching or raising them whole." They were also asked whether a pre-selected term was appropriate "for describing this new way of producing just the parts of salmon/tuna/shrimp that people eat, instead of catching or raising them whole?"[6] From their survey, they found that participants had the highest likelihood of correctly identifying cell-cultured products when the word "cell" was included in the terminology (*e.g.*, "Cultivated from the Cells of," "Cell-Based," "Cell-Cultured," "Grown Directly from the Cells of").[7] Based on the results, Hallman & Hallman conclude that "cell-based seafood" is the best terminology for animal cell cultured seafood.

This year, Hallman and Hallman will publish a second study regarding nomenclature for cell-cultured seafood.[8] This study builds on the prior research and more closely examines the use of the terms "cell-based" and "cell-cultured," the two phrases preferred by consumers in the first study. The 2021 study reaffirmed that both terms are good options for labeling seafood made by cell technology but found a greater likelihood of purchase for "cell-based" products over "cell-cultured" seafood products.

Based on the results of the two Hallman and Hallman studies, CSPI finds that both "cell-cultured" and "cell-based" would inform consumers of material facts and not be misleading, as well as portray the product in a neutral fashion. FDA should closely consider these options, and other peer-reviewed studies, in addition to conducting its own studies before making a final decision on its final label phrase.

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[5] William K. Hallman and William K. Hallman II. "An empirical assessment of common or usual names to label cell-based seafood products," *Journal of Food Science*, vol. 85:8 (2020) doi: 10.1111/1750-3841.15351;

[6] Hallman & Hallman (2020)

[7] Hallman & Hallman (2020) at 2271. About 40% of participants were able to correctly identify products labeled "cultured" or "produced using cellular aquaculture" as "neither wild caught nor farm raised." And about 40% of those participants mistaking products labeled as such as "farm-raised." Note that "cultivated" had the poorest performance with over 50% of participants mistakenly believing it to be "farm-raised" and about 30% of participants correctly identifying "cultivated" seafood products as "neither wild caught nor farm raised."

[8] William K. Hallman and William K Hallman II, "A Comparison of Cell-Based and Cell-Cultured as Appropriate Common or Usual Names to Label Products Made from the Cells of Fish." 2021, *Journal of Food Science*, https://doi.org/10.1101/2021.02.26.433119.

III. Cell-Cultured Seafood Products that also contain Traditionally Produced Seafood Should Identify the Percentage of Cell-Cultured Seafood.

Products in the first generation of cell-cultured seafood sold to consumers might contain a mixture of cell-cultured seafood and traditionally produced seafood. Consumers may purchase cell-cultured seafood products because they have attributes or benefits that they wish to support, such as increased sustainability, reduced carbon footprint, or reduction in animal suffering (all claims which currently have been identified by different developers, but not independently verified).

If a consumer purchased a cell-cultured salmon because they believed the method of production was more sustainable, only to learn that the product contained only 20% cell-cultured protein and 80% traditional protein, they would likely feel misled. To prevent cell-cultured seafood products from misleading consumers, such "mixed" product labels should clearly identify the percentage of seafood protein attributable to cell-culture technology and the amount that comes from other methods of production.[9] When a product is fully cell-cultured, it would be best if it included 100% on the product label.

IV. FDA and USDA Should Use the Same Terms to Identify Food Products Comprised in Whole or Part with Cell-Cultured Meat, Poultry, or Seafood Cells. [Question 1]

The technology used to produce cell-cultured seafood is not substantially different from the technology used to produce cell-cultured beef, pork, or poultry. The labeling of those products should inform consumers about the product and how it is different from familiar conventionally produced products. FDA and USDA should use identical terms for the different animal products they regulate.

It would be needlessly confusing to consumers if meat and poultry products used one term for cell-cultured products (*e.g.*, cell-cultured) while seafood products used a different term (*e.g.*, cell-based). Some consumers might consider those products to be produced using different technologies or methods when they are not. With such a new technology, and one that is not well known to consumers, it would facilitate consumer understanding if products that are similarly produced also are labeled using the same words or phrases, regardless of the agency that regulates them.

In the FDA-USDA formal agreement on regulation of food produced using animal cell technology, the agencies state that they have agreed "to develop joint principles for

[9] FDA also might consider whether the introduction of cell-cultured seafood requires FDA to identify a term to describe "traditional" seafood. This only becomes an issue when there are multiple categories of seafood production and reasons to differentiate between them.

product labeling and claims to ensure that products are labeled consistently and transparently." While this commitment is admirable, it is not clear that it means USDA and FDA will use identical wording on the cell-cultured products they regulate. FDA and USDA should agree on the specific terms that will be used to identify these products to consumers and ensure that the foods derived from cell-cultured animals use those terms in their common name, to promote consumer understanding, and prevent consumer confusion.

V. If the Cell-Cultured Seafood is "Bioengineered," FDA Should Alert the Developer and USDA that the Food May Require Disclosures under the USDA Bioengineered Disclosure Regulations [Question 5]

Although much is still unknown about how cell-cultured seafood products will be produced, it is likely that for some products the original cell lines will be modified with genetic engineering. If the cells are engineered, then the cell-cultured seafood product may fall within the definition of a "bioengineered food" and require disclosure under the National Bioengineered Disclosure Law. That law requires that manufacturers disclose to consumers foods that contain a bioengineered ingredient.

During the FDA food safety assessment, FDA should be provided with sufficient information about the cell line development and the types of manipulations made to the cells taken from the live animal to ensure their uniformity and longevity. That information should allow FDA to identify whether those products might fall within the definition of a "bioengineered" food.

If the product is bioengineered and requires disclosure, FDA should alert the developer to the federal disclosure obligation, and alert USDA about a possible food that requires disclosure, so it can include the new food on its list of bioengineered foods.

CSPI appreciates the opportunity to provide this comment to FDA. CSPI would welcome the opportunity to meet with the staff at FDA to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

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