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VIA ELECTRONIC SUBMISSION

Ms. Kristin Koegel
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Re: Dietary Guidelines for Americans: Request for Comments on Topics and Questions. FNS-2018-0005. 83 Fed. Reg. 8649.

The Council for Responsible Nutrition (CRN) [1] appreciates this new opportunity to provide comments to the U.S. Departments of Agriculture and Health and Human Services, and looks forward to engaging at future junctures in the Departments' enhanced and more transparent process for developing the *Dietary Guidelines for Americans*. Overall, the topics proposed by the Departments meet the four criteria of relevance; importance; potential for Federal impact; and avoiding duplication. CRN suggests that the supporting questions also probe the relationship between diet and development from infancy through adolescence, as development in early life is equally as important an indicator of health as growth, size, and body composition. In addition, bone health should be examined for each life stage because bone health is crucial across the life span. Further, because the Dietary Guidelines set the framework for national nutrition and public health policy, programs, and interventions, it is critical that the Dietary Guidelines and the Dietary Guidelines Advisory Committee (DGAC) recommendations are based on the complete body and strength of scientific evidence and that the review process is open and transparent.

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

CRN notes that, although dietary supplements are a topic for the life stages to be included in the *Dietary Guidelines* for the first time in the 2020-2025 edition (infants and toddlers from birth to 24 months and pregnancy and lactation) they were not included as a topic for the traditionally included stages of life (children and adolescents, adults, and older adults). CRN suggests that dietary supplements should be a topic included for all life stages.

Relevance – Dietary supplements, a category of food, fall within the scope of the Dietary Guidelines. Dietary supplements are already a proposed topic for two specific life stages.

Importance – Dietary supplement use is widespread in the U.S.,[2] and dietary supplements are a good option to help individuals that consistently do not achieve nutrient adequacy, such as iron for adolescent females[3]; iron, folic acid, and iodine for women who are pregnant or capable of pregnancy[4],[5],[6]; and vitamin D for the general population.[3] Because of their prevalence in American diets, dietary supplements should be considered as part of dietary patterns and their contribution to health promotion and meeting nutrient needs should be examined for all life stages. In addition to micronutrients, the intake and status of dietary bioactive components, such as lutein and the omega-3 fatty acids EPA and DHA, should also be examined because studies have shown that these dietary bioactive components are important for maintaining and promoting health, as well as for optimal development in infants and children.

Potential Federal Impact – Guidance on dietary supplementation in the Dietary Guidelines would complement science-based information about foods and beverages so that Americans could have a range of choices when it comes to building and sustaining healthy eating patterns for their families. The 2015 DGAC Scientific Report identified that most Americans fall short in key micronutrients such as potassium, magnesium, calcium, and vitamins A, D, E, and C. Over the past decade, it has been apparent that Americans' nutrient requirements are not being consistently met through food and beverages alone. As a widely available nutrient-dense category of food, dietary supplements should be examined as a component of healthy eating patterns in future Dietary Guidelines.

Avoiding Duplication – Dietary supplements are not currently addressed through existing evidence-based Federal guidance other than the Dietary Guidelines.

CRN's comments specific to the topics and questions for each life stage are detailed below.

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[2]Bailey RL, Gahche JJ, Lentino CV, et al. Dietary supplement use in the United States, 2003-2006. J Nutr. 2011 Feb;141(2):261-6. doi: 10.3945/jn.110.133025.

[3] 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015.

[4]American Congress of Obstetrics and Gynecology. ACOG Practice Bulletin No. 95: anemia in pregnancy. Obstet Gynecol 2008;112:201-7.

[5] Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 187: Neural Tube Defects. Obstet Gynecol. 2017 Dec;130(6):e279-e290. doi: 10.1097/AOG.0000000000002412.

[6] Alexander EK, Pearce EN, Brent GA, et al. 2017 Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease During Pregnancy and the Postpartum. Thyroid. 2017 Mar;27(3):315-389. doi: 10.1089/thy.2016.0457.

Infants and toddlers from birth to 24 months (healthy, full-term infants)

CRN recommendations:

(1) The "dietary supplements" topic should also include essential micronutrients calcium, choline and iodine as examples and dietary supplements that are dietary bioactive components important for optimal health, development and reduction of disease risk. Examples of beneficial dietary bioactive components include eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), and lutein. Although the National Academy of Medicine (formerly IOM) has not established specific intake recommendations for EPA and DHA for ages 1 and older, the World Health Organization (WHO)/Food Agriculture Organization of the United Nations (FAO), European Food Safety Authority (EFSA), and other global authoritative bodies and expert scientific organizations have set recommendations.

(2) The questions should be expanded to include the relationship between provision of nutrition (i.e., human milk, infant formula, dietary supplements, complementary foods and beverages) and dietary bioactive component status, as well as development (e.g., musculoskeletal, cognitive, and visual development) of infants and toddlers.

(3) The second topic should include "composition" in addition to "frequency" and "volume" in relation to human milk and/or infant formula feeding because the nutritional profile of milk and/or infant formula may impact essential micronutrient status, growth, size, body composition, as well as development (e.g., musculoskeletal, cognitive, and visual development). In addition, dietary bioactive component status should be examined.

(4) The question on the relationship between complementary feeding and bone health should be changed to a question on the relationship between complementary feeding and bone development, as it is more appropriate to examine bone development in the early stages of life and bone health in adulthood.

(5) The second question for the fourth topic should be expanded to include the relationship between complementary feeding and achieving dietary bioactive component recommendations for infants and toddlers.

(6) Consideration of evidence related to dietary patterns should include dietary supplements consumed during the complementary feeding period.

Please see suggested edits to the topics and questions below, in blue.

Topic	Question(s)
Recommended duration of exclusive human milk or infant formula feeding	What is the relationship between the duration of exclusive human milk or infant formula consumption and 1) growth, size, ~~and~~ body composition, and development; 2) food allergies and other atopic allergic diseases; and 3) long-term health outcomes?
Composition, frequency and volume of human milk and/or infant formula feeding	What is the relationship between the composition, frequency and volume of human milk and/or infant formula consumption and 1) micronutrient ~~status;~~ and dietary bioactive component status; and 2) growth, size, ~~and~~ body composition, and development?
Dietary supplements (e.g., iron, vitamin D, vitamin B12, calcium, choline, iodine, EPA, DHA, lutein)	What is the relationship between specific dietary supplements of micronutrients ~~supplements~~ and dietary bioactive components for infants fed human milk and/or infant formula and 1) micronutrient ~~status;~~ and dietary bioactive component status; and 2) growth, size, ~~and~~ body composition, and development?
Complementary foods and beverages*: Timing of introduction, types, and amounts *Beverages (cow's milk, water, 100% fruit juice, sugar-sweetened beverages, milk alternatives)	What is the relationship between complementary feeding and 1) micronutrient ~~status;~~ and dietary bioactive component status; 2) growth, size, and body composition; 3) developmental milestones; 4) food allergies and other atopic allergic disease; and 5) bone ~~health~~ development? What is the relationship between complementary feeding, including foods and beverages, and achieving essential nutrient, dietary bioactive component, and food group recommendations of infants and toddlers? Note: Evidence related to dietary patterns (including beverage patterns and dietary supplements) consumed during the complementary feeding period will be considered as part of these questions.

Children and adolescents, ages 2-18 years old (with data reviewed by age group)

CRN recommendations:

(1) The topics should include "dietary supplements" of micronutrients and dietary bioactive components important for optimal health, development and reduction of disease risk. Examples of beneficial dietary bioactive components include EPA, DHA, and lutein. The questions relevant to this topic ask about the relationship between specific supplements of micronutrients and dietary bioactive components consumed during childhood and adolescence and promotion of health, normal growth and development (e.g., musculoskeletal, cognitive, and visual development), and achieving adequacy for essential nutrients and dietary bioactive components. A question should also be asked about dietary supplement recommendations that are needed based on the relationships identified.

(2) The questions for the first topic should be expanded to include the relationship between specific dietary patterns and dietary bioactive component status, as well as development (e.g., musculoskeletal, cognitive, and visual development) in children and adolescents.

(3) The question on the relationship between specific dietary patterns and bone health should be changed to a question on the relationship between specific dietary patterns and bone development, as it is more appropriate to examine bone development in the early stages of life and bone health in adulthood.

(4) The questions for the first topic should be expanded to explore how well the USDA Food Patterns variations meet dietary bioactive component and food group recommendations for children and adolescents.

Please see suggested edits to the topics and questions below, in blue.

Topic	**Question(s)**
Dietary patterns to promote health and normal growth and meet nutrient needs	What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed during childhood and adolescence and 1) micronutrient and dietary bioactive component status; 2~~1~~) growth, size, ~~and~~ body

	composition, and development; ~~and 2~~3) bone ~~health~~ development? Are changes to the USDA Food Patterns needed based on the relationships identified? If so, how well do USDA Food Pattern variations meet essential nutrient, dietary bioactive component, and food group recommendations for children and adolescents?
Dietary supplements (e.g., iron, calcium, vitamin D, vitamin B12, EPA, DHA, lutein)	What is the relationship between specific supplements of micronutrient and dietary bioactive components consumed during childhood and adolescence and 1) micronutrient and dietary bioactive component status; 2) growth, size, body composition, and development; and 3) bone development? Should dietary supplement recommendations be developed based on the relationships identified? If so, which dietary supplement recommendations help to meet essential nutrient and dietary bioactive component recommendations for children and adolescents?
Beverages (cow's milk, water, 100% fruit juice, sugar-sweetened beverages, milk alternatives, caffeinated beverages)	What is the relationship between beverage consumption during childhood and adolescence and achieving nutrient and food group recommendations?
Added sugars	What is the relationship between added sugars consumption during childhood and adolescence and achieving nutrient and food group recommendations? How much added sugars can be accommodated in a healthy diet during childhood and adolescence while still meeting food group and nutrient needs?

Adults, ages 19-64 years old (with data reviewed by age group)

CRN recommendations:

(1) Supporting questions for the first topic should include a question about the relationship between specific dietary patterns and risk of age-related ocular and cognitive diseases because nutrition may play a role in preventing these diseases. In addition, the relationship between specific dietary patterns and bone health, as well as micronutrient and dietary bioactive component status should be examined.

(2) The first topic should include an additional question on the relationship between meal replacement products consumed as part of a dietary pattern during adulthood and body weight or obesity, as well as micronutrient and dietary bioactive component status. Evidence shows that meal replacement products can be an effective tool for weight management; thus, their contribution to a healthy dietary pattern should be examined.

(3) Supporting questions for the first topic should be expanded to explore how well the USDA Food Patterns variations meet dietary bioactive component and food group recommendations for adults.

(4) Topics should include "dietary supplements" of micronutrients and dietary bioactive components important for optimal health, development and reduction of disease risk. Examples of beneficial dietary bioactive components include EPA, DHA, and lutein. The questions relevant to this topic ask about the relationship between specific supplements of micronutrients and dietary bioactive components consumed during adulthood and promotion of health, prevention of disease, and achieving adequacy for essential nutrients and dietary bioactive components. A question should also be asked about dietary supplement recommendations that are needed based on the relationships identified.

Please see suggested edits to the topics and questions below, in blue.

Topic	**Question(s)**
Dietary patterns to promote health, prevent disease, and meet nutrient needs	What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed

	during adulthood and 1) body weight or obesity; 2) risk of cardiovascular disease; 3) risk of type 2 diabetes; ~~and~~ 4) risk of certain types of cancer; 5) risk of age-related ocular diseases; 6) risk of age-related cognitive diseases; 7) bone health; and 8) micronutrient and dietary bioactive component status? What is the relationship between meal replacement products consumed as part of a dietary pattern during adulthood and 1) body weight or obesity and 2) micronutrient and dietary bioactive component status? Are changes to the USDA Food Patterns needed based on the relationships identified? If so, how well do USDA Food Pattern variations meet essential nutrient and dietary bioactive component, and food group recommendations for adults?
Dietary supplements (e.g., iron, calcium, vitamin D, vitamin B12, Mg, EPA, DHA, lutein)	What is the relationship between specific dietary supplements of micronutrients and dietary bioactive components consumed during adulthood and 1) body weight or obesity; (2) risk of cardiovascular disease; 3) risk of type 2 diabetes; 4) risk of certain types of cancer; 5) risk of age-related ocular diseases; 6) risk of age-related cognitive diseases; 7) bone health; and 8) micronutrient and dietary bioactive component status? Should dietary supplement recommendations be developed based on the relationships identified? If so, which dietary supplement recommendations help to meet

	essential nutrient and dietary bioactive component recommendations for adults?
Beverages (cow's milk, water, 100% fruit juice, sugar-sweetened beverages, milk alternatives, caffeinated beverages)	What is the relationship between beverage consumption during adulthood and achieving nutrient and food group recommendations?
Added sugars	What is the relationship between added sugars consumption during adulthood and achieving nutrient and food group recommendations? How much added sugars can be accommodated in a healthy diet during adulthood while still meeting food group and nutrient needs?
Saturated fats	What is the relationship between saturated fats consumption (types and amounts) during adulthood and risk of cardiovascular disease?

Pregnancy and lactation

CRN recommendations:

(1) The "dietary supplements" topic should also include calcium, iodine, and choline as examples and dietary supplements that are dietary bioactive components important for optimal health, development and reduction of disease risk. Examples of beneficial dietary bioactive components include EPA, DHA, and lutein. The questions relevant to this topic ask about the relationship between specific supplements of micronutrients and dietary bioactive components consumed during pregnancy and lactation and micronutrient and dietary bioactive component status; birth outcomes; human milk composition and quantity; and neurocognitive development of the infant. A question should also be asked about dietary supplement recommendations that are needed based on the relationships identified.

(2) The questions for the first topic should be expanded to explore how well the USDA Food Patterns variations meet dietary bioactive component and food group recommendations for women who are pregnant or lactating.

Please see suggested edits to the topics and questions below, in blue.

Topic	**Question(s)**
How additional calorie needs should be met during pregnancy and lactation	What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed among women who are pregnant and 1) risk of gestational diabetes; 2) risk of hypertensive disorders during pregnancy; 3) gestational age at birth; and 4) birth weight standardized for gestational age and sex? What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed among women who are lactating and human milk composition and quantity? Are changes to the USDA Food Patterns needed based on the relationships identified? If so, how well do USDA Food Pattern variations meet essential nutrient and dietary bioactive component, and food group recommendations for women who are pregnant or lactating?

Dietary supplements (e.g., iron, folate, vitamin D, calcium, iodine, choline, EPA, DHA, lutein)	What is the relationship between supplements of micronutrients ~~supplements~~ and dietary bioactive components consumed during pregnancy and lactation and 1) micronutrient and dietary bioactive component status; 2) birth outcomes; and 3) human milk composition and quantity; and 4) neurocognitive development of the infant? Should dietary supplement recommendations be developed based on the relationships identified? If so, which dietary supplement recommendations help to meet essential nutrient and dietary bioactive component recommendations for women who are pregnant or lactating?
Diet during pregnancy and lactation and risk of food allergy in the infant	What is the relationship between maternal diet during pregnancy and lactation and risk of infant allergies and other atopic allergic disease?
Seafood	What is the relationship between seafood consumption during pregnancy and lactation and neurocognitive development of the infant?
Beverages (cow's milk, water, 100% fruit juice, sugar-sweetened beverages, milk alternatives, caffeinated beverages)	What is the relationship between beverage consumption during pregnancy and lactation and 1) achieving nutrient and food group recommendations; 2) birth outcomes; and 3) human milk composition and quantity?
Alcoholic beverages	What is the relationship between maternal alcohol consumption during

	lactation and human milk composition and quantity?

Older adults, ages 65 years and older (with data reviewed by age group)

CRN recommendations:

(1) Supporting questions for the first topic should include a question about the relationship between specific dietary patterns and risk of age-related ocular and cognitive diseases because diet may play a role in preventing these diseases. In addition, the relationship between specific dietary patterns and micronutrient status, as well as dietary bioactive component status should be examined.

(2) The questions for the first topic should be expanded to explore how well the USDA Food Patterns variations meet dietary bioactive component and food group recommendations for older adults.

(3) The topics should include "dietary supplements" of micronutrients and dietary bioactive components important for optimal health, development and reduction of disease risk. Examples of dietary bioactive components include EPA, DHA, and lutein. The questions relevant to this topic seek to identify the relationship between specific supplements of micronutrients and dietary bioactive components consumed across the lifespan and promotion of health, prevention of disease, and achieving adequacy for essential nutrients and dietary bioactive components. A question should also be asked about dietary supplements that are effective in preventing or reversing declines in muscle mass or bone density in older adults, and whether dietary supplement recommendations are needed based on the relationships identified.

(4) Supporting questions for the topic, "Specific nutritional needs related to older adults," should include the role of oral nutritional supplements in the promotion of meeting nutrient needs in older adults with impaired dentition, dry mouth, or other aspects of aging that interfere with food and beverage consumption. Oral nutritional supplements provide macronutrients and micronutrients for individuals who have difficulties chewing and/or swallowing solid food.

(5) Supporting questions for the topic, "Specific nutritional needs related to older adults," should include a question about the use of medications in older adults and micronutrient and dietary bioactive component status. Use of one or more medications is prevalent in older adults, and it is well established that certain medications cause depletions of nutrients. For example, thiazide diuretics used to treat high blood pressure deplete vitamin D, calcium, magnesium, phosphorus, potassium, zinc, and coenzyme Q10. Moreover, certain drugs are known to reduce

appetite, and thus, would negatively impact intake of micronutrients and dietary bioactive components from foods and beverages.

Please see suggested edits to the topics and questions below, in blue.

Topic	Question(s)
Dietary patterns to promote health, prevent disease, and meet nutrient needs	What is the relationship between specific dietary patterns (Dietary Guidelines-related, Mediterranean-style, Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, and low-carbohydrate diets) consumed across the lifespan and 1) body weight or obesity; 2) risk of cardiovascular disease; 3) risk of type 2 diabetes; 4) risk of certain types of cancer; ~~and~~ 5) risk of osteoporosis; 6) risk of age-related ocular disease; 7) risk of age-related cognitive diseases; and 8) micronutrient and dietary bioactive component status? What modifications to dietary patterns are effective in preventing or reversing declines in muscle mass or bone density in older adults? Are changes to the USDA Food Patterns needed based on the relationships identified? If so, how well do USDA Food Pattern variations meet essential nutrient and dietary bioactive component, and food group recommendations for older adults, age 65-80 years and those age 81+ years?
Dietary supplements (e.g., protein, iron, calcium, vitamin D, vitamin B12, Mg, EPA, DHA, lutein)	What is the relationship between specific micronutrient and bioactive nutrient supplements consumed across

	the lifespan and 1) body weight or obesity; (2) risk of cardiovascular disease; 3) risk of type 2 diabetes; 4) risk of certain types of cancer; 5) risk of osteoporosis; 6) risk of age-related ocular diseases; 7) risk of age-related cognitive diseases; and 8) micronutrient and dietary bioactive component status? What dietary supplements are effective in preventing or reversing declines in muscle mass or bone density in older adults? Should dietary supplement recommendations be developed based on the relationships identified? If so, which dietary supplement recommendations help to meet essential nutrient and dietary bioactive component recommendations for older adults, age 65-80 years and those age 81+ years?
Specific nutritional needs related to older adults	What modifications to food and beverage choices promote meeting nutrient needs in older adults with impaired dentition, dry mouth, or other aspects of aging that interfere with food and beverage consumption? What is the role of oral nutritional supplements in the promotion of meeting nutrient needs in older adults with impaired dentition, dry mouth, or other aspects of aging that interfere with food and beverage consumption? What is the relationship between use of medications in older adults and

	micronutrient and dietary bioactive component status?

Thank you for considering our comments.

Sincerely,

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