



March 8, 2021

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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 (Published October 7, 2020)

Dear Sir or Madam,

The Alaska Seafood Marketing Institute (ASMI), on behalf of the Alaska seafood industry, appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) "Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information" (Request). ASMI commends the careful thought and diligence present in the crafting of the questions, as well as the FDA's evident comprehension of the novelty and wide-ranging impacts potentially offered by the new cell based seafood product types being discussed.

ASMI is a partnership between the State of Alaska and the Alaska seafood industry representing over 60,000 Alaskan harvesters, processors and businesses that take pride in providing nutritious, wild, natural, and sustainable seafood to consumers worldwide. Alaska naturally produces more seafood than any other part of the United States, and for decades has sustainably managed this renewable resource with rigorous science to maintain healthy ecosystems.

ASMI, and more importantly the seafood producers of the State of Alaska, have worked tirelessly for decades to establish an earned reputation for high quality, transparently produced, wild capture seafood products across the globe. ASMI has worked diligently on behalf of our stakeholders to highlight the qualities that differentiate Alaska seafood, and to educate consumers regarding its quality and value. The Alaska seafood industry is guided by firm commitments to quality, sustainability, and transparency in the products it produces, and ASMI believes giving the consumer the ability to make informed purchasing decisions is an invaluable and inalienable aspect of marketplace transparency.

Proteins derived from the cell cultures of animals are a novel development in the food industry. While the initial market concepts have been on terrestrial protein sources, it has never been in doubt that these same technologies would also be applicable to seafood. While the regulation of this burgeoning industry in the terrestrial sphere is not without its challenges, the variety of product types on offer in the seafood aisle from wild caught, farmed, and plant-based versions of a just a single particular fish species among hundreds of others, means that naming and labeling of these new cell-based products must be clear, precise, and above all accurate. The regulatory and legal frameworks which in most cases have yet to be built must be carefully considered at all



levels not only for the immediate future, but to anticipate the possible developments that seem to be coming forward at an exponentially accelerating pace.

ASMI provides the following answers to the FDA's Request for Information in support of that effort:

Question 1

ASMI believes the name or statement of identity of foods comprised of or containing cultured seafood cells should explicitly inform the consumers about how the animal cells were produced. In the modern seafood aisle, the multitude of products available are already myriad, with an ever-increasing number of options on offer. Consumers today must choose between wild capture, aquaculture/farmed fish, and plant-based products, to say nothing of additional variables such as certifications for sustainability, nutritional value, or simple taste preferences. ASMI believes that any regulations put into practice should endeavor to avoid misleading consumers in any way, but rather assist in navigating these choices with overt and transparent messaging regarding the products they choose to buy, be it wild capture fish from Alaska or a cell-cultured product.

Question 2:

ASMI agrees with the FDA that a great deal of care should be taken in the determination of nomenclature for any product derived from cultured seafood cells, perhaps even more so than when compared to cell-based products generated from terrestrial animal protein with an identical methodology due to possible confusion among the comparatively numerous species, types, and production methods of seafood products. ASMI believes that 'cell-based' or 'cell-cultured' will be the terms of best use. Numerous variables have led to this determination, perhaps best summarized in the work of Hallman and Hallman (2020) which explored the naming conventions of best suitability for cell-based seafood products, testing many potential names for both the ability to accurately convey the product's nature to the consumer, as well as avoiding the creation of inherent undue bias against the product (2).

The parameters of Hallman and Hallman (2020) determined that any term given must differentiate the product from wild capture fish, farmed fish, and plant-based seafood-like products. It must make the product's makeup easily understood, and must communicate that seafood allergens are present, in order to be suitable. It was also recommended that the term avoid oxymoronic language such as 'fishless fish,' as this is not only confusing but does not adequately differentiate from plant-based seafood-like products. The product should also not utilize terms which while potentially accurate, have established meanings in the context of seafood and seafood consumers such as 'sustainable' which may mislead buyers. These parameters were developed with FDA compliance in mind (2, 2a).

The study's findings asserted that terms specifically using the word 'cell' best resulted in consumers being able to differentiate the product from existing seafoods. 'Cell-based,' 'cell-cultured,' and 'grown from the cells of...' all performed best in terms of consumer understanding. The use of the word 'cell' along with any subsequent descriptor differentiates the product sufficiently, and as many have at least casual awareness of *in vitro* food research, most consumers were able to accurately infer the product's origin. This is especially notable in



comparison to some of the other language suggested: ‘cultured’ (in isolation without the word ‘cell’), ‘produced using cellular aquaculture,’ and ‘cultivated,’ all of which often led to the perception among consumers that the product was from an aquaculture operation or was fermented. Based on these findings, ASMI recommends the terms ‘cell-based seafood’, ‘cell-cultured seafood’, or ‘cell-cultivated seafood’ be utilized (2, 2a, 2b).

Question 3

ASMI concurs with the FDA’s view that foods comprised of or containing cultured seafood cells do not yet have a common name according to The Seafood List, as these products are not yet in the market (3). It is ASMI’s opinion that a goal of the Request is to establish a set of naming conventions to become that set of common and usual names (3).

Regarding the possible use of established common or usual names utilized of conventional seafood for cell-based products, ASMI believes that the FDA’s own words may be the best guidance:

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. (Common or Usual Names for Nonstandardized Food, 2011)

The first of these criterion is that it must simply and accurately describe the characterizing properties or basic nature of the food item. While attaching the monikers of the species used to make the cell-based product would be simple, it would neither be accurate nor sufficiently forthcoming of the characterizing properties. Similarly, because of the differences in origin, ASMI would argue that regarding the second criterion, a cell-based product and a wild capture product both comprised of a Pacific salmon, are not similar enough to bear the same name. Rather, ASMI would state that the second point of this criterion, wherein names may not be confusingly similar, would apply. While sensory and nutritional analysis of cell based products are still a knowledge gap in peer reviewed literature, even with an assumption of their being 100% indistinguishable, the difference in origin alone is sufficient in the minds of many consumers to separate cell-based product as a distinct class or subclass that needs language differentiating it from other foods, per the FDA’s own definition (3b, 3d).

ASMI suggests that common and usual names in isolation should be reserved for products harvested from actual whole fish, but advises that cell-based products should be named according to the DNA of the species their product utilizes, accompanied by qualifying language such as ‘made/derived/cultivated from the cells of ...’ to again provide a clear delineation for consumers, allowing them to tell the product’s origin, but still be able to discriminate by the type of seafood flavor and culinary experience they are seeking. This would also put in place language that will remain accurate if modifications are engineered into the cells for purposes of



nutritional alteration, removal of nervous system structures, or other alterations as many have speculated may occur. If such modifications are eventually introduced, ASMI is of the opinion that additional language disclosing modification should also be considered, but the qualifiers would remain accurate. With that qualifying language in place, as well as the suggested statement of identity of ‘cell-based/cultured seafood’, consumers will be able to clearly differentiate between product types. All labels should be clear, and however the wording is determined, it should remain consistent across the spectrum of cell-based products for ease of consumer understanding (3b, 3c, 3d).

ASMI also recommends that the FDA should take up the task of updating *The Seafood List*. *The Seafood List* must reflect what is in the marketplace, with specific reference that this product is derived from the cells of specific species. As previously argued, this new product form is a new class or subclass, but due to allergens present and the raw material origin it must also be discussed in the context of seafood. *The Seafood List* must therefore be updated to reflect these new product types as being a part of the seafood world (3e).

Question 4

ASMI recommends that the specification of type or cut of seafood should remain consistent with current definitions from regulatory agencies such as the National Oceanographic Association (NOAA) and the Food and Agriculture Organization of the United Nations’ (FAO’s) Codex Alimentarius (Codex) which have set the standard for terms used for seafood products. As an example, the Codex has standards for the creation of seafood fillets and fillet blocks, which explicitly define the term fillets as “slices of fish of irregular size and shape which are removed from the carcass of the same species of fish suitable for human consumption by cuts made parallel to the backbone,” (Codex Stan 190-1995) and as “slices of fish of irregular size and shape which are removed from the carcass by cuts made parallel to the back bone and pieces of such fillets, with or without the skin,” (Codex Stan 165-1989) respectively. Similarly, the Codex’s comprehensive document *Code of Practice for Fish and Fishery Products* describes fillets as “A slice of fish of irregular size and shape removed from the carcass by cuts made parallel to the backbone,” (*Code of Practice for Fish and Fishery Products*, 2020). While differing slightly, these definitions all state the phrase ‘removed from the carcass,’ implying a necessary connection of the terminology to an actual marine organism (4).

Work by NOAA has previously used comparable definitions. Martin, Doyle, and Brooker (1983) detailed the difficulties of seafood nomenclature, an endeavor which required clear and precise definitions of various product forms. Fillets are defined as “strips of flesh cut parallel to the central bone of the fish and from which fins, main bones and sometimes belly flap have been removed; presented with or without skin,” (Martin et al., 1983). In their work, fillets, steaks, and many more seafood product forms more are all defined, and all feature the word ‘fish’ as a part of their definition, which NOAA defines as “including mollusks, crustaceans and any aquatic animal which is harvested” (Fisheries, 2021). This work was published in the journal *Marine Fisheries Review*, a publication directed by NOAA’s National Marine Fisheries Service (NMFS). Many of the same definitions used in this publication are still those utilized in current terminology (Fisheries, 2021) (4, 4a).



Based on these definitions, ASMI cannot recommend product forms of established seafood such as fillet and steak being attached to cell-based products. These terms imply a specific action being done to a specific biological aspect of a marine organism (shucked, filleted, steak, etc.) or to a specific anatomical feature (claw, cheek, etc.). Using these names increases the odds that consumers would be misled by the product type, especially if the product in question aims to mimic these naturally occurring structures in form. ASMI instead would recommend terms which while used by the seafood industry, are not as definite in their meaning, such as chunks, portions, or pieces. ASMI considers these terms to be accurate, inoffensive to consumers, and least likely to mislead (4, 4a, 4b).

Question 5

Having consulted with the wide network of seafood retailers, buyers, and foodservice experts with which ASMI regularly interacts, there are innumerable differences which may possibly exist between a cell based product and a wild capture fish, but both sensory and nutritional comparison is currently a large and important gap in knowledge. While the technology is likely becoming increasingly proficient in mimicking naturally occurring fish in terms of flavor, nutritional content, texture, and more, cell-based products are not yet sufficiently available to be subject to such comparisons, and even comparative analyses for the purposes of academic research currently remain sparse. ASMI would have to see the results of such undertakings before providing any answer to this question. Because the issue may be swayed by consumer beliefs, perspective, and even feeling, the FDA would need to play an active role in fact gathering and research. (5, 5a).

The Alaska seafood industry generally, and ASMI specifically, is proud of the strong relationship it has with the FDA in jointly promoting best practices throughout the seafood supply chain, ensuring that not only is high quality seafood being produced and delivered, but that customers have the tools and access to information necessary to make knowledgeable choices of the food sources they take home for themselves and their families. ASMI believes that with the addition of the novel products derived from cultured seafood cells, regulating authorities such as the FDA must be particularly custodial of this consumer transparency.

ASMI is mindful of both the importance and complexity of the FDA's arduous task and grateful for this opportunity to provide input. While our producers and stakeholders are still getting acquainted with the regulatory and other issues associated with cell-based products, they are following the developments closely. ASMI sincerely hopes that the answers provided above are helpful to the FDA in its efforts. We look forward to a continuing dialogue on this and the other related issues that are right behind it, and once again thank the FDA for the opportunity to provide comment.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Woodrow", is written over a light blue horizontal line.

Jeremy Woodrow, Executive Director
Alaska Seafood Marketing Institute



Works Cited

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