



October 22, 2018

Dr. Susan Mayne
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive, HFS-009
College Park, MD 20740-3835

Re: Petition to Label Eggs “Healthy” (FDA-2018-P-1593)

Dear Dr. Mayne,

The Center for Science in the Public Interest (CSPI) opposes the petition by Pete and Gerry’s Organics LLC to the Food and Drug Administration asking the agency to amend the regulatory definition of “healthy” to include eggs as single-ingredient foods and to amend the 2016 guidance¹ to allow a “healthy” claim on eggs despite current limits on cholesterol² for the claim.³ Contrary to the petition’s assertions, this action would not make the regulation consistent with federal dietary guidance and the strongest scientific evidence, as we explain below. Furthermore, CSPI urges the FDA to consider Pete and Gerry’s request for eggs only as part of the agency’s broader rulemaking to update the “healthy” definition. To grant eggs enforcement discretion before such rulemaking would be premature.

CSPI urges the FDA to retain current limits on cholesterol in the “healthy” definition and to consider the public health impact of putting a “healthy” claim on whole eggs, which would likely encourage overconsumption. Eggs are a major source of dietary cholesterol, which, as demonstrated below, raises LDL cholesterol and is already overconsumed by many Americans. Cholesterol is limited in the healthy eating patterns recommended in the *2015-2020 Dietary Guidelines for Americans*, which advises the public to eat “as little cholesterol as possible while consuming a healthy eating pattern.”⁴

CSPI is a nonprofit consumer education and advocacy organization that, since 1971, has worked to improve the public’s health through better nutrition and food safety. CSPI’s work is supported

¹ Food and Drug Administration. September 2016. Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry. Available at:

<https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm521692.pdf>.

² Most foods labeled “healthy” can contain no more than 60 milligrams per RACC. A large egg clearly violates this limit because it contains 186 mg.

³ Pete and Gerry’s Organics LLC. April 23, 2018. Citizen petition from Pete and Gerry’s Organics LLC. Available at: <https://www.regulations.gov/contentStreamer?documentId=FDA-2018-P-1593-0001&attachmentNumber=1&contentType=pdf>.

⁴ U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at: https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf (p. 32)

primarily by the 500,000 subscribers to its *Nutrition Action Healthletter*, one of the nation's largest-circulation health newsletters. CSPI is an independent organization that does not accept government or corporate donations. For decades, CSPI has worked to ensure that food labeling claims are truthful, backed by evidence, and not misleading. CSPI previously commented on eggs and dietary cholesterol in response to the FDA's requests for comments on updating the definition for the term "healthy,"⁵ and in comments on the *2015-2020 Dietary Guidelines Advisory Committee Report*.⁶ We present a summary of those comments and respond to the petitioner's assertions here.

I. Dietary cholesterol raises LDL cholesterol.

Pete and Gerry's petition cites the 2015 DGAC report, which stated that it "will not bring forward [the recommendation in previous editions of the Dietary Guidelines to limit cholesterol to 300 mg/day] because available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum cholesterol, *consistent with the conclusions of the AHA/ACC report*."⁷ [*Emphasis added.*]

However, the AHA/ACC report reviewed only studies published in 1997 or later.⁸ This is a significant omission given the conclusion drawn. A comment submitted in 2015 by CSPI and a number of prominent scientists noted that "[t]here is absolutely no valid scientific justification for the AHA/ACC's or DGAC's ignoring studies that were done before 1997. Given the strict control of diets in metabolic-ward studies—and the paucity of recent metabolic ward studies—the results from those studies should be given extra credence." With regard to the findings and importance of the pre-1997 studies, we explained that:

Weggemans et al. identified 17 studies—including 11 metabolic-ward studies—involving 556 individuals conducted between 1974 and 1999.^{9,10} The diets were designed to maintain stable body weight. The authors' meta-analysis found that for each additional 100 mg/day of dietary cholesterol, serum LDL cholesterol increased by roughly 2 mg/dL. Among the studies they included, 10 involved individuals who consumed an increase of 167 to 560 mg/day of cholesterol...Those increases indicate that consuming one to three egg yolks per day would increase LDL by 4 to 12 mg/dL (0.10 to 0.31 mmol/L). The authors concluded that "the advice to limit the consumption of eggs and other foods rich in dietary cholesterol may still be important in the prevention of coronary heart disease."

⁵ Center for Science in the Public Interest. April 26, 2017. Re: Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments; Docket No. FDA-2016-D-2335. Available at: <https://cspinet.org/sites/default/files/attachment/CSPI%20Healthy%20Comment%20%28002%29.pdf>.

⁶ For more details, see the attached dietary cholesterol comment sent from CSPI and scientists to the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture in advance of the final *2015-2020 Dietary Guidelines for Americans*, and incorporated by reference here. See also Djoussé L, Khawaja OA, Gaziano JM. Egg consumption and risk of type 2 diabetes: a meta-analysis of prospective studies. *American Journal of Clinical Nutrition*. 2016;103:474-80. doi:10.3945/ajcn.115.119933.

⁷ Dietary Guidelines Advisory Committee. 2015. *Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture*. Available at: <https://health.gov/dietaryguidelines/2015-scientific-report/>. (Part D, Chapter 1, p. 58)

⁸ Eckel RH, Jakicic JM, Ard JD, et al. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk. *Circulation*. 2014;129(suppl 2):S76-S99.

⁹ Weggemans RM, Zock PL, Katan MB. Dietary cholesterol from eggs increases the ratio of total cholesterol to high-density lipoprotein cholesterol in humans: a meta-analysis. *American Journal of Clinical Nutrition*. 2001;73:885-91.

¹⁰ Two studies in that meta-analysis published in 1998 had similar findings to the rest of the studies reviewed.

It should be noted that most participants in the studies included in the Weggemans et al. meta-analysis were normal-weight young adults. Few of those studies investigated the impact of dietary cholesterol on people who are middle-aged or older, who are overweight or obese, or who have diabetes, prediabetes, hypertension, or prehypertension, even though those groups comprise major segments of the U.S. population.

In a 1997 meta-analysis of metabolic-ward studies, Clarke et al. concluded that 200 mg/day (equivalent to about one egg/day) of dietary cholesterol increases LDL cholesterol by roughly 4 mg/dL, a calculation that is consistent with Weggemans et al.¹¹ (Only two studies on a total of 21 people were included in both meta-analyses.^{12,13})

The AHA/ACC report appeared to minimize the importance of the findings of Clarke et al. by noting that earlier meta-analyses were based on 6 studies on 128 participants and that “these studies predate our search.”

In contrast, the National Academy of Medicine (formerly the Institute of Medicine) 2002 Dietary Reference Intakes (DRI) report included a dose-response analysis of clinical trials¹⁴ to evaluate the relationship between dietary cholesterol and blood total cholesterol¹⁵ and concluded that cholesterol consumption should be as low as possible while consuming a nutritionally adequate diet.¹⁶ In fact, the DRI report did not set a Tolerable Upper Intake Level because any incremental increase in cholesterol intake increases the risk of coronary heart disease. (This underscores our concerns that characterizing eggs as “healthy” could lead to overconsumption, with important health consequences.) Likewise, the 2015-2020 Dietary Guidelines recommends eating “as little cholesterol as possible while consuming a healthy eating pattern,” citing the DRI report’s conclusion.¹⁷ Furthermore, the 2015-2020 Guidelines notes that the absence of the earlier 300 mg/day target “does not suggest that dietary cholesterol is no longer important to consider when building healthy eating patterns.” Allowing a “healthy” claim on eggs would send the opposite message to consumers.

II. Eggs are associated with an increased risk of heart disease.

Several meta-analyses of cohort studies on egg consumption have not reported an association with eggs and heart disease. However, it is a tall order to expect any single food to be associated with disease risk in prospective cohort studies, in part because many studies report a narrow

¹¹ Clarke R, Frost C, Collins R, Appleby P, Peto R. Dietary lipids and blood cholesterol: quantitative meta-analysis of metabolic ward studies. *BMJ*. 1997;314:112-7.

¹² Ginsberg HN, Karmally W, Siddiqui M, et al. Increases in dietary cholesterol are associated with modest increases in both LDL and HDL cholesterol in healthy young women. *Arteriosclerosis, Thrombosis, and Vascular Biology*. 1995;15:169-78.

¹³ Chenoweth W, Ullmann M, Simpson R, Leveille G. Influence of dietary cholesterol and fat on serum lipids in men. *The Journal of Nutrition*. 1981;111:2069-80.

¹⁴ These clinical trials included metabolic-ward studies and studies in which subjects selected their own diets.

¹⁵ National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. Washington, DC: National Academies Press, 2002. The DRI report’s analysis noted that “on average, an increase of 100 mg/d of dietary cholesterol is predicted to result in a 0.05 to 0.1 mmol/L increase in total serum cholesterol, of which approximately 80 percent is in the LDL fraction.” (p. 569)

¹⁶ *Ibid.* (p. 573-74)

¹⁷ U.S. Department of Health and Human Services and U.S. Department of Agriculture, op. cit. Thus, Pete and Gerry’s characterization of the Dietary Guidelines’ absence of a quantitative cholesterol limit as indicating that “dietary cholesterol no longer needs to be limited” is inaccurate. See Pete and Gerry’s Organics LLC, op. cit. (p. 2)

range of egg consumption and even those are at fairly low levels. Yet, as the 2015 scientists' comment noted, several well-designed and appropriately adjusted cohort studies in the general U.S. population and included in those meta-analyses report—and many such studies in adults with diabetes consistently report—an association between egg consumption and mortality, heart disease, or heart failure. In one meta-analysis of people with diabetes, those who consumed the most eggs (at least one per day) had a 69 percent higher risk of cardiovascular disease than those who consumed the least (less than one per week or never).¹⁸ Similarly, a meta-analysis by Rong et al. reported that people with diabetes who consumed the most eggs had a 54 percent higher risk of coronary heart disease than those who consumed the least.¹⁹ Because an estimated 12 percent of U.S. individuals age 18 or older have diabetes—and an additional 34 percent have prediabetes—putting a “healthy” label on whole eggs could misdirect and mislead a sizeable at-risk group and harm their health.²⁰

III. Dietary cholesterol is overconsumed by many Americans.

As the FDA noted in the final Nutrition Facts label rule,²¹ many U.S. adults—46 percent of men and 28 percent of women in 2013-2014²²—consume more than 300 mg of cholesterol per day. The FDA therefore retained a mandatory cholesterol declaration and Daily Value on the label. It is critical to note that a single (large) egg contains about 62 percent of the DV for cholesterol, and a serving of eggs often includes at least two eggs. U.S. adults now consume 25 percent of their dietary cholesterol from eggs.²³ Allowing a “healthy” claim on eggs would send an “eat more” message to consumers. That message would greatly increase the risk of overconsuming cholesterol and would lead to high levels of LDL cholesterol, which is a major risk factor for heart disease.

IV. The FDA retained cholesterol and the cholesterol DV on the new Nutrition Facts label.

The FDA's May 2016 decision to retain a mandatory cholesterol declaration and DV of 300 mg on the Nutrition Facts label relied on the preponderance of evidence that has demonstrated a positive association between cholesterol intake and blood cholesterol levels. As the FDA acknowledged in the final rule:²⁴

Relying on information provided in the NHLBI Lifestyle Evidence Review, the 2015 DGAC Report concluded that cholesterol is not a nutrient of public health concern. The 2015–2020 DGA noted that, while adequate evidence is not available for a quantitative limit for dietary cholesterol specific to the Dietary Guidelines, individuals should eat as little dietary cholesterol as possible while consuming a healthy dietary pattern that includes eggs and shellfish...

¹⁸ Shin JY, Xun P, Nakamura Y, He K. Egg consumption in relation to risk of cardiovascular disease and diabetes: a systematic review and meta-analysis. *American Journal of Clinical Nutrition*. 2013;98:146-59. doi:10.3945/ajcn.112.051318.

¹⁹ Rong Y, Chen L, Zhu T, Song Y, Yu M, Shan Z, Sands A, Hu FB, Liu L. Egg consumption and risk of coronary heart disease and stroke: dose-response meta-analysis of prospective cohort studies. *BMJ*. 2013;346:e8539. doi:10.1136/bmj.e8539.

²⁰ Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Available at: <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>.

²¹ 81 Fed. Reg. 33741 at 33792.

²² Xu Z, McClure ST, Appel LJ. Dietary cholesterol intake and sources among U.S adults: results from National Health and Nutrition Examination Surveys (NHANES), 2001–2014. *Nutrients*. 2018;10:E771. doi:10.3390/nu10060771.

²³ Ibid.

²⁴ 81 Fed. Reg. 33741 at 33792.

Much of the published evidence, as was analyzed and reported by the IOM, has demonstrated a positive association between cholesterol intake and total cholesterol in the blood. The IOM conducted a dose-response analysis of clinical trials to evaluate the relationship between dietary cholesterol and blood total cholesterol because most of the available evidence was on total cholesterol. From this IOM analysis, it was concluded that, on average, an increase of 100 mg/day of dietary cholesterol is predicted to result in a 0.05 to 0.1 mmol/L increase in total serum cholesterol, of which approximately 80 percent is in the LDL fraction...

[Findings from NHANES] are indicative that a significant portion of the U.S. population consumes amounts of cholesterol in excess of the DRV of 300 mg. We do not consider there to be new information that alters the conclusions of the 2002 IOM report. Therefore, we conclude that the declaration of cholesterol on the Nutrition Facts label can assist consumers in maintaining healthy dietary practices and therefore should remain mandatory. [Citations omitted.]

Likewise, the FDA noted that “the IOM Labeling Committee had recommended that the DV for cholesterol (along with saturated fat and trans fat) be set at a level that is as low as possible in keeping with an achievable health-promoting diet.”²⁵ The agency’s decision to retain the cholesterol declaration and DV—and the agency’s reliance on the DRI report’s analysis showing a relationship between dietary and serum cholesterol—is directly relevant to the question of whether eggs should bear the term “healthy,” an implied nutrient content claim. To grant Pete and Gerry’s petition would be inconsistent with the dietary recommendations on the FDA’s updated Nutrition Facts label and the underlying science.

V. Contrary to assertions in the petition, the FDA’s 2016 “healthy” guidance does not assert that the agency will exercise enforcement discretion with respect to *saturated* fat in eggs or other foods.

Pete and Gerry’s petition mischaracterizes the FDA’s 2016 guidance regarding the enforcement discretion asserted by the agency, which provides for enforcement discretion for products using the term “healthy” on products that are not low in *total* fat. In contrast, the petition incorrectly suggests that the FDA will likely allow “healthy” claims on foods that are not low in *saturated* fat. In addition to greatly exceeding the 60 mg limit on dietary cholesterol in “healthy” foods, most eggs also slightly exceed the 1 g saturated fat limit²⁶ for “healthy” foods.

Pete and Gerry’s writes: “FDA did not specifically address the saturated fat requirements in its guidance document, and there appears to be some uncertainty as to whether FDA intended to exercise enforcement discretion only for products that exceed the limit for total fat or for products that exceed the limits for total as well as saturated fat. However, the additional requirements that must be met for FDA to exercise enforcement discretion indicate that the limit on saturated fat need not be met.”²⁷

In fact, the agency’s guidance does not extend its enforcement discretion to the saturated fat limit, as the FDA has confirmed (oral communication between Vincent de Jesus, Nutritionist,

²⁵ 81 Fed. Reg. 33741 at 33794.

²⁶ A typical whole egg contains 1.5 g saturated fat per 50 g RACC (one large egg). Limits on dietary cholesterol and saturated fat for “healthy” foods are per RACC for most individual foods.

²⁷ Pete and Gerry’s Organics LLC, op. cit. (p. 4)

FDA Office of Nutrition and Food Labeling, and Lindsay Moyer, CSPI, November 10, 2016). CSPI has previously requested that the agency provide this clarification.²⁸ We repeat this request here.

VI. Conclusion.

In conclusion, CSPI urges the FDA to deny Pete and Gerry's petition to amend the regulatory definition of "healthy" to include eggs as single-ingredient foods and to extend the 2016 "healthy" enforcement discretion guidance to allow "healthy" claims on eggs. CSPI urges the FDA to consider Pete and Gerry's request for eggs only as part of the agency's rulemaking to update the "healthy" definition.

To grant the petition would run afoul of the 2015-2020 Dietary Guidelines' advice to "eat as little cholesterol as possible while consuming a healthy eating pattern" and could mislead consumers. Permitting a "healthy" label on whole eggs could lead to overconsumption in a manner inconsistent with federal dietary guidance and scientific evidence and could impair, rather than inform, consumers' choices and health.

²⁸ The FDA's guidance states that "[f]oods that use the term 'healthy' on their labels that are not low in total fat should have a fat profile makeup of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food)." CSPI was concerned that this sentence might lead companies to erroneously conclude—as Pete and Gerry's has—that the FDA will disregard the saturated fat limit if a food's fat is predominantly unsaturated. *See* Center for Science in the Public Interest, *op. cit.*