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Public Comments of the National Consumers League
FDA's Nutrition Innovation Strategy

Executive Summary

The National Consumers League (NCL) commends the FDA for convening a public meeting on the Multi-Year Comprehensive Nutrition Innovation Strategy. The July 26, 2018 meeting was well-attended by both food industry leaders and consumer groups, serving as an informative first conversation about modernizing FDA processes in regulating production innovation and appropriate labeling.

At the meeting, NCL's Food and Nutrition Policy Fellow, Haley Swartz, MPP, spoke about the League's 100-year history in advocating for a safe, nutritious, and accurately represented food marketplace. NCL has been an active participant in food labeling regulation and litigation for over three decades. We have long worked with the FDA to ensure transparency on food labels, including mislabeling on:

- "Fresh" canned tomatoes and pasta sauce (2009);
- Artificially sweetened dried cranberries in cranberry juice (2009); and
- Watered-down lemon juice (2012).

We work tirelessly alongside our colleagues in the National Alliance for Nutrition and Physical Activity to ensure that blatant forms of false food advertising are eliminated from the food marketplace. We also must thank the FDA for its continual willingness to consider innovative regulatory actions. As we approach new challenges in the context of changing consumer demands and rapidly evolving technology, we are thrilled to actively participate in dialogues between the food industry, regulators, and consumers.

In this document, we delve deeper into the issues Swartz raised in her speech. We list both our enthusiasm and concerns for several specific components of the Strategy.

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We look forward to working with the food industry and the FDA to ensure any proposed changes reflect sound science, benefit public health, and encourage production innovation. Thank you for your time in reading these comments.

Sincerely,



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National Consumers League
Executive Director



Haley Swartz,

National Consumers League
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I. Modernizing Claims – Avoid a “Technofix” Marketplace

NCL commends FDA for taking on one of the most fraught areas of confusion in the food marketplace where visual cues extend far beyond a one-word claim and include all elements of a product package. Dizzying colors, fonts, texts, and images now accompany consumers as they walk through grocery store aisles. Navigating nutrition information along with dozens of health, environmental, or labor-related labels and logos may increase access to information but ultimately has the unintended effect of overwhelming and confusing consumers. Decision fatigue, choice overload, and even “the tyranny of too much” have been studied extensively as both a cause and consequence of unhealthy consumer choices.^{1,2,3}

As choice overload has come to define the consumer marketplace, we see a concerning rise in the use of implied technofix labeling regimes. *Though technofixes are similar to health halo or structure/function claims⁴, they encompass greater segments of the food supply chain, illustrating consumers desire for transparent and ethically produced foods.*

Technofixes are frequently ascribed to everything from certain ingredients (e.g., superfoods, antioxidants) to nutrient product lines (e.g., protein juices), as well as diets (e.g., whole30, keto, etc.) and product-associated lifestyles (e.g., vegan). These trends suggest consumers want their food choices to be beneficial – or at least, not harmful – to both their health and the health of the environment.

Technofixes refer to the idea that long-standing food systems problems can be simply solved through advancements in science or engineering, and in the case of food products, how individual purchases can single-handedly reduce diet-related health conditions and/or reduce food production’s impacts on the environment.¹

Implied technofix claims are a complex and growing area of study in the consumer-facing end of food systems research. While food systems science has much to learn about the promises and weaknesses of evolving engineering or food science approaches, the FDA now can support consumers as they navigate an increasingly noisy marketplace with both health halo and technofix claims at every turn. We strongly urge FDA to carefully review any potential changes to the regulatory regime with a close eye to technofixes. **Any new or additional label on packaged foods should assist,**

¹ Baumeister, R.F. 2003. The Psychology of Irrationality, in *The Psychology of Economic Decisions: Rationality and Well-being* (eds. Brocas, I. & Carrillo, J.D.), pp. 1–15

² Scheibehenne, B., Greifeneder, R. and Todd, P.M., 2010. Can there ever be too many options? A meta-analytic review of choice overload. *Journal of Consumer Research*, 37(3), pp.409-425

³ The Economist, 2010. The Tyranny of Choice: You Choose. Available online at: <https://www.economist.com/christmas-specials/2010/12/16/you-choose>

⁴ Fernan, C., Schuldt, J.P. and Niederdeppe, J., 2017. Health halo effects from product titles and nutrient content claims in the context of “protein” bars. *Health communication*, pp.1-9

not *inhibit* the consumer’s ability to evaluate the product’s health, environmental, or nutritional claims.

Most technofixes are merely implied through broader product marketing and branding, none of which falls under FDA’s jurisdiction and, incidentally, is what makes them so pervasive in the marketplace. However, we argue that claims of both natural and health-promoting properties on food products, along with their many corollaries, can contribute to the technofix mentality surrounding both human and environmental health.

What we are suggesting is not a regulatory strategy, but a cautionary reminder that these terms exist in a much larger marketing strategy for food producers.

What matters is not just the mere definition of the label, but what implications may follow consumer perceptions within the product’s recognized brand.

a. Front-of-Pack Holistic Label – Not a “Healthy” Icon

We commend the FDA for continuing the conversation on defining the parameters for what constitutes a “healthy” food product. The 2016 voluntary guidance for industry, while a well-meaning start, just scratches the surface of how nutrition scientists, behavioral economists, and public health researchers truly define a “healthy” diet – one that is nutritious, diverse, balanced, and inclusive of all seven food groups.⁵ It is extremely difficult for a food product to be considered healthy without placing its consumption in the context of an individual’s overall dietary patterns and its coexistence or contribution to any diet-related non-communicable diseases – the approach used by the Dietary Guidelines for Americans (DGAs).^{6,7} **We believe the regulatory definition of “healthy” must be strengthened before any packaging requirements change.**

“Healthy” as a regulatory term must incorporate minimums for nutrients (*e.g.*, carbohydrates, protein) and foods (*e.g.*, whole grains, fruits, vegetables) that are required for human sustenance. It should set maximum levels for nutrients of public health concern (*e.g.*, saturated fat, sodium, added sugars). Exemptions should be carefully evaluated for their impact on the nutrient density of a food (*e.g.*, concentrates, powders, isolates, or purees of ingredients must maintain nutrient levels of the original ingredient to qualify for an exemption).

⁵ High Level Panel of Experts, 2017. Nutrition and food systems: A report by the HLPE on Food Security and Nutrition of the Committee on World Food Security of the United Nations: Rome, Italy.

⁶ Willett, W.C. and McCullough, M.L., 2008. Dietary pattern analysis for the evaluation of dietary guidelines. *Asia Pacific journal of clinical nutrition*, 17(S1), pp.75-78

⁷ Hu, F.B., 2002. Dietary pattern analysis: a new direction in nutritional epidemiology. *Current opinion in lipidology*, 13(1), pp.3-9

As the FDA begins to finalize “healthy” as a regulatory framework, attention should then move to implementing a mandatory front-of-pack label that provides the nutrition information and health impacts that consumers demand. NCL has long advocated for the development of a standardized, mandatory front-of-pack label that can balance the overwhelming visual and textual cues on product packaging that consumers face every day in the grocery store.^{8,9} The intent of front-of-pack labeling is not to simplify or dilute all nutrition information into a single color, numerical score, or rating, but to provide a summarized snapshot of the product’s overall contribution to a healthy diet – a critical component to preventing and treating diet-related diseases.

Given the strengths of dietary pattern analysis and the variety in individual nutrition needs, we urge FDA to **implement a holistic front-of-pack label – rather than a healthy icon – so consumers can easily access nutrition information in the context of the crowded food marketplace.** The label can include both quantitative nutritional elements (*e.g.*, sodium, carbohydrates, and protein levels) as well as a concise qualitative description of the product’s overall health impacts.

NCL has long advocated for the development of a front-of-pack label that can provide consumers with the information they demand. We urge the FDA to work with the food industry and consumer insight researchers to develop and pilot a front-of-pack labeling scheme that incorporates consumers’ desire for food system transparency with the product’s actual nutrition content. In the coming years, we look forward to working with the FDA, industry partners, and our colleagues in developing and piloting a cost-effective and behaviorally sound front-of-pack labeling scheme.

b. Reduce Deceptive Packaged Labeling for Fruits and Vegetables

As mentioned above, we wish to caution the FDA on implementing a “healthy” icon or a front-of-pack label without simultaneously reviewing the same product within a broader context of the packaged food marketplace – one that may conflict with other visual cues perceived by consumers. This holistic approach is particularly necessary in packaged fruits and vegetable products, often marketed towards children. These products can depict images of fruits and/or vegetables on the package; use words such as “fruit” or “veggie” in the product name (*e.g.*, “Veggie Sticks,” “Fruit Snacks”); and make claims of “made with vegetables” or “contains real fruit” – despite these ingredients having a minimal or non-meaningful contribution to the integrity of the product.¹⁰

⁸ National Consumers League. 2011. NCL statement on IOM’s front-of-package labeling recommendations. Available online at:

http://www.nclnet.org/ncl_statement_on_iom_rsquo_s_front_of_package_labeling_recommendations

⁹ Scott-Thomas, C. 2012. Consumer groups complains to FDA about ‘inconsistent’ NuVal nutrition ratings. FoodNavigator-USA. Available online at: https://www.foodnavigator-usa.com/search?q=nuval&t=all&p=1&ob=score&range_date=date

¹⁰ Gottlieb, S. 2018. Reducing the Burden of Chronic Disease. Speech at the National Food Policy Conference, Washington DC. Available online at: <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>

In the event that a packaged fruit or vegetable product does not meet the “healthy” standard, the product should bear a disclosure on the package that indicates it contains no real fruits or vegetables. Similarly, products that make fruit and vegetable content claims should be required to disclose its amount on the package in household measures (*i.e.*, a measurement that consumers can reasonably be expected to understand, such as “contains ¼ teaspoon of spinach per 1-cup serving).

It is in the best interest of both consumers and food producers to clarify the exact amount of fruit and vegetables within a product. Such a regulatory change is in line with standardizing the term “healthy” in the context an entire food package. We believe it is a necessary step for a holistic regulatory system that benefits, not confounds consumers.

c. Standardize Whole Grain Labels Using a Ratio of % Whole to % Refined

Like packaged fruits and vegetables, product claims in the whole grains category have proliferated in the last decade. Labels indicating “100% whole wheat,” “made with whole grain,” and “multigrain” are placed alongside images of wheat stalks and other positive, healthful depictions of seeds and grains. With no formal regulation on these terms, consumers may be misled to believe a pasta, cracker, bread, or chip product is derived from whole grains – when it may, in fact, be made primarily refined grains, a leading source of “empty calories.”¹¹

Quite like packaged fruits and vegetables discussed above, whole grains may have a minimal or non-meaningful contribution to the integrity of the grain-based product, despite an outward appearance of healthfulness. Understandably, this surplus and sometimes conflicting visual information confuses consumers. Substantial data indicates consumers in all demographics systematically under-consume nutritionally-dense whole grains and overeat refined or processed grains of little nutritional value, a primary correlate to diet-related non-communicable diseases.¹²

Given the systematic labeling issues in the whole grain marketplace, **we urge the FDA to create a “whole grain” threshold, above or below which a product cannot claim to be a whole grain or derived from any of the term’s derivatives** (*e.g.*, “whole wheat,” “multigrain,” etc.). This threshold should **reflect the ratio of whole grains to refined grains per serving, displayed by percentage (*i.e.*, 80% whole/20% refined) or weight (*i.e.*, 30 grams/70 grams).**

If a wheat-based packaged product meets neither the “healthy” nor “whole grain” standard, the product should bear a short text disclosure on the package. All other

¹¹ Guenther, P.M., Kirkpatrick, S.I., Reedy, J., Krebs-Smith, S.M., Buckman, D.W., Dodd, K.W., Casavale, K.O. and Carroll, R.J., 2013. The Healthy Eating Index-2010 Is a Valid and Reliable Measure of Diet Quality According to the 2010 Dietary Guidelines for Americans1–3. *The Journal of nutrition*, 144(3), pp.399-407

¹² Newby, P., Maras, J., Bakun, P., Muller, D., Ferrucci, L., & Tucker, K. L. 2007. Intake of whole grains, refined grains, and cereal fiber measured with 7-d diet records and associations with risk factors for chronic disease. *The American Journal of Clinical Nutrition*, 86(6), 1745–1753

visual or textual depictions alluding to healthfulness or whole grain origins should likewise be prohibited.

d. Establish “Natural” Claims Category – Not a Label

Unlike “healthy” claims, products carrying a “natural” claim refer only to the source and quality of a product’s ingredients. “No artificial ingredients,” “100% natural,” “naturally sourced,” and other variations of this claim have little bearing on the health and nutrition of those who consume them, reflecting only a product’s supply chain history and efforts at transparency from manufacturers. Unlike the relationship between health and diet, little evidence can definitively identify the components of “natural” diet. Natural claims that appear on packaged food products succinctly capture the complexity of our food system – a system which is not yet fully addressed by our current regulatory framework. As it stands, natural claims do not fit into any of the four labeling categories currently under FDA’s jurisdiction – nor should they.

For nearly two decades, the National Consumers League has strongly urged the federal government to reject any proposal for a “natural” label on human food or personal care products without further standardization of product content.¹³ Our consumer research found that “natural” products were not necessarily safer or more effective than conventional products. Further, consumers want more clarity on the difference between a natural product and one that will improve their health rather than a label that claims it has “natural” origins.¹⁴

Rather than implementing a “natural” label, we urge the FDA to create a new category of label claims centered on the term natural, creating thresholds for the limits of “natural” in both ingredients and foods – a process that was started in 2016 but not completed. The Administration should then enforce this definition, **identifying violations (i.e., misleading claims on the links or relationships between a “natural” product and human or environmental health)**, proceeding on a case-by-case basis.

As consumers increasingly demand greater transparency from the food industry, we commend FDA for taking on this complex subject and simultaneously urge caution in moving forward with a standardized definition of natural or its label. We do not believe the FDA should issue a voluntary or mandatory “natural” label, logo, or symbol simply because the term is largely irrelevant to consumer health. The Administration should instead focus efforts on the implications of the term natural and what consumers truly look for: supply chain transparency.

¹³ National Consumers League. 2001. Naturally Misleading: Consumers’ Understanding of “Natural” and “Plant-Derived Claims.”

¹⁴ Ibid.

II. Modernizing Standards of Identity – Case Recommendations

Accurate and adequate information is critical to ensuring the consumer marketplace is defined by trust. Likewise, consistency in product quality and nutritional value is essential to an equitable yet competitive marketplace. Updating standards of identity (SOIs) to reflect the marketplace that consumers experience today is an important first step to renewed public trust and food industry innovation. We commend the FDA for starting the modernization process, proceeding with three specific recommendations.

a. Canned Tuna

The 2015 DGAs lists tuna as a primary food source to achieve greater protein, potassium, and vitamin D.¹⁵ However, the standard of identity for canned tuna has not been updated since 1957.¹⁶ NCL believes the SOI for canned tuna can be modernized in two areas.

First, we urge **FDA to modify the canned tuna SOI to allow manufacturers greater flexibility to use of “safe and suitable” ingredients.** As written, the canned tuna SOI limits manufacturers to use of a single flavor, lemon oil. Modifying the SOI would allow producers and manufacturers to create canned tuna products with chopped red pepper, celery, or relish, for example, all of which would align with consumer tastes and preferences for tuna salad and tuna fish eaten at home.

Second, the FDA should revise the SOI fill method for canned tuna from pressed cake to drained weight. As is, the weight of tuna is determined by fill from pressed cake, an antiquated method used only in the United States. Modifying the SOI to a drained weight method would provide streamline production while simultaneously easing the burden on consumers as they attempt to understand the weight of the product. Further, **the drained weight method is consistent with the international standards** set by the United Nations Food and Agriculture Organization (FAO)’s Codex Alimentarius.¹⁷

b. Olive Oil

In 2015, the National Consumers League made headlines for exposing the mislabeling of nearly a dozen olive oil brands.¹⁸ Of the 11 products that claimed to be extra virgin olive oil (EVOO), only five ultimately met the International Olive Oil Council’s standards

¹⁵ US Health and Human Services (HHS) and US Department of Agriculture (USDA). 2015. Dietary Guidelines for Americans, 2015 – 2020. Eighth Edition.

¹⁶ 21CFR161.190 1957. Code of Federal Regulations Title 21, Volume 2 Sec 161.190

¹⁷ CODEX STAN 70-1981. Codex Standard for Canned Tuna and Bonito. Adopted 1981, Revised 1995, Amended 2011, 2013.

¹⁸ Mitchell, D. 2015. This is the Big Lie About Your Olive Oil. TIME. Available online at: <http://time.com/3894609/extra-virgin-olive-oil/>

for EVOO.¹⁹ Consumers expected to buy the most nutrient-dense olive oil – EVOO, high in monounsaturated fats – but were faced with a largely deceptive marketplace.

The mislabeling of olive oil persisted despite the implementation of the voluntary U.S. grades for olive oil by the U.S. Department of Agriculture (USDA) in 2010.²⁰ The grades provide a reliable quality scale for consumers to reference when making purchasing decisions, but the grades are voluntary and often lack enforcement – leading to a proliferation of EVOO claims despite lower graded products. The discrepancy between international standards, U.S.-based grades of EVOO, and consumer access necessitates action by the FDA.

We urge the FDA to implement a standard of identity for olive oil, given that no such SOI currently exists. The SOI should follow the grading standards set forth by the USDA, but should be mandatory for all olive oil products that are present in the U.S. marketplace. EVOO is a nutrient-dense, popular cooking oil and every bottle should maintain the standardized quality American consumers expect.

c. Greek Yogurt

The dairy industry has answered increasing consumer demand for high protein products by introducing Greek yogurt to the U.S. marketplace. “Greek” yogurt simply refers to the process of straining the whey out of yogurt to produce a thicker consistency while maintaining taste. Because this process can produce a wide variety of dairy products, no international standard for Greek yogurt currently exists.²¹ Without regulatory standards, the product’s nutritional value varies widely – most notably, that of total fat, sugars, and protein content. With no consistency in nutritional value, consumers are left to interpret labels on their own and make choices based solely on advertising and branding – rather than on consistent nutrient density.

The SOI for yogurt has not been updated since 1993.²² **We believe the rapidly evolving yogurt marketplace requires the FDA to create an SOI for Greek (“strained”) yogurt** to ensure production and nutrition consistency for producers and consumers alike.

¹⁹ NCL. 2015. Olive oil mislabeling: Are consumers catching on? National Consumers League: Washington, DC. Available online at: <http://www.nclnet.org/evo>

²⁰ 75 FR 22363. USDA. 2010. US Standards for Grades of Olive Oil and Olive-Pomace Oil. USDA Agricultural Marketing Service, Fruit and Vegetable Programs, Processed Products Branch.

²¹ CODEX STAN 243-2004. Codex Standard for Fermented Milks. Food and Agriculture Organization of the United Nations

²² 21 CFR 131.200-206. 1993. US Code of Federal Regulations.