December 20, 2022
TO: U.S. Food and Drug Administration
FROM: Environmental Working Group
RE: Definition of Term "Healthy" (Docket No. FDA-2016-D-2335)

I. Summary

The Environmental Working Group is pleased to submit this comment on FDA's proposed rule to update the criteria for "healthy" labeling claims on food products. We commend FDA's effort to update food labeling regulations in accordance with current science, but we believe that current science on the relationship between diet and health goes beyond the benefits of nutrient-dense foods in a healthful diet. Specifically, we encourage FDA to consider expanding the criteria for foods labeled "healthy" to include requirements that such foods do not contain food additives that have been associated with health risks, such as propylparaben,[1] FD&C Red No. 3,[2] butylated hydroxytoluene (BHT),[3] and titanium dioxide.[4]

Consumers expect FDA-regulated food ingredients to be safe and free of adverse health risks. However, many food additive ingredients that have been linked to adverse health effects are still sold on the American market. Because of the immense nature of the food ecosystem, there is a gap in FDA regulation pertaining to food chemicals that were approved or designated GRAS many decades ago but are now associated with significant health harms. Incorporating toxicity risks into "healthy" labeling claims would empower consumers to make more healthful diet choices while the agency continues its important work of evaluating the safety of additives allowed in food products.

As discussed below, there are strong consumer choice, public health, and administrability reasons for promulgating requirements that "healthy"-labeled foods do not contain food additive ingredients with known risks.

II. Arguments

First, consumers are likely to understand a "healthy" claim to mean wholesome *and* safe, as the word is used in common parlance. We appreciate that FDA has acknowledged this possibility after comments to the agency's 2016 request for information on the topic and seek to reemphasize the importance of this concern.[5]

The word "healthy" is broad in meaning[6] – compared to more specific claims that a food product is, for example, "nutritious," consumers who spot "healthy" on a packaging label are likely to reasonably believe that the product contains only ingredients that are assuredly safe according to the current science. Indeed, throughout the proposed rule, FDA necessarily specifies that the existing rule for "healthy" product labels pertains specifically to nutrient value.[7] While we appreciate that FDA has long considered "healthy" to concern only nutrient content, we encourage the agency to consider this rulemaking as an opportunity to update the definition according to consumer understandings and current science on food additive safety.

The proliferation of health-related branding in grocery stores underscores the reality that consumers pay attention to ingredient safety in addition to nutrition content when seeking healthful foods. Many major food manufacturers and retailers have modified their formulations and created labeling programs in response to consumer demands for safer food ingredients. For instance, Whole Foods Market, Kroger, and Wild Oats Marketplace do not sell foods containing parabens, Red 3, and BHT in their stores.[8] Other major grocery retailers including Trader Joes, Publix, Ahold Delhaize, Harris Teeter, Aldi, Meijer, Supervalu, and H-E-B have created store brands or shelf labeling systems characterized by their "free-from" lists, whereby all products with that store brand or shelf label are free from certain risky food additives.[9] Many of these store brands are named so as to imply health-related benefits, with brand names such as Simply Nature and True Goodness.[10]

This growing trend among food manufacturers and retailers shows that consumers perceive foods with health-related branding as being healthy in their entirety – that when they choose foods with health-related branding, they are choosing foods that do not contain risky additive ingredients. A central purpose of this rulemaking is to ensure consumers can make informed and healthful choices, so it is critical to account for the breadth of concerns that consumers consider when choosing foods that are marketed as healthy.

Second, adding food additive safety considerations would enable FDA to fulfill its goal to promote public health in the long term through informed dietary choices. That is, rather than focusing on the individual nutrients of individual foods as the original regulation did, this rulemaking is an opportunity to help consumers cultivate a more holistic healthy dietary pattern that has the potential to improve and maintain overall health over time.

The motivating public health goal of this regulation is to "help reduce the burden of nutrition-related chronic diseases" affecting Americans.[11] FDA acknowledges that while these health burdens are caused by a multitude of factors, dietary patterns "throughout the lifespan" contribute to an increased risk. Current science shows exposure to food additives including propylparaben, FD&C Red No. 3, BHT, and titanium dioxide can contribute to increased risks of endocrine disruption, cancer, and neurotoxic health impacts.[12]

Furthermore, studies have shown that some endocrine-disrupting chemicals, including parabens, can cause obesogenic effects.[13] While obesity is a complex condition linked to a multiplicity of factors including biological, social, and environmental causes, a growing body of literature on obesogenic chemicals supports a link between obesogen exposure and adverse health outcomes.[14] Foods are the main source of obesogens, with most obesogens entering food as additives or contaminants rather than occurring naturally.[15]

Because recent scientific research has established links between certain food additives and the adverse health outcomes that FDA seeks to prevent by updating the definition of "healthy," the public health goals of this rulemaking would be best served with ingredient safety requirements behind the implied claim.

Finally, adding ingredient safety criteria would be consistent with the proposed regulatory structure without requiring significant administrative changes on behalf of FDA. The existing and proposed criteria already require that products labeled "healthy" limit certain ingredients that are associated with risks at high intake levels, such as sodium and added sugar.[16] It would be aligned with the proposed regulatory design to require that "healthy"-labeled products also restrict additives with known health risks. Furthermore, the information required to enforce a ban on ingredients with known toxic effects in "healthy"-labeled foods is readily available because ingredients such as propylparaben, FD&C Red No. 3, BHT, and titanium dioxide are already disclosed on product labels.

Incorporating ingredient safety requirements into "healthy" labeling claims would also align the rule with trends in the health foods market without imposing a significant cost on the regulated community. As discussed above, many major grocery retailers have already created food brands invoking health and wellness benefits. By requiring "healthy"-labeled foods to omit certain food additives with known health risks, FDA can encourage food companies to move toward safer ingredient substitutions without going so far as to ban these additives from all foods.

III. Conclusion

FDA's regulatory definition of "healthy" should reflect consumers' expectations of the word, which go beyond nutrient value. Ensuring that "healthy"-labeled foods restrict specific additives that have scientifically-demonstrated health risks would help FDA advance the rule's purpose: providing consumers with information to choose foods that support a holistically healthy dietary pattern.

While it is impractical to communicate full information on the risks of various food additives on a product label, it is important to prevent consumers from being predictably mistaken about the scope of a "healthy" claim. To have nutrient content disambiguated from food additive safety under the general label of "healthy" is to potentially encourage consumers to choose foods that, while nutrient-dense, may contain harmful additive ingredients. As such, companies permitted to claim that a food is healthy should ensure that the food not only includes the requisite nutritional value, but also excludes ingredients that have been linked to adverse health impacts.

Sincerely,

Environmental Working Group

Bibliography

1. FDA designated propylparaben (or propyl paraben) as "generally recognized as safe" (GRAS) in 1977. 21 CFR 184.1670. However, multiple studies since then have linked the preservative to endocrine-disrupting effects. S. Oishi, *Effects of propyl paraben on the male reproductive system*, 40 Food & Chemical Toxicology 1807 (2002); Thuy T. B. Vo et al., *Estrogen receptor α is involved in the induction of Calbindin-D(9k) and progesterone receptor by parabens in GH3 cells: a biomarker gene for screening xenoestrogens*, 76 Steroids 675 (2011); Kristen W. Smith et al., *Urinary Paraben Concentrations and Ovarian Aging among Women from a Fertility Center*, 121 Envtl. Health Persp. 1299 (2013); Anna Maria Wróbel & Ewa Łucja Gregoraszczuk, *Actions of methyl-, propyl- and butylparaben on estrogen receptor-α and -β and the progesterone receptor in MCF-7 cancer cells and non-cancerous MCF-10A cells*, 230 Toxicology Letters 375 (2014).

2. In 1990, FDA banned the use of FD&C Red No. 3 in cosmetics and externally applied drugs after concluding that the additive causes cancer in rats. 21 CFR 81.10(u). In 2021, the California Office of Environmental Health Hazard Assessment (OEHHA) released a study finding that synthetic food dyes, including FD&C Red No. 3, are linked to neurotoxic effects in children. California Environmental Protection Agency, *Potential Neurobehavioral Effects of Synthetic Food Dyes in Children* 137-8 (Apr. 2021). In the European Union, FD&C Red No. 3 (E127) is not allowed in food except for the narrow exception of cocktail and candied cherries. Commission Regulation No. 1129/2011.

3. FDA currently considers BHT GRAS. 21 CFR 182.3173. In 2012, the European Food Safety Authority (EFSA) released a scientific opinion on the safety of BHT as a food additive, finding that consumption of BHT should be limited due to its effects on thyroid, reproduction, and hematological effects in rats. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) *Scientific Opinion on the re-evaluation of butylated hydroxytoluene BHT (E 321) as a food additive*, 10 EFSA J. 2588 (2012).

4. In 2021, EFSA released a scientific opinion concluding that titanium dioxide (E171) could no longer be considered safe in food because a concern for genotoxicity could not be ruled out. EFSA Panel on Food Additives and Flavorings (FAF), *Safety assessment of titanium dioxide (E171) as a food additive*, 19 EFSA J. 6585 (2021). Following this study, the European Commission banned the use of titanium dioxide in food in 2022. Commission Regulation (EU) 2022/62. FDA approved titanium dioxide for use in food in 1966. *Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices*, U.S. Food and Drug Administration (May 2015).

5. *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"*, 87 Fed. Reg. 59168, 59173-4 (Sept. 29, 2022).

6. Merriam-Webster's dictionary defines "healthy" as "beneficial to one's physical … state; conducive to or associated with good health or reduced risk of disease." *Healthy*, Merriam-Webster (last visited Dec. 13, 2022).

7. Examples include: "[T]he claim ["healthy"] indicates that a food, *because of its nutrient content,* may help consumers maintain healthy dietary practices…" *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"*, 87 Fed. Reg. 59168, 59169 (Sept. 29, 2022); "We view the 'healthy' claim as an opportunity to … provide information to consumers on which food products, *because of their nutrient content*, can be most helpful in maintaining healthy dietary practices …" *Id.* at 59174. "The claim 'healthy' on its face is an implied claim

because it suggests that the food, *because of its nutrient content*, may help consumers maintain healthy dietary practices." *Id*. at 59175.

8. *Food Ingredient Quality Standards*, Whole Foods Market (last visited Dec. 13, 2022); *Eat Closer to the Way Nature Intended*, Kroger (last visited Dec. 13, 2022); *125 Unwanted Ingredients*, Wild Oats Marketplace (last visited Dec. 13, 2022). Wild Oats Marketplace also forbids titanium dioxide from foods sold in its stores.

9. *Product FAQs*, Trader Joe's (last visited Dec. 13, 2022); *Made Without Certain Ingredients*, Publix (last visited Dec. 13, 2022); *Nature's Place*, Ahold Delhaize (Jan. 2017) (Ahold Delhaize is the parent company of Food Lion and Giant); *Free From*, Harris Teeter (last visited Dec. 13, 2022); *Simply Nature*, Aldi (last visited Dec. 13, 2022) ("you won't find any added artificial ingredients and preservatives";"no artificial flavors or colors in any of our food"); *Free From*, Meijer (last visited Dec. 13, 2022); *Free from over 140 undesirable ingredients you don't want*, Wild Harvest last visited Dec. 13, 2022); *NOT Included in H-E-B Select Ingredients ®*, H-E-B (July 2022). The aforementioned companies all forbid propylparaben, BHT, and Red 3 from items sold under their health-related store brands and shelf labels. Foods sold under Ahold Delhaize's Nature's Place brand and foods sold under Supervalu's Wild Harvest brand also do not contain titanium dioxide.

10. *Simply Nature*, Aldi (last visited Dec. 13, 2022); *Free From*, Meijer (last visited Dec. 13, 2022).

11. *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"*, 87 Fed. Reg. 59168, 59170 (Sept. 29, 2022).

12. See footnotes 1-4.

13. Sun-Il Choi et al., *Environmental obesogens (bisphenols, phthalates and parabens) and their impacts on adipogenic transcription factors in the absence of dexamethasone in 3T3-L1 cells*, 214 J. Steroid Biochemistry & Molecular Biology 105995 (Nov. 2021); Jerrold J. Heindel, *History of the Obesogen Field: Looking Back to Look Forward*, 10 Frontiers in Endocrinology (2019).

14. Iva Kladnicka et al., *Obesogens in Foods*, 12 Biomolecules 680 (2022).

15. *Id*.; Kimberly Berger et al., *Prenatal Exposure to Mixtures of Phthalates, Parabens, and Other Phenols and Obesity in Five-Year-Olds in the CHAMACOS Cohort*, 18 Int'l. J. Envtl. Res. & Pub. Health 1796 (2021).

16. 21 CFR § 101.65(d)(2)(ii); *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"*, 87 Fed. Reg. 59168, 59180 (Sept. 29, 2022).