

April 19, 2018

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Commissioner:

The undersigned, Pete and Gerry's Organics LLC (Pete and Gerry's), respectfully submits this Citizen Petition, under the Federal Food, Drug, and Cosmetic Act (FDCA) and the U.S. Food and Drug Administration's (FDA's) implementing regulations at 21 C.F.R. § 101.65(d), requesting that the Commissioner update FDA's regulation for the term "healthy" to make the regulation consistent with current federal dietary guidance as set forth in the 2015-2020 Dietary Guidelines for Americans (DGA) and with the latest scientific evidence. Specifically, Petitioner requests that the Commissioner 1) amend 21 C.F.R. § 101.65(d) to allow eggs, as single ingredient foods, to bear the claim "healthy" and, in the interim, 2) amend FDA guidance "Use of the Term 'Healthy' in the Labeling of Human Food Products" so that, under FDA's enforcement discretion, eggs may be labeled "healthy" even though eggs contain cholesterol at levels exceeding the current limit in 21 C.F.R. § 101.65(d).

I. Action Requested

Over the last decade the dietary guidelines have shifted to place emphasis on certain foods as compared to specific nutrients in the diet. Notably, the 2015-2020 DGA shine attention on the importance of eating certain whole foods, including eggs, rather than specific nutrients to achieve better health and wellness. However, the current labeling regulation for the term "healthy," in 21 C.F.R. § 101.65(d), is based on the past thinking about nutrients and prevents single ingredient foods that contain beneficial nutrients recommended by the 2015-2020 DGA, such as eggs, from bearing the word "healthy" in their labeling.

Under FDA's current food labeling regulation, whether a food can be labeled "healthy" is based on specific nutrient levels in the food rather than its overall nutrition quality. In 2016, FDA announced that it had started a public process to redefine the "healthy" nutrient content claim for food labeling. FDA issued a notice requesting input on the definition of healthy. In addition, FDA issued a guidance document, "Guidance for Industry: Use of the Term 'Healthy' in the Labeling of Human Food Products," stating that FDA does not intend to enforce the regulatory requirements for products that use the term healthy if certain criteria

described in the guidance document are met. In line with the 2015-2020 DGA, FDA decided that it would exercise enforcement discretion for foods that exceeded the fat level content provided the fat was primarily unsaturated fat which was disclosed in the nutrition facts box. FDA's guidance did not reconsider its position regarding cholesterol limits despite the DGA's position that dietary cholesterol no longer needs to be limited. As a result, even though eggs are specifically called out in three model diets in the 2015-2020 DGA, they remain ineligible for the healthy claim.

The 2015-2020 DGA (like previous editions) recommends building healthy dietary patterns around nutrient-dense foods. According to the DGA, eggs are a nutrient dense food, i.e., they have large amounts of beneficial nutrients in relation to their total caloric content. In fact, eggs are included in all three model diets outlined in the 2015-2020 DGA. Moreover, eggs are recognized as a good source of high-quality protein. Eggs are among the most affordable sources of protein and also have significant amounts of other nutrients, including vitamin D and choline.¹ Yet, under FDA's current regulation and guidance, eggs may not be labeled "healthy."

In this Petition, Pete and Gerry's requests that FDA modify the terms of its guidance document and initiate new rulemaking to permit eggs to use the term "healthy." Specifically, Petitioner requests that:

1. FDA initiate rulemaking to amend 21 C.F.R. § 101.65(d), to specifically allow a healthy claim for eggs.
2. FDA amend current guidance so that, pending amendment of 21 C.F.R. § 101.65(d), FDA will exercise enforcement discretion for eggs that are labeled "healthy."

II. Statement of Grounds

Educating consumers about the key components of a healthful diet has become increasingly important for public health. The 2015-2020 DGA emphasized the need to improve the dietary patterns of the American public. FDA's current regulatory approach for food labeling claims focuses on nutrients rather than on foods and limits the ability of food producers to tell consumers that certain foods, such as eggs, are healthy, even though they are currently recommended as key

¹ Other advantages of eggs include ease and speed of preparation, acceptability across a wide range of cultures, and popularity among population groups that may need additional protein, such as seniors because of the risk of sarcopenia.

components of a healthful diet. Petitioner is asking FDA to allow the use of the healthy claim for eggs. This would help the American public to better understand that eggs fit in a healthy dietary pattern that is affordable to most Americans. The requested action would make FDA's regulatory regime consistent with current federal dietary recommendations, would be consistent with current scientific evidence about the health benefits of eggs, and would significantly benefit the public health by ensuring that consumers fully understand the dietary value of eggs.

A. Regulatory Background

The Nutrition Labeling and Education Act of 1990 (NLEA), among other things, amended the FDC Act to give FDA the authority to regulate the use of so-called nutrient content claims authorized by FDA in the labeling of food.²

Under this authority, FDA issued various regulations defining certain nutrient content claims, including the definition of "healthy."³ FDA relied on the 1990 DGA and various U.S. Department of Health and Human Services and National Academy of Sciences publications.⁴ The intent of the nutrient content regulations was to assist consumers in making appropriate dietary choices. FDA noted that it would be "inappropriate if the definition of 'healthy' were to exclude an entire category of foods that is recommended in dietary guidelines."⁵ Nevertheless, the regulations do exclude several categories of foods that are currently recommended in the 2015-2020 DGA, including eggs, from bearing a healthy claim because of their fat and cholesterol content.

Specifically with regard to the use of the term "healthy" as a nutrient content claim, FDA established a definition of the term "healthy" and certain requirements for when the term "healthy" can be used as a nutrient content claim in the labeling of food. FDA set limits for total fat, saturated fat, cholesterol, and sodium content and minimum levels of certain nutrients which should be consumed more (vitamin A, vitamin C, calcium, iron, protein, or fiber) for certain categories of food in order to bear a "healthy" nutrient content claim. Under the resulting regulation, which remains in effect more than 20 years later, foods that bear a "healthy" nutrient content claim generally must be "low fat," "low saturated fat," and contain no more than a specified amount of cholesterol as defined in FDA

² See FDC Act §§ 403(r)(1)(A) and 403(r)(2).

³ 21 C.F.R. § 101.65; Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. 24,232 (May 10, 1994).

⁴ See 59 Fed. Reg. 24,232.

⁵ *Id.* at 24,233.

regulations. These limitations were based on the then prevailing view that Americans needed to reduce the dietary intake of fat, saturated fat, and cholesterol. However, scientific understanding of nutrition has advanced, and the 2015-2020 DGA no longer focuses on nutrients, such as total fat and cholesterol, but focus on certain foods and dietary patterns.

Recognizing the changes in nutrition science and public health, FDA has updated its nutrition labeling requirements. Moreover, in 2016, FDA issued guidance announcing that it will exercise enforcement discretion with respect to certain aspects of its regulation governing the use of the term “healthy” as a nutrient content claim pending amendment of the regulation.⁶ Under this guidance, FDA will not take enforcement action against a food that is labeled with the claim “healthy” and related descriptors even if that food does not qualify as low-fat under 21 C.F.R. § 101.62.⁷

Specifically, under the enforcement discretion, a food may bear the label claim “healthy” even if it does not qualify as low in total fat, as long as it meets the following requirements:

- (1) The food “should have a fat profile makeup of predominantly mono and polyunsaturated fats”
- (2) The “amounts of mono and polyunsaturated fats are declared on the label”
- (3) The food is a good or excellent source of vitamins A or C, iron, calcium, protein, dietary fiber, potassium or vitamin D.⁸

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. Notably, FDA’s requirement that a food “should have a fat profile makeup of

⁶ FDA, Guidance for Industry: Use of the Term “Healthy in the Labeling of Human Food Products (Sept. 2016), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm521690.htm>.

⁷ 21 C.F.R. § 101.62(b)(2), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?fr=101.62>.

⁸ FDA, Use of the Term “Healthy” in the Labeling of Human Food Products: Guidance for Industry, 5-6 (Sept. 2016).

predominantly mono and polyunsaturated fats” would be redundant if FDA had intended to allow more than 3 g fat (the limit for low fat) but would have intended to continue to require that food to be low in saturated fat, i.e., contain no more than 1 g saturated fat per reference amount customarily consumed (RACC). After all, a food with more than 3 g fat per RACC but no more than 1 g saturated fat per RACC would always have a fat profile makeup of predominantly mono- and polyunsaturated fat; the food would contain at least 2 g unsaturated fat per RACC.

Even though the current DGA did not set a limit for the dietary cholesterol intake, FDA’s guidance did not address the requirement that a healthy food must contain no more than 60 mg cholesterol per RACC.⁹

B. Current Dietary Guidelines and Nutrition Science Support That Eggs Are Healthy

Several lines of evidence, including recommendations presented in the 2015-2020 Dietary Guidelines for Americans (DGA), scientific evidence on the relationship between dietary cholesterol and blood cholesterol levels, and evidence in the published literature on eggs and disease risk, support eggs as a “healthy” food in the context of a balanced and healthy dietary pattern.

1. Dietary Guidance Emphasizes Healthy Patterns with Nutrient-Dense Foods, Including Eggs

(a) Current Dietary Guidance Emphasizes Healthy Dietary Patterns

The DGA are published every five years by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA) as required under the National Nutrition Monitoring and Related Research Act of 1990.¹⁰ The DGA is a science-based document that provides focused guidance to help promote health and reduce chronic disease risk in the U.S. population while also providing the foundation for development of federal food, nutrition, and health policies and programs.¹¹

⁹ 21 C.F.R. § 101.65(d)(2)(i)(F),

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.65>.

¹⁰ National Nutrition Monitoring and Related Research Act of 1990, Pub. L. 101-445, § 301 (1990); 7 U.S.C. § 5341, Title III.

¹¹ 2015 Dietary Guidelines Advisory Committee, USDA & FDA, *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* Appendix E-6, p. 3 (Feb. 2015), <http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> [hereinafter *2015 DGAC Report*].

Over the years, the foundation of dietary guidance has shifted from an emphasis on intake of specific nutrients to consumption of a healthy dietary pattern that provides necessary nutrients at an appropriate energy intake. The 2015-2020 DGA emphasize that the focus of a healthy dietary pattern is variety, nutrient density, and amount.¹² In developing the 2015-2020 DGA, healthy dietary patterns that can help consumers understand recommended amounts to consume from each food group to create a healthy diet were identified. These dietary patterns include Healthy U.S.-Style, Mediterranean-Style, and Healthy Vegetarian-Style diets.¹³ The recommended amounts and types of foods characterized by each of these diets are intended to meet the Recommended Daily Allowances (RDA) for nutrients such that nutritional adequacy is met without exceeding recommended energy intake and 2010 DGA limits for sodium and saturated fat.¹⁴

(b) Eggs are a Nutrient-Dense Food and a Component of Healthy Dietary Patterns

Nutrient-dense foods are central to the healthy dietary patterns promoted in the 2015-2020 DGA. In the DGA, nutrient-dense foods are described as foods that “provide substantial amounts of vitamins and minerals (micronutrients) and relatively few calories compared to forms of the food that have solid fat and/or added sugars.”¹⁵ The DGA state that “all vegetables, fruits, whole grains, seafood, **eggs**, beans and peas, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats and poultry—when prepared with little or no added solid fats, sugars, refined starches, and sodium—are nutrient-dense foods.”¹⁶ Eggs are additionally identified as a specific type of food in the protein food group that can contribute to recommended intakes for the food group.¹⁷ In fact, an egg is among the examples of a protein food depicted on the purple icon for the protein food group represented on the MyPlate graphics, and this image is repeated throughout the DGA materials as a visual indicator of representative foods in this food group.¹⁸ Furthermore, in the DHHS and USDA’s calculations to confirm that each

¹² U.S. Department of Health and Human Services and U.S. Department of Agriculture, *2015–2020 Dietary Guidelines for Americans*, 8th Edition, p. xii (December 2015), <http://health.gov/dietaryguidelines/2015/guidelines/>.

¹³ *2015-2020 DGA*, p. 18, 35-36.

¹⁴ *2015 DGAC Report*, Part D, Chapter 1, p. 26.

¹⁵ *2015 DGAC Report*, Appendix E-5, p. 8.

¹⁶ *2015-2020 DGA*, p. xiv (emphasis added).

¹⁷ *2015-2020 DGA*, p. xiii.

¹⁸ *2015-2020 DGA*, pp. xv, 19, 69.

dietary pattern meets recommended nutrient intakes, consumption of eggs was assumed for the protein foods group.¹⁹ Notably, one large egg provides 6 grams of protein, which is equivalent to 12% of the Daily Value for protein, and thus qualifies as a “good source” of this nutrient.^{20, 21}

In addition to being a high-quality source of protein,²² eggs are a source of varying levels of 13 essential vitamins and minerals.²³ Notably, some of the nutrients of concern for the U.S. population recognized by the DGA, including choline and vitamin D, are present in eggs.²⁴ A large egg (50 grams) provides 147 mg choline,²⁵ which is equivalent to approximately one-quarter to one-third of the choline Adequate Intake level of this nutrient for an adult.²⁶ The 2015-2020 DGA note that “[e]ggs provide the most choline,”²⁷ thus conveying the importance of eggs for dietary intake of this under-consumed nutrient in the U.S. A 2017 analysis of dietary intakes by the U.S. population indicates that, compared to non-consumers of eggs, adult egg consumers are more likely to have adequate intake of this important nutrient.²⁸ Eggs are also included among the ranked food sources of vitamin D in the DGA²⁹ and are highlighted as a source of vitamin D within the dietary patterns analyses.³⁰ Eggs contain a variety of other micronutrients important for health and can contribute to intake of these important nutrients, including calcium, iron, potassium, which, in addition to vitamin D,³¹ are nutrients

¹⁹ 2015 DGAC Report, Appendix E-3.7, p. 6.

²⁰ 21 C.F.R. § 101.54(c).

²¹ USDA, 01123, Egg, whole, raw, fresh, National Nutrient Database for Standard Reference Release Legacy April, 2018, Software v.3.9.1 2018-04-10, The National Agricultural Library, <https://ndb.nal.usda.gov/ndb/search/list> [hereinafter “USDA National Nutrient Database, 2018”]. Accessed April 18, 2018.

²² American Egg Board, 2018. *Biological Value*, <https://www.incredibleegg.org/eggyclopedia/b/biological-value/>. Accessed March 23, 2018.

²³ Egg Nutrition Center. *Nutrients in Eggs*, <https://www.eggnutritioncenter.org/topics/nutrients-in-eggs/>. Accessed April 13, 2018.

²⁴ 2015-2020 DGA, p. 60.

²⁵ USDA National Nutrient Database, 2018.

²⁶ Institute of Medicine. Food and Nutrition Board. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B₆, Folate, Vitamin B₁₂, Pantothenic Acid, Biotin, and Choline*, Washington, DC: National Academy Press (1998).

²⁷ 2015-2020 DGA, p. 23.

²⁸ Wallace TC & Fulgoni VL, *Usual Choline Intakes Are Associated with Egg and Protein Food Consumption in the United States*, *Nutrients*, Aug 5;9(8) (2017), pii: E839, doi: 10.3390/mu9080839.

²⁹ 2015-2020 DGA, p. 113.

³⁰ 2015 DGAC Report, Appendix E-3.2, p. 5.

³¹ USDA National Nutrient Database, 2018.

that must be declared in the Nutrition Facts Panel under the new nutrition labeling requirements.³²

2. U.S. Dietary Guidance No Longer Sets a Specific Limit for Intake of Dietary Cholesterol

One large egg (50 grams) provides approximately 186 mg cholesterol.³³ Eggs and egg dishes are thus a major source of dietary cholesterol in the U.S. diet, accounting for approximately 24% and 30% of dietary intake by children³⁴ and adults³⁵, respectively. Previous versions of the DGA, for example DGA 2005 and DGA 2010, set a limit for cholesterol intake of no more than 300 mg cholesterol per day. This limit was based on the long-held belief that dietary cholesterol adversely impacted blood lipids and in turn increased risk for coronary heart disease (CHD).^{36,37} The 2010 DGA recommended reduced intake of foods high in cholesterol as a strategy to help maintain normal blood cholesterol levels, citing as an example use of egg substitutes in place of whole eggs, while also noting, “[i]ndependent of other dietary factors, evidence suggests that one egg (i.e., egg yolk) per day does not result in increased blood cholesterol levels, nor does it increase the risk of cardiovascular disease [CVD] in healthy people.”³⁸

In reviewing the scientific evidence for development of the 2015-2020 DGA, the Dietary Guidelines Advisory Committee acknowledged that cholesterol is not a nutrient of concern for overconsumption by the U.S. population and recommended the discontinuation of a specific limit on cholesterol.³⁹ This recommendation was based on evidence from a 2013 report issued by the American Heart Association and the American College of Cardiology (AHA/ACC),⁴⁰ which the Committee

³² U.S. Food and Drug Administration. Changes to the Nutrition Facts Label. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm>. Page Last Updated: 03/15/2018.

³³ USDA National Nutrient Database, 2018.

³⁴ Keast DR et al., *Food sources of energy and nutrients among children in the United States: National Health and Nutrition Examination Survey 2003-2006*, *Nutrients*, Jan 22;5(1):283-301 (2013), doi: 10.3390/nu5010283.

³⁵ O'Neil CE et al., *Food sources of energy and nutrients among adults in the US: NHANES 2003-2006*, *Nutrients*, Dec 19;4(12):2097-120 (2012), doi: 10.3390/nu4122097.

³⁶ U.S. Department of Health and Human Services and U.S. Department of Agriculture, *Dietary Guidelines for Americans, 2005*, 6th Edition, p. 34.

³⁷ U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Dietary Guidelines for Americans, 2010*, 7th Edition, p.3.

³⁸ *Id.* at 27.

³⁹ *2015 DGAC Report*, Part D, Chapter 1, p. 17.

⁴⁰ Eckel RH et al., *2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice*

concluded, showed “no appreciable relationship between consumption of dietary cholesterol and serum cholesterol.”⁴¹ The AHA/ACC report states, “[t]here is insufficient evidence to determine whether lowering dietary cholesterol reduces [low-density lipoprotein cholesterol] LDL-C.” For control of LDL-C, the AHA/ACC report recommends following a healthy dietary pattern such as the DASH (Dietary Approaches to Stop Hypertension) dietary pattern, the USDA Food Pattern, or the American Heart Association Diet.⁴² These healthy dietary patterns are similar to patterns recommended in the DGA. The AHA/ACC report did not provide a recommendation to limit consumption of eggs.

Based on the available evidence, the 2015-2020 DGA therefore dropped the limit of 300 mg dietary cholesterol per day. In the key recommendations provided in current dietary guidance, only saturated fats and *trans* fats, added sugars, and sodium are identified as components of “healthy eating pattern limits.”⁴³ Although the guidelines do not set a specific limit for intake of dietary cholesterol, the guidelines encourage consuming “as little dietary cholesterol as possible while consuming a healthy eating pattern.”⁴⁴ The current guidelines additionally state, “[a] few foods, notably egg yolks and some shellfish, are higher in dietary cholesterol but not saturated fats. Eggs and shellfish can be consumed along with a variety of other choices within and across the subgroup recommendations of the protein foods group.”⁴⁵ This exception for eggs in the dietary guidance conveys that eggs can indeed be a component of healthy dietary patterns.

Guidance from several expert groups as well as dietary recommendations outside the U.S., although not consistent with regard to recommendations for consumption of eggs and/or cholesterol, consistently allow for consumption of eggs in the context of a healthy diet. Examples include:

- American Heart Association/American College of Cardiology: No upper limit for egg or dietary cholesterol⁴⁶, though a follow-up statement with evidence-based dietary recommendations notes that reduced intake of egg

Guidelines, *Circulation*, Jun 24;129(25 Suppl 2):S76-99 (2013), doi: 10.1161/01.cir.0000437740.48606.d1. No abstract available. Erratum in: *Circulation*, Jun 24;129(25 Suppl 2):S100-1 (2014); *Circulation*, Jan 27;131(4):e32 (2015).

⁴¹ 2015 *DGAC Report*, Part D, Chapter 1, p. 17.

⁴² Eckel et al., 2013, at S86-87.

⁴³ 2015-2020 *DGA*, p. xii.

⁴⁴ *Id.* at 32.

⁴⁵ *Id.* at 34.

⁴⁶ Eckel et al., 2013, at S86.

yolks may be appropriate for some individuals such as those with elevated LDL-C.⁴⁷

- Australian Heart Foundation: “Eating 6-7 eggs a week will not increase your risk of heart disease when eaten as part of a healthy eating pattern.”⁴⁸
- British Heart Association: Recommendations note that eggs are part of a balanced diet.⁴⁹
- New Zealand Heart Foundation: Those at increased risk of heart disease “can eat up to six eggs per week as part of a heart-healthy eating pattern.”⁵⁰ “For the general healthy population, eggs can be included as part of a heart-healthy eating pattern.”⁵¹
- Nordic Nutrition Recommendations 2012: No upper limit for either egg or dietary cholesterol.⁵²

3. Evidence in the Recent Published Literature Supports Consumption of Eggs in a Healthy Diet

A risk apportionment analysis published in 2008 found egg consumption to account for a minute fraction of CHD risk compared to other modifiable risk factors such as smoking, weight, alcohol consumption, and exercise, leading the researchers to conclude, “across all risk groups that represent over 85% of U.S. males age 25 and older, and 86% of U.S. females of similar ages, consumption of one egg per day contributes to less than 1% of the CHD mortality risk.”⁵³ This study thus helped put into perspective the role of eggs in cardiovascular health, though the subject of eggs and health, particularly cardiovascular outcomes and

⁴⁷ Van Horn L. et al., *Recommended Dietary Pattern to Achieve Adherence to the American Heart Association/American College of Cardiology (AHA/ACC) Guidelines: A Scientific Statement From the American Heart Association*, *Circulation*. Nov 29;134(22):e505-e529 (2016). Erratum in: *Circulation*. Nov 29;134(22):e534 (2016).

⁴⁸ The Australian Heart Foundation, *Eggs*, <https://www.heartfoundation.org.au/healthy-eating/food-and-nutrition/protein-foods/eggs>.

⁴⁹ British Heart Foundation, *Healthy Eating*, <https://www.bhf.org.uk/heart-health/preventing-heart-disease/healthy-eating>.

⁵⁰ The New Zealand Heart Foundation, *Eggs and the heart* (2017), <https://www.heartfoundation.org.nz/shop/submissions/eggs-position-statement.pdf>.

⁵¹ *Id.* at 2.

⁵² Nordic Council of Ministers, *Nordic Nutrition Recommendations 2012: Integrating Nutrition and Physical Activity*, <http://www.norden.org/en/theme/former-themes/themes-2016/nordic-nutrition-recommendation/nordic-nutrition-recommendations-2012> (2014).

⁵³ Barraj L. et al. *A comparison of egg consumption with other modifiable coronary heart disease lifestyle risk factors: a relative risk apportionment study*. *Risk Anal.* 2009 Mar;29(3):401-15. doi: 10.1111/j.1539-6924.2008.01149.x.

biomarkers of cardiovascular health, continues to be a topic of considerable research and discussion.

A 2018 review of intervention studies and cohort studies conducted in the 10 years prior to Spring 2015, provides insight on the current understanding of the relationship between eggs and disease risk.⁵⁴ Results from high-quality intervention studies, including healthy individuals and patients with type 2 diabetes (T2D) or hyperlipidemia, have shown that dietary cholesterol, primarily from eggs, does not have a clinically relevant effect on serum cholesterol; thus, there is no clear mechanistic rationale for eggs to increase the risk of CVD or T2D. Given the absence of mechanistic support, the authors note that findings of apparent increased risk for heart disease and diabetes in some observational studies may likely be attributed to lack of adequate control for dietary factors (e.g., *trans* fat or other dietary components often present with high egg intake), other lifestyle factors, or genetics. Overall, the authors found “no consensus of an association of egg consumption and the risk of CVD” in observational studies and no support for clinically relevant effects from intervention studies. Furthermore, the authors concluded that for all “up to seven eggs per week can be safely consumed,” though for patients with established conditions such as CVD or T2D consumption in the context of an overall healthy diet and medical care are particularly important.

Blesso and Fernandez also recently examined the relationship between dietary cholesterol, serum lipids, and CVD with a specific focus on egg consumption. The authors concluded that recent evidence from intervention studies with eggs does not show a negative effect of added dietary cholesterol on blood lipid profile, and in fact the profile of lipoprotein particles and functionality of high density lipoprotein (HDL) may be improved.⁵⁵

Evidence from meta-analyses published since release of the current dietary guidelines continues to support the absence of an effect of eggs on cardiovascular risk in the general population. In 2016, Alexander and colleagues published a meta-analysis of cohort studies conducted through August 2015 evaluating the effect of high (approximately 1 egg per day) versus low (approximately <2 eggs per week) consumption on risk of stroke and CHD.⁵⁶ Based on respective

⁵⁴ Geiker NRW, Larsen ML, Dyerberg J, Stender S, Astrup A. *Egg consumption, cardiovascular diseases and type 2 diabetes*. Eur J Clin Nutr. 2018 Jan;72(1):44-56. doi: 10.1038/ejcn.2017.153.

⁵⁵ Blesso CN, Fernandez ML. *Dietary Cholesterol, Serum Lipids, and Heart Disease: Are Eggs Working for or Against You?* Nutrients. 2018 Mar 29;10(4). pii: E426. doi: 10.3390/nu10040426.

⁵⁶ Alexander DD, Miller PE, Vargas AJ, Weed DL, Cohen SS. *Meta-analysis of Egg Consumption and Risk of Coronary Heart Disease and Stroke*. J Am Coll Nutr. 2016 Nov-Dec;35(8):704-716.

analyses of 7 studies, high egg consumption was found to reduce the risk of stroke by 12% (summary relative risk estimate [SRRE] = 0.88, 95% confidence interval [CI] 0.81, 0.97) and had no effect on risk of CHD (SRRE = 0.97, 95% CI 0.88, 1.07).

Similarly, in an independently conducted dose-response meta-analysis of prospective studies conducted through March 2017 examining intake of major food groups and risk of adverse cardiovascular outcomes, Bechthold and colleagues reported that an incremental intake of one serving of egg per day (50 g/day) was not associated with risk of CHD (n = 11 studies; RR = 0.99, 95% CI 0.95, 1.06) or risk of stroke (n = 10 studies; RR = 0.99, 95% CI 0.93, 1.05).⁵⁷ For both CHD and stroke, there was no evidence of a non-linear dose response association. An additional analysis of 4 studies suggested that an incremental intake of 50 g/day of egg was associated with increased risk of heart failure (RR = 1.16, 95% CI 1.03, 1.31); this finding was consistent with results reported in another 2017 meta-analysis of high versus low consumption of eggs and risk of incident heart failure (RR = 1.25, 95% CI 1.12, 1.39).⁵⁸ In the meta-analysis by Bechthold and colleagues, risk of heart failure with increased egg consumption showed a non-linear dose response association, with an approximately 50% increased risk observed with an increasing intake up to 100 g/day. The investigators concluded, “because definite mechanisms of possible effects of eggs and observed relationships are not clear and vary regarding individual outcomes, respectively, the association between egg consumption and [heart failure] should be interpreted with caution.”⁵⁹

It is recognized that the literature on consumption of eggs and risk for diabetes is difficult to interpret,⁶⁰ though some evidence has suggested that egg consumption may be associated with increased cardiovascular risk in the subpopulation with diabetes.⁶¹ Several recent, independently conducted systematic meta-analyses of cohort studies using either high versus low or dose-response comparisons present

⁵⁷ Bechthold A, Boeing H, Schwedhelm C, Hoffmann G, Knüppel S, Iqbal K, De Henauw S, Michels N, Devleesschauwer B, Schlesinger S, Schwingshackl L. *Food groups and risk of coronary heart disease, stroke and heart failure: A systematic review and dose-response meta-analysis of prospective studies*. Crit Rev Food Sci Nutr. 2017 Oct 17;1-20. doi: 10.1080/10408398.2017.139228.

⁵⁸ Khawaja O, Singh H, Luni F, Kabour A, Ali SS, Taleb M, Ahmed H, Gaziano JM, Djousse L. *Egg Consumption and Incidence of Heart Failure: A Meta-Analysis of Prospective Cohort Studies*. Front Nutr. 2017 Mar 27;4:10. doi: 10.3389/fnut.2017.00010.

⁵⁹ Bechthold et al., 2017.

⁶⁰ Tran NL, Barraj LM, Heilman JM, Scrafford CG. *Egg consumption and cardiovascular disease among diabetic individuals: a systematic review of the literature*. Diabetes Metab Syndr Obes. 2014 Mar 24;7:121-37. doi: 10.2147/DMSO.S58668.

⁶¹ Geiker et al., 2018.

an unclear relationship between egg consumption and the risk of developing T2D.^{62,63,64,65} These meta-analyses consistently report no overall association between egg consumption and risk of T2D, but find a direct association between these variables when performing a sub-analysis with studies of U.S. populations. Due to the heterogeneity among non-U.S. studies in all meta-analyses and the possibility of confounding in U.S. studies due to high consumption of processed meats, it is not possible to determine the true nature of the relationship between egg consumption and T2D risk at this time. The authors of one study concluded “the possibility that these results may be due to residual confounding by dietary behaviours restricted to certain populations cannot be excluded.”⁶⁶

A recently published systematic review of randomized controlled trials with durations ≥ 12 weeks reported no effect of consumption of 6-12 eggs/week as compared to control diets with consumption of < 2 eggs/week on risk factors for CVD in individuals at risk of developing or diagnosed with T2D.⁶⁷ Risk factors for CVD considered included blood levels of total cholesterol, LDL-C, triglycerides, fasting glucose, insulin, and C-reactive protein. Additionally, an increase in HDL cholesterol was observed with egg consumption in 4 of 6 studies.

In summary, the effect of egg consumption on health has been a much studied subject. The available evidence generally does not suggest increased risk for CVD among healthy individuals with consumption of eggs. Some associations between eggs and T2D have been observed, though the results are neither clear nor consistent, and have not been replicated in intervention trials. As recently concluded by Geiker and colleagues, “dietary patterns, physical activity and genetics affect the predisposition of CVD and T2D more than a single food item as eggs” and “up to seven eggs per week can safely be consumed,” including intake among patients with established CVD or T2D if a healthy diet and lifestyle are

⁶² Djoussé L, Khawaja OA, Gaziano JM. *Egg consumption and risk of type 2 diabetes: a meta-analysis of prospective studies*. Am J Clin Nutr. 2016 Feb;103(2):474-80.

⁶³ Tamez M, Virtanen JK, Lajous M. *Egg consumption and risk of incident type 2 diabetes: a dose-response meta-analysis of prospective cohort studies*. Br J Nutr. 2016 Jun;115(12):2212-8.

⁶⁴ Tian S, Xu Q, Jiang R, Han T, Sun C, Na L. *Dietary Protein Consumption and the Risk of Type 2 Diabetes: A Systematic Review and Meta-Analysis of Cohort Studies*. Nutrients. 2017 Sep 6;9(9).

⁶⁵ Wallin A, Forouhi NG, Wolk A, Larsson SC. *Egg consumption and risk of type 2 diabetes: a prospective study and dose-response meta-analysis*. Diabetologia. 2016 Jun;59(6):1204-13.

⁶⁶ Tamez et al., 2016.

⁶⁷ Richard C, Cristall L, Fleming E, Lewis ED, Ricupero M, Jacobs RL, Field CJ. *Impact of Egg Consumption on Cardiovascular Risk Factors in Individuals with Type 2 Diabetes and at Risk for Developing Diabetes: A Systematic Review of Randomized Nutritional Intervention Studies*. Can J Diabetes. 2017 Aug;41(4):453-463.

maintained.⁶⁸ The current available scientific literature therefore supports consumption of eggs in the context of healthy patterns of diet and lifestyle for all individuals.

Overall Conclusions of the Evidence on Eggs and “Healthy”

The DGA stress the importance of healthy dietary patterns and nutrient dense-foods. Dietary guidance in the United States specifically identifies eggs as a nutrient-dense food, and as a component of the protein foods group, dietary guidance illustrates that eggs can be incorporated into healthy dietary patterns. In addition to providing a good source of protein, eggs are a source of under-consumed nutrients including choline and vitamin D, and eggs can contribute to intake of a variety of other micronutrients important for health.

Dietary guidance no longer recognizes a specific limit on dietary cholesterol intake as the available evidence shows “no appreciable relationship between consumption of dietary cholesterol and serum cholesterol.”⁶⁹ Additionally, evidence in the recently published scientific literature supports that eggs may be consumed as part of a healthy dietary pattern.

Given the recognized nutrient-density of eggs and the absence of a specified limit on dietary cholesterol, eggs can be considered a “healthy” food when consumed as part of a healthy dietary pattern such as the patterns promoted in the DGA.

C. FDA’s Regulation for Healthy is Inconsistent with Modern Science and Should be Updated to Allow a Healthy Claim for Eggs

There is no question that FDA has the authority to amend its nutrient content claim regulations in 21 C.F.R. § 101.65 to update the requirements for making a “healthy” nutrient content claim. Twenty years ago, when 21 C.F.R. § 101.65 was promulgated, FDA’s regulation was consistent with the then prevailing notion that “healthy dietary practices” involved, almost exclusively, limiting the levels of certain nutrients, including fat, saturated fat and cholesterol, in the diet and, at the same time, increasing the consumption of other specific nutrients through the diet.

As evidenced by its updated nutrition labeling regulations, its notice for comments regarding the definition for healthy, and the issuance of guidance to allow the healthy claim for certain foods, FDA has recognized that science has evolved and

⁶⁸ Geiker et al., 2018.

⁶⁹ 2015 DGAC Report, Part D, Chapter 1, p. 17.

that currently “healthy dietary practices” focus on consuming more of certain categories of whole foods and limiting consumption of other categories of processed foods.

Petitioners are aware that FDA has indicated that it plans to amend its regulations to ensure that requirements FDA imposes on the use of the term “healthy” as a nutrient content claim reflect current federal dietary recommendations.⁷⁰ Recognizing that the process of rulemaking is slow, FDA issued a guidance describing under what conditions the Agency would allow healthy claims for foods that would not qualify for the claim under the current regulations. This guidance is more consistent with the 2015-2020 DGA and current nutrition science. However, the Agency has failed to recognize the current science showing that dietary cholesterol is no longer a concern and that eggs fit in a healthy dietary pattern, despite their fat, saturated fat, and cholesterol content. As a result, the current regulatory framework and guidance prohibits the use of a “healthy” claim on eggs, a nutrient-dense food that meets current federal dietary recommendations, and contains ingredients that Americans should be consuming.

The Nutrition Facts Panel (reflecting new requirements) for an egg is shown in the figure below. Notably, one large egg provides 12% of the Daily Value for protein, and thus qualifies as a “good source” of this nutrient.⁷¹ Eggs also are a source of smaller quantities of micronutrients that, according to FDA’s updated regulations, are nutrients of public health concern, i.e., vitamin D, calcium, iron, and potassium. Furthermore, eggs are a key dietary source of choline, with one large egg providing 25% of this nutrient.

⁷⁰ See, Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments, FDA Request for Comments, 81 Fed. Reg. 66,562 (Sept. 28, 2016); see also FDA, Reducing the Burden of Chronic Disease (Mar. 29, 2018), <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>.

⁷¹ 21 C.F.R. § 101.54(c).

Nutrition Facts	
12 servings per container	
Serving size 1 egg (50g)	
Amount per serving	
Calories	70
% Daily Value*	
Total Fat 5g	6%
Saturated Fat 1.5g	8%
Trans Fat 0g	
Cholesterol 185mg	62%
Sodium 70mg	3%
Total Carbohydrate 0g	0%
Dietary Fiber 0g	
Total Sugars 0g	
Includes 0g Added Sugars	0%
Protein 6g	12%
Vitamin D 1mcg	6%
Calcium 28mg	2%
Iron 1mg	6%
Potassium 69mg	2%

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To align the healthy definition with current nutrition science and the 2015-2020 DGA, the definition of healthy should be expanded to include eggs, based on the following considerations:

- Given the removal of a limit on dietary cholesterol in the 2015-2020 DGA in recognition of the absence of a meaningful effect of dietary cholesterol on blood cholesterol, it is reasonable to dismiss the current requirement for cholesterol (no more than 60 mg/RACC) as outdated when considering if a food is “healthy.”
- Eggs are a source of fat, but, consistent with FDA guidance on the term “healthy,” the fats consist primarily of mono- and polyunsaturated fats.
- Eggs are a good source of protein, which is consistent with their designation in the Protein Foods group.

The DGA reference to eggs as a nutrient-dense food is consistent with the status of a “healthy” food in the context of a healthy dietary pattern.

Petitioner requests that FDA update the regulation regarding healthy claims to recognize that regulatory thresholds for fat, saturated fat and cholesterol are outdated and recognize that nutrient-dense single-ingredient eggs are healthy. Petitioner also asks that, pending regulatory action, which as FDA has recognized is time-consuming, FDA modify the enforcement discretion outlined in its guidance document to permit eggs to bear a “healthy” claim.

III. Conclusion

For the reasons set forth above, Pete and Gerry's requests that FDA take the actions outlined in Section I.

IV. Environmental Impact

This petition is categorically excluded from the requirement for an environmental assessment or environmental impact statement under 21 C.F.R. § 25.30(k).

V. Economic Impact

Information on the economic impact of the petition will be provided upon request.

VI. Certification

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the Petitioner relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

Respectfully,

A handwritten signature in black ink, appearing to read "Jesse Laflamme", is written over a faint, circular official stamp.

Jesse Laflamme
Chief Executive Officer
Pete and Gerry's Organics LLC
140 Buffum Road, Monroe, NH 03771
(603) 638-2827
jesse@peteandgerrys.com