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

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

The Good Food Institute (GFI) appreciates the opportunity to comment on the important issue of how to label foods comprised of or containing cultured seafood cells, which in this comment we refer to collectively as “cultivated seafood.”

GFI is an international 501(c)(3) nonprofit organization that is developing the roadmap for a sustainable, secure, and just protein supply. GFI’s team of scientists, entrepreneurs, and policy experts supports research and innovation in alternative proteins—including cultivated seafood—to meet consumer demand and feed a growing world. We also support fair public policy that places conventional and alternative proteins on a level playing field.

Sensible and carefully considered regulation of cultivated seafood will be essential to creating the marketplace of the future, in which consumers may choose freely among safe, nutritious options of greater variety than ever before. GFI appreciates FDA’s proactive approach to cultivated seafood labeling and the important questions FDA is asking at this stage; this comment will address each of these questions in turn below. First, we discuss the existing seafood landscape, to provide essential context about the relevant market that will be shared by cultivated seafood and conventional seafood, and FDA’s current regulatory approach to that market.

Background

The vast biodiversity of ocean life is illustrated in small part by the nearly 2,000 entries comprising FDA’s Seafood List. The Seafood List similarly illustrates FDA’s simplified, practical approach to permissible nomenclature for the diverse array of animal species eaten as seafood, appropriately accounting for the limited number of words in common use for the ordinary consumer. For example, at least 53 distinct species or genera may be marketed simply as “shrimp,” 46 distinct species may be marketed simply as “flounder,” and 70 distinct species may be marketed simply as “grouper.” Within broad classifications like these, sellers of seafood are not *required* to denote the precise animal species on a scientific level or even in layperson’s terms, though some may *choose* to make such distinctions (for example, between albacore tuna and skipjack tuna) where they are known to consumers.

In a similar vein, sellers of seafood are not required to disclose details such as how the seafood was caught or harvested, such as by traditional fishing on lines or by trawling or dredging methods that may damage the seafloor or generate substantial bycatch. Nor are farmed fish producers required to disclose, for example, their feedstocks or the use of antimicrobials. Here again, some sellers *choose* to disclose more specific information to consumers (if the seller, for example, believes it can build trust or command a higher price by doing so), but that decision ultimately is left to these voluntary forces of the free market.¹

FDA’s longstanding view on the scope of “materiality”—and thus what it requires to be disclosed to consumers—places emphasis, first, on the attributes or characteristics of a finished product rather than the processes by which it was produced (and in the case of seafood, harvested).² Under FDA’s interpretation, if a food or ingredient is not significantly different when produced by a new or different method, the exact method by which it is produced is not considered “material” information within the meaning of section 201(n) of the Federal Food, Drug, and Cosmetic Act.³ Differences between

¹ Although a USDA regulation (7 C.F.R. § 60.300) restricts the use of certain terms (such as “line caught”) as a substitute for required language in the country-of-origin/production disclosure, this does not restrict producers from providing such information to consumers elsewhere on the label or in advertising.

² See, for example, *Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon: Draft Guidance for Industry*, at 8 (rev. March 2019) (“Voluntary Labeling Draft Guidance for Genetically Engineered Atlantic Salmon”), available at <https://www.fda.gov/media/120960/download> (additional labeling would be required if a food has “characteristics that are materially different from those of comparable foods (e.g., differences in the basic nature of the food, material differences in the consequences of use, material differences in the nutritional properties, or [] any allergens that the consumer would not expect to be in the food”).

³ This is discussed in greater detail in our response to question 1, below.

production or harvesting methods may be meaningful to some consumers (e.g., for environmental reasons), but may not have a consistently measurable impact on the texture, flavor, composition, or nutrition of the product itself. At the same time, measurable differences will not warrant disclosure if they hold no significance for consumers; for example, it may be that two species of “flounder” are biologically distinct, but without differences in performance characteristics that are meaningful to ordinary consumers.

This existing regulatory framework should be applied to cultivated seafood in the interests of regulatory consistency and the even-handed treatment FDA has previously extended to other novel products. The principles outlined above suggest the following general principle for cultivated seafood labeling: labels should provide disclosures when the cultivated product differs materially, and in a way that is significant to consumers, from conventional counterparts.

As suggested above, the need for disclosure will not encompass every scientifically quantifiable difference. Some measurable differences (detectable by biologists or fish connoisseurs) may not be significant to consumers, and in those cases FDA has not concluded that such differences compel a different market name. Consider, for example, the multiple species of shrimp that share the common name “shrimp,” or the measurable nutritional differences that can sometimes be shown between fish of the same species grown or produced in different places, with different feedstocks, or with different methods. Consumer expectations for a particular seafood product often correspond only to a *range* of acceptable species, with a *range* of nutritional or culinary attributes, within a *range* of production conditions. Different options within these ranges may optionally be labeled to appeal to consumers particularly concerned with those distinct attributes, but as described more fully below, FDA has historically not considered these distinctions material to the degree that would *compel* different market names or other disclosures on labels.

Finally, an additional consideration is that cultivated seafood has not yet reached the American marketplace, and therefore consumer expectations for it are still developing. FDA thus should proceed carefully if it wishes to develop a framework that will respond to consumer understanding, because that understanding is still taking shape. Premature and prescriptive regulations bear the risk of contributing to consumer confusion: for example, the agency could prescribe a common name that future consumers neither use nor understand, or could mandate a disclosure that misleads consumers about a factor they might not otherwise consider material.

With these general considerations in mind, GFI offers the following answers to the agency’s questions.

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.

Requiring disclosure of the production method would be reasonable and appropriate where a cultivated product is materially different from its conventional counterparts in a manner that is significant to consumers; such a disclosure would be appropriate in the statement of identity or elsewhere on the label depending on the nature and magnitude of the material differences. This approach would be consistent with FDA's existing regulatory framework, including its interpretation of "material" information under section 201(n) of the Act.

FDA has addressed the question of materiality in considering whether to require special labeling for the products of other novel technologies, including foods derived from bioengineered salmon,⁴ milk products from cows given a recombinant growth hormone,⁵ foods derived from cloned animals or their progeny,⁶ and foods derived from bioengineered crops.⁷ In each case, FDA concluded that if there is no significant difference in the composition of the product itself, the process by which it is made is not material information. Accordingly, the agency concluded not only that it had no *authority* under section 201(n) to mandate labeling reflecting the production process, but also that different labeling in the absence of intrinsic material differences could itself be misleading to consumers. Courts reviewing these determinations have deferred to FDA's interpretation of materiality.⁸ In the words of one court, "[a]bsent unique risks to consumer health or uniform changes to food derived through [new] technology, FDA does not read [21 U.S.C.] § 321(n) to authorize an agency imposed food labeling requirement."⁹

⁴ Voluntary Labeling Draft Guidance for Genetically Engineered Atlantic Salmon, *supra* note 2, at 7.

⁵ FDA, *Interim Guidance: Voluntary Labeling of Milk and Milk Products from Cows that have not been treated with Recombinant Bovine Somatotropin*, 59 Fed. Reg. 6279, 6280 (February 10, 1994).

⁶ FDA, *FDA's Response to Public Comment on the Animal Cloning Risk Assessment, Risk Management Plan, and Guidance for Industry*, at section H. (2008), available at <https://www.fda.gov/animal-veterinary/animal-cloning/fdas-response-public-comment-animal-cloning-risk-assessment-risk-management-plan-and-guidance>.

⁷ FDA, *Statement of Policy: Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992); FDA, Petition Denial, FDA to Center for Food Safety, Dkt. No. FDA-2011-P-0723 (Nov. 19, 2015).

⁸ See *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166, 178–79 (D.D.C. 2000) (affirming FDA's decision not to require labeling for products from genetically modified crops); *Stauber v. Shalala*, 895 F.Supp. 1178, 1192–93 (W.D. Wisc. 1995) (affirming FDA's decision not to require labeling for milk products from rbST-treated cows).

⁹ *Alliance for Bio-Integrity*, 116 F.Supp.2d at 178–79.

Consistent with this guidance and precedent, a mandated disclosure would be appropriate to notify consumers about any unique health risks posed by specific cultivated products (if, for example, a cultivated product were found to trigger allergies in some consumers who are not allergic to corresponding conventional products). Similarly, if a cultivated product has characteristics that are measurably distinct from its conventional counterparts (e.g., in composition, nutrition, or function) in a way that is significant to consumers, the agency may appropriately require some form of disclosure.

To date, as with bioengineered crops, cultivated seafood products *as a class* have not been shown to differ significantly from conventional seafood products in any predictable uniform way, and the technology to produce these foods is still under development. If some are materially different from their conventional counterparts,¹⁰ any mandated disclosure should be appropriately tailored to account for the differences in those particular products.¹¹

Further, as with other types of seafood, it is possible that cultivated seafood products may be measurably different in a way that does not bear on consumer expectations. (Consider, for example, the multiple distinct species often marketed under a single market name like “shrimp” or “grouper.”) In an analogous context, FDA decided not to require labeling of differences in performance characteristics when a difference (though real and measurable) is “not of material interest to consumers”—for example, the freezing point of eggnog—and noted that unnecessary disclosure of such differences may itself confuse consumers.¹² The Seafood List reflects the same principle: the ultimate decision of whether to compel disclosure does not turn solely on whether there are *any* scientifically

¹⁰ Indeed, some cultivated products may ultimately be different *by design*, e.g. with consistently improved nutrition, elimination of toxins, or elimination of allergenic proteins.

¹¹ Government-mandated labeling that is misleading to consumers would also raise significant free-speech concerns under the First Amendment. Although the government has some discretion to mandate disclosures of factual, uncontroversial information in order to prevent consumer deception, a disclosure that is itself misleading (e.g. because it wrongly implies material differences or derides the product) would be neither factual nor uncontroversial, nor would it serve an interest in preventing consumer deception. *See, e.g. Nat. Ass’n of Mfrs. v. SEC*, 800 F. 3d 518, 530 (D.C. Cir. 2015); *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 642 (6th Cir 2010). For this reason, a mandate that products bear factually inaccurate, derogatory, or misleading terms favored by competing industries (e.g. “lab-grown”) would likely be unconstitutional.

¹² FDA, *Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term*, 58 Fed. Reg. 2431, 2437 (Jan. 6, 1993) (revising new 21 C.F.R. § 130.10(c) to require label disclosure in the event of a “significant difference in performance characteristics that materially limits the uses of the food” compared to the uses of the standardized food, and reasoning that “differences in performance characteristics that consumers may not deem to be important” do not require disclosure under this standard).

measurable differences, but also on whether those differences are of material interest to consumers.

Additionally, if some cultivated products have material differences that are significant to consumers, altering the product name or statement of identity is not the only potential means of requiring disclosure of those differences to consumers: disclosure may alternatively be made elsewhere on the label. An analogous example is the long-awaited AquAdvantage genetically modified salmon: its common name will be “Atlantic salmon” because FDA has concluded that the “composition and basic nature” of the food “does not significantly differ from its non-[genetically-engineered] counterpart,”¹³ but pursuant to USDA rules, it also will be labeled as “bioengineered.”¹⁴ As another example, for some products that differ nutritionally from what consumers might expect based on the product name or other representations on the label, FDA requires a disclosure that simply directs consumers to the Nutrition Facts panel.¹⁵

Finally, any requirement that producers make disclosure using specifically mandated nomenclature must be supported by evidence of consumer understanding. Data regarding these products as a class are still developing, and as yet there is only limited evidence around consumer understanding of related terminology. As a result, FDA would face significant challenges in tailoring specific disclosure requirements at this early stage. Mandating a specific disclosure in every cultivated product’s name might itself carry real risks to clear and accurate labeling: before these products reach the market, consumers may adopt a different common or usual name through common usage, or indeed, in the absence of any demonstrated measurable differences from conventional products, consumers may find the use of this production method as immaterial as they now find the distinctions between different species currently sold under the same name.¹⁶ Either

¹³ Voluntary Labeling Draft Guidance for Genetically Engineered Atlantic Salmon, *supra* note 2, at 7.

¹⁴ 7 C.F.R. §§ 66.1, 66.3.

¹⁵ See 21 C.F.R. §§ 101.13(h); 101.54(d). These requirements implement the nutrient content claim provisions of section 403(r) of the Federal Food, Drug, and Cosmetic Act (in addition to section 403(q) and other misbranding provisions) and are aimed at prohibiting misbranding through the use of unauthorized nutrient content claims. Importantly for this purpose, FDA reached the conclusion that consumer understanding could be meaningfully advanced by directing consumers to additional information.

¹⁶ Of course, a subset of consumers may prefer seafood from conventional sources, just as a subset of consumers currently prefers line-caught over farm-raised seafood, or wild Atlantic salmon over AquAdvantage salmon. Such consumers’ preferences do not decide materiality for *all* consumers for FDA’s regulatory purposes, and voluntary labeling by producers currently caters successfully to consumers with these preferences. See Voluntary Labeling Draft Guidance for Genetically Engineered Atlantic Salmon, *supra* note 2, at 7 (“[W]e have concluded that there is no material difference between food derived from AquAdvantage Salmon and food derived from other non-GE, farm-raised Atlantic salmon that is required to be disclosed Nonetheless,

development might point in a different direction than a previously defined, required term in the product's name.

A more prudent course would be to continue to observe the development of consumer understanding of relevant terminology as producers inform consumers about these new products and their benefits. And the earliest producers of cultivated products are certain to prominently disclose the source of the first products to reach the market, for the simple reason that they will be premium products with higher prices to support their early development and production costs. Just as no seller of bluefin tuna (valued at \$20-\$40 per pound—at the low end) would sell its premium product in ordinary cans labeled simply as “tuna,” no early seller of cultivated seafood will be able to compete with mass-produced conventional seafood without specifically and prominently advertising the origin of its product. By the time production costs reach parity with conventional products, the agency will have much more information available to it about these products and the terminology that consumers best understand—and both producers and consumers may also have settled on an accepted common terminology for these products as well.

In sum, while disclosure of material differences that are significant to consumers is both desirable and legally required, and while some cultivated products may ultimately be shown (or perhaps designed) to have intrinsic material differences, cultivated products *as a class* have not yet been shown to be materially different in any uniform way from their conventional counterparts. As with genetically engineered foods, a general disclosure applied to all cultivated products could wrongly imply such a difference. Any mandated disclosure should be based on the nature of any material differences in each product; such a disclosure requirement would therefore be inappropriate at this time.

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.

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

Where cultivated products are materially different from conventional products, FDA should allow producers to disclose those differences using a range of appropriate terms or explanatory language, so long as the language is clear to consumers and not misleading. Possible language for denoting cultivated products might include short descriptive

we recognize that some consumers are interested in knowing whether a food is derived from genetically engineered Atlantic salmon, and some manufacturers may want to respond to this consumer interest. FDA supports voluntary labeling...”).

adjectives in the product name (e.g. “cultivated salmon” or “cell-cultured salmon”), or alternatively descriptive phrases (“salmon grown from cells”). The language that producers and consumers use to describe these products is evolving, as is consumers’ familiarity with these products.

The high price point at which these products are certain to be introduced will require producers to describe their products clearly in order to give consumers an understanding of the value proposition. As this conversation continues and consumer familiarity grows, a favored shorthand for referring to these products may develop among consumers and producers alike. FDA should not seek a shortcut around this needed conversation. Any single term chosen by FDA today runs the risk of becoming quickly outdated if consumers adopt different terminology for referring to cultivated products. At this point producers and FDA lack direct, demonstrated experience with the language that will be clearest to consumers. A restrictive approach, moreover, would hamper the free-speech interests of producers who seek to communicate with consumers on their level (which is likely to change over time), as well as consumers’ recognized First Amendment interest in receiving information and ideas.¹⁷

We additionally note that FDA and USDA have stated their joint intention to develop a coordinated framework for the labeling of cultivated products.¹⁸ As discussed below, there has been some early research into consumer understanding of terminology for cultivated seafood. But similar research with respect to cultivated meat and poultry, the labeling of which is subject to USDA jurisdiction, may yield different results (for example, “aquaculture” is not associated with meat and poultry products, and thus the term “cultured” is not likely to carry the same associations). We are unaware of any significant research to date into consumer understanding of nomenclature for these products. A coordinated framework for labeling of all cultivated products would likely have benefits to consumer understanding, and more information is needed before a unified approach can be adopted.

For these reasons, the most constructive approach at this point would be for the agency to give guidance on permissible labeling approaches. In doing so, FDA should also consider that at this stage of developing consumer understanding, descriptive phrases (e.g. “grown from cells”) may convey the nature of the production process more clearly to consumers than any single term, and new terminology may yet be adopted in common usage. Thus,

¹⁷ *Va. State Bd. of Pharmacy v. Va. Consumer Council*, 425 U.S. 748, 757 (1976) (acknowledging “a First Amendment right to ‘receive information and ideas,’ and that freedom of speech ‘necessarily protects the right to receive.’”).

¹⁸ Formal Agreement Between the U.S. Department of Health And Human Services Food and Drug Administration and U.S. Department of Agriculture Office of Food Safety, at 4 (Mar. 7, 2019) (“The Parties will develop joint principles for product labeling and claims to ensure that products are labeled consistently and transparently.”), available at <https://bit.ly/3r8hgEB>.

if FDA follows the approach of issuing guidance on different acceptable terminology, it may wish to leave open the possibility of other terms or language that accurately and clearly describe the product to consumers.

Some early research has been done about consumer understanding of different labeling shorthand terms, including the recent consumer surveys conducted by Professor W. Hallman (commissioned by BlueNalu)¹⁹ and by the Yale Center for Customer Insights (commissioned by Wildtype, Inc.).²⁰ This research is valuable and contains some early insights. It also reflects an unavoidable limitation: the limited degree of current consumer familiarity with these products that are not yet on the market. And of course, if any of the terms surveyed by Hallman and Yale/Wildtype eventually are adopted by large numbers of consumers to refer to cultivated products, this fact alone would inevitably and dramatically change overall consumer understanding of those terms for the better.

For all these reasons, FDA should move cautiously in mandating the use of specific terminology for label disclosures for cultivated products.

b. 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.

Terms like these would be appropriate if supported by consumer use and understanding, and if one of these became a favored and well-understood term, further differentiation would not be necessary. As suggested by this question, Hallman (2020) found a small effect suggesting that consumers may associate “culture” with “aquaculture” in the context of seafood, as evidenced by the share of consumers identifying “cultured” products as “farm raised.” But consumers would learn to distinguish “culture” or “cell culture” from “aquaculture” if those terms were to enter common usage once cultivated products become common: in the context of widespread use, a consumer would quickly learn exactly what is meant by the term. And “cultured” and “cell cultured” are similar to

¹⁹ W.K. Hallman & W.K. Hallman, II *An empirical assessment of common or usual names to label cell-based seafood products*. 85 *Journal of Food Science* 2267 (2020), <https://doi.org/10.1111/1750-3841.15351>; W.K. Hallman & W.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) bioRxiv preprint available at <https://doi.org/10.1101/2021.02.26.433119>.

²⁰ Wildtype, *Labeling the future: _____ salmon*, *Medium* (March 8, 2021), available at https://medium.com/@wild_type/labeling-the-future-salmon-4adaba23b555.

language most commonly used by scientists in describing the production process,²¹ and are also similar to the language FDA itself frequently has used to describe these products.

This example further illustrates why the agency should rely on solid evidence of consumer understanding should it move to issue mandates around specific terminology. A term that is mandated too early may result in greater consumer confusion in the event that consumers later widely adopt a different term. Until the available evidence indicates that consumer understanding has coalesced around specific nomenclature, FDA's focus should be on ensuring that labels are clear and not misleading, rather than on mandating specific nomenclature. In the future, a common or usual name for cultivated products may become established through common usage and consumer understanding, and future regulatory decisions would be better informed by such demonstrated experience.

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.

a. 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?

We agree with FDA's view that there is no name established by common usage at this time.

b. 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.

Cultivated seafood labels should include names used for conventionally produced seafood products of the species of origin (regardless of whether those names were established by common usage, statute, or regulation). The species of origin of the fish is often reflected by the conventional name, is the source of the food (because the product is derived from cells of the species of origin), and is meaningful for both conventional and cultivated seafood, providing culinary, health, and safety information to consumers.

Where the product is not materially different from a conventional product, the conventional name (whether established by common usage or prescribed by law or regulation) should be the name or statement of identity for cultivated products based on

²¹ We note that "cultivated," the term preferred by GFI and some producers, has the same benefit of emphasizing the production process, but with less similarity to the term "aquaculture."

the cells' species of origin and the form of the product. Where there is no material difference in the product, the common conventional name or market name of the conventional product is the clearest way to convey the essential characteristics of the cultivated product to consumers.

Most critically, consumer safety demands that cultivated seafood labels include the common or market name consumers associate with biologically identical products. Consumers with allergies to specific types of fish will have the same allergic reaction to cultivated varieties of the same species. Fish and shellfish are two of the eight “major food allergens” for which the Federal Food Drug & Cosmetic Act requires prominent disclosure.²² Prominently displaying the common or market name of the fish or shellfish²³ is critical to alert consumers to the potential for allergic reactions. Failure to use the name for the conventional product prominently on the label may be dangerous or even fatal for these consumers.

Finally, *excluding* those common names from cultivated product labels would be an unconstitutional restriction of commercial free speech. Where there is no material difference in the product, the government has no legitimate interest (e.g., in protecting consumers or preventing deception) that supports an outright speech ban. But even if the government had such an interest (e.g., where the product is materially different in some respect), courts strongly disfavor outright speech bans, because disclosure requirements offer a more narrowly tailored and direct means of preventing any possible deception.²⁴

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

Qualifying language could be added to the conventional name if the product is materially different from the conventional analogue. If the nature of the difference can be described clearly and succinctly, it could be part of the name, but this is not always practical. As discussed in our answer to question (1) above, label disclosures may be made effectively elsewhere on the product label rather than in the product's name.²⁵ For example, if the differences are minor but material differences in nutrition, it may be unhelpful to consumers to try to incorporate those details into the product name. A note directing

²² See 21 U.S.C. § 321(qq), 343(w).

²³ In some cases, this alert may be provided via the name of a seafood product commonly associated with that type of seafood by common usage (e.g. lox, scampi, jambalaya), or by regulation, *see, e.g.* 21 C.F.R. § 102.54 (“seafood cocktail”); § 102.45 (“fish sticks made from minced fish”).

²⁴ *See, e.g. Ocheesee Creamery v. Putnam*, 851 F.3d 1228, 1240 (11th Cir. 2017); *Pearson v. Shalala*, 164 F. 3d 650, 657 (D.C. Cir. 1999).

²⁵ *Cf. FDA, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry* at 10–11 (rev. Mar. 2019), available at <https://www.fda.gov/media/120958/download>.

consumers to the nutritional panel, or perhaps front-of-package disclosure of significant nutritional differences, might be a more appropriate means of disclosure than an attempt to qualify the product's name.

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

It is only necessary for FDA to mandate that labels clearly distinguish a cultivated seafood product if it is materially different from the conventional counterpart and the difference is significant to consumers; however, we believe that until a common or usual name is established through common usage, a range of terms or explanatory language may be clear to consumers and not misleading, and sufficient to distinguish cultivated seafood from conventional seafood.

A qualifying term or descriptor provides, at a minimum, the basic function of notifying consumers that the product is somehow different. Such terms can alert consumers to consult additional relevant information on the label or elsewhere (e.g., the producer's website).

Of course, for consumers who are entirely unfamiliar with cultivated food products, no one term on the label can be expected to fully inform consumers by itself. A useful analogy can be found in FDA's reasoning in adopting its regulation governing nutrient content claims, 21 C.F.R. § 130.10. In that regulation, FDA allows foods using a nutrient content claim plus a standardized term to deviate from consumer expectations for the standardized food in a variety of significant ways, including moisture content, solids content, processing conditions, and the addition of various ingredients to "improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness." None of these material differences can be expected to be condensed into simple language in the product's name. Rather, the existence of qualifying language of some kind—the nutrient content claim itself—alerts consumers to "accompanying label statements" (if any) and "nutrition labeling," and this "enable[s] consumers to distinguish traditional foods from modified versions of these foods."²⁶

Similarly, where a cultivated product is shown to be materially different from its conventional counterpart, any of these qualifying terms or descriptors can alert consumers to the fact that the product is different, prompting them to consult other information (on the label or elsewhere) about these differences. As in the case of a nutrient content claim, one cannot expect a complete and informative description of a new product through a single term on a label. But the terms suggested by the agency and

²⁶ FDA, Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993).

other interested parties are generally sufficient to, at a minimum, appropriately distinguish cultivated products from conventional products.

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

This is unnecessary; such foods would be appropriately marketed using the market name already reflected on The Seafood List. We refer to our answer in Question 3.b., above.

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, where the product has the qualities consumers associate with that term, as described below.

a. 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.

Each of these terms would appropriately be used when a product has the structural and textural characteristics associated with that term. Terms like “fillet” and “steak” convey important information about the form and structure of a product and how to incorporate the product into culinary applications or recipes. They already are used in conjunction with other terms to characterize a wide range of products (beef steak, swordfish steak, tuna steak). As with conventional products, these terms provide helpful information to consumers about relevant structural and organoleptic characteristics.

Companies are now researching how to grow cultivated meat and seafood products into the “cuts” that bear the structural characteristics familiar to consumers. If a cultivated product is grown in the form of a “steak” or “fillet” and has all the characteristics consumers associate with that structure, then the terms would be appropriate and useful to describe the product to consumers.²⁷ Both the organoleptic features of the product as well as the method by which it is produced should be considered in determining whether a cultivated seafood product could appropriately use structure-related culinary terms.

²⁷ As with conventional seafood products, a product created from smaller collections of cells (analogous to minced fish) would likely lack the structural characteristics of a “steak” or “fillet,” in which case the use of the conventional term would not be appropriate. See, e.g. 21 C.F.R. § 102.45 (“Fish sticks or portions made from minced fish.”).

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

The use of any of these terms would not be misleading if the product has the relevant structural and textural characteristics denoted by the term.

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.

Differences affecting nutrition, taste, texture, and aroma could be material to consumers' purchasing and consumption decisions. But no categorical statement can be made regarding how cultivated products will differ (if at all) from conventional products on these attributes in some uniform way that is significant to consumers.²⁸

In considering which attributes are material to consumer decision-making, it should be recognized that conventional seafood that bears a single common or market name can vary significantly in qualities such as nutrition, taste, texture, and aroma. This may include, for example, culinary or nutritional variation between different species sharing the same market name, and nutritional variation between wild-caught and farm-raised fish of the same species.²⁹ Under the existing regulatory framework, these differences are not necessarily considered material, in the sense that a wide variety of products of differing culinary or nutritional attributes may be marketed under the same name. Thus, a cultivated product made from the same species' cells should similarly not be considered materially different where the product falls within the range of existing variation of conventional products bearing that name.³⁰

²⁸ Cf. FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

²⁹ Compare, e.g. Fish, salmon, Atlantic, farmed, raw (NDB 15236) with Fish, salmon, Atlantic, wild, raw (NDB 15076) in USDA National Nutrient Database for Standard Reference, Release 21, data available at <https://fdc.nal.usda.gov> (showing wild Atlantic salmon to have less fat than farmed Atlantic salmon, with significantly higher levels of several vitamins and minerals including iron, potassium, zinc, thiamin, and riboflavin); Fish, tuna, fresh, yellowfin, raw (NDB 15127), with Fish, tuna, fresh, skipjack, raw (NDB 15123) in *ibid.* (showing yellowfin to be higher in protein and lower in fat than skipjack, with significant variation in levels of most essential vitamins and minerals). These data may be most readily accessed by entering the corresponding NDB numbers into the FoodData Central search box at <https://fdc.nal.usda.gov>.

³⁰ As noted earlier, FDA does not generally consider genetic modification to be a material feature of a product. But in any case, if some cultivated seafood is produced using genetic modification of cell lines, disclosure would be required under USDA's National Bioengineered Food Disclosure Standard. See 7 C.F.R. §§ 66.1, 66.3.

a. 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.

We are not aware of any other characteristics that can or should be considered material. In the history of FDA's regulations, as described above, differences in the production process that do not affect the safety, nutrition, performance, or organoleptic qualities of the product have not been considered material. There is no principled basis for treating cultivated products differently.

* * *

Thank you for the opportunity to submit these comments. We appreciate your efforts to support industry innovation and provide clear labeling for this exciting class of innovative products. Please let us know if we can be of assistance in any way.

Sincerely,



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