



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)