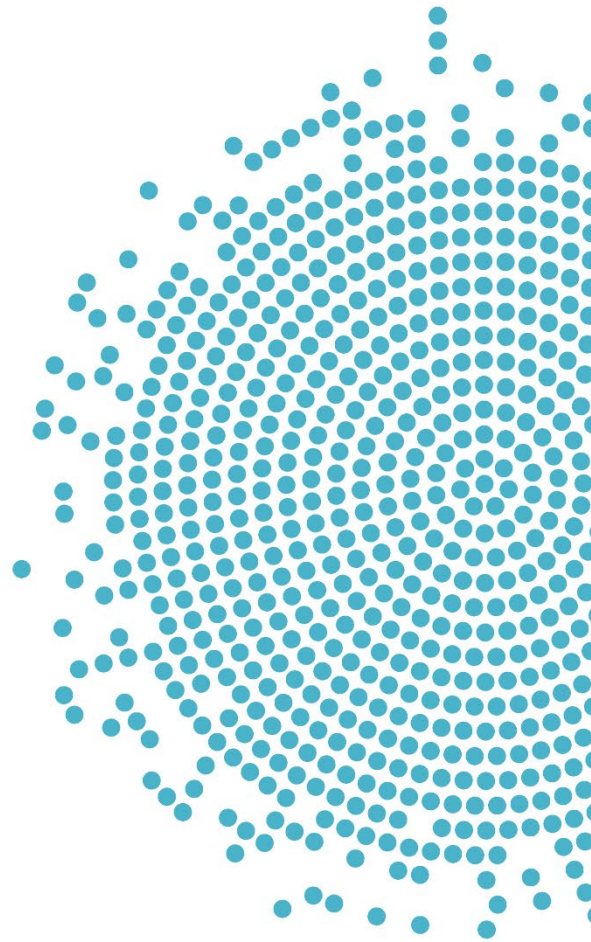


# Complementary Feeding and Growth, Body Composition, and Risk of Obesity: A Systematic Review Protocol

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**Related citations:**

English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Timing of Introduction of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0305>.

English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Types and Amounts of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0306>.

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## Introduction

To prepare for the development of the *Dietary Guidelines for Americans, 2025-2030*, the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) identified a proposed list of scientific questions based on relevance, importance, potential federal impact, and avoiding duplication, which were posted for public comment.\* The Departments appointed the 2025 Dietary Guidelines Advisory Committee (Committee) in January 2023 to review evidence on the scientific questions. The proposed scientific questions were refined and prioritized by the Committee for consideration in their review of the evidence. Their review forms the basis of their independent, science-based advice and recommendations to HHS and USDA, which is considered as the Departments develop the next edition of the *Dietary Guidelines*. As part of that process, the following systematic review question has been identified: What is the relationship between complementary feeding and growth, body composition, and risk obesity? The Committee will conduct a systematic review to address this question, with support from USDA's Nutrition Evidence Systematic Review (NESR) team. This question will update the systematic reviews conducted by the Pregnancy and Birth to 24 Months (P/B-24) Project's Complementary Feeding Technical Expert Collaborative (**Table 1**).

**Table 1. Review history**

Date	Description	Citation
April 2019	Original systematic reviews conducted by the Pregnancy and Birth to 24 Months Project, Complementary Feeding Technical Expert Collaborative published	<p>English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Timing of Introduction of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://doi.org/10.52570/NESR.PB242018.SR0305">https://doi.org/10.52570/NESR.PB242018.SR0305</a>.</p> <p>English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Types and Amounts of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://doi.org/10.52570/NESR.PB242018.SR0306">https://doi.org/10.52570/NESR.PB242018.SR0306</a>.</p>
May 2023	Systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	<p>Fisher JO, Abrams SA, Andres A, Byrd-Bredbenner C, Deierlein AL, Eicher-Miller HA, Odoms-Young A, Palacios C, Obbagy J, Bahnfleth C, Kim JH, Nevins J, Higgins M, Butera G, Terry N. Complementary Feeding and Growth, Body Composition, and Risk of Obesity: A Systematic Review Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/protocols">https://nesr.usda.gov/protocols</a></p>

\* Dietary Guidelines for Americans: Learn About the Process. 2022. Available at: <https://www.dietaryguidelines.gov/work-under-way/learn-about-process>

## Methods

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The NESR methodology manual<sup>\*</sup> has a detailed description of the NESR methodology as it will be applied in the systematic reviews for the Dietary Guidelines for Americans, 2025-2030 Project. This section presents an overview of the specific methods that will be used to by the Committee to answer the systematic review question: What is the relationship between complementary feeding and growth, body composition, and risk of obesity?

This systematic review updates existing NESR systematic reviews completed as part of the P/B-24 Project by the Complementary Feeding Technical Expert Collaborative on the timing of introduction<sup>†</sup> and types and amounts<sup>‡</sup> of complementary foods and beverages and growth, size, and body composition, which included evidence published from January 1980 to July 2016. This updated systematic review will synthesize the studies from the existing reviews with eligible studies published since July 2016 as one body of evidence, according to the methods described below.

### Develop a protocol

A systematic review protocol is the plan for how NESR's methodology will be used to conduct a specific systematic review and is established by the Committee, *a priori*, before any evidence is reviewed. The protocol is designed to capture the most appropriate and relevant body of evidence to answer the systematic review question. Development of the protocol involves discussion of the strengths and limitations of various methodological approaches relevant to the question, which then inform subsequent steps of the systematic review process. The protocol describes all of the methods that will be used throughout the systematic review process. Additionally, the protocol includes the following components, which are tailored to each systematic review question: the analytic framework, the inclusion and exclusion criteria, and the synthesis plan. When updating an existing review, the Committee uses the analytic framework and the inclusion and exclusion criteria from the existing review and makes adjustments to the protocol, if necessary. Differences in the inclusion and exclusion criteria between existing and updated reviews are documented in **Appendix 1**.

### Develop an analytic framework

An analytic framework visually represents the overall scope of the systematic review question and depicts the contributing elements that will be examined and evaluated. **Figure 1** is the analytic framework for the systematic review and shows that the interventions or exposures of interest are the timing of the first introduction of any complementary food or beverage, the timing of the first introduction of a specific type of complementary food or beverage (further subdivided by the following food and beverage groups: fruit, including 100% fruit juice, vegetables, grains, protein foods, dairy and fortified soy alternatives, food/beverage sources of added sugars, and other complementary foods and beverages), and types and amounts of complementary foods and beverages (further subdivided by the following food and beverage groups: fruit, including 100% fruit

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<sup>\*</sup> USDA Nutrition Evidence Systematic Review Branch. USDA Nutrition Evidence Systematic Review: Methodology Manual. February 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/methodology-overview>

<sup>†</sup> English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Timing of Introduction of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0305>.

<sup>‡</sup> English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Types and Amounts of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0306>.

juice, vegetables, grains, protein foods, dairy and fortified soy alternatives, food/beverage sources of added sugars, and other complementary foods and beverages) in infants and toddlers (birth up to 24 months). The comparators are different timing of the first introduction of any complementary food or beverage, different timing of the first introduction of a specific type of complementary food or beverage, and different amount of the same complementary food or beverage or different type of complementary food or beverage. The outcomes are: Growth (in infants, toddlers, children, adolescents) including: height, length/stature-for-age, weight, weight-for-age, stunting, failure to thrive, wasting, BMI-for-age, weight-for-length/stature, body circumferences (arm, neck, thigh), head circumference; Body composition (in infants, toddlers, children, adolescents, adults, older adults) including: skinfold thickness, fat mass, ectopic fat, fat-free mass or lean mass, waist circumference, waist-to-hip-ratio; Risk of obesity (in children, adolescents, adults, older adults) including: BMI, overweight and obesity, underweight, normal/healthy weight. The key confounders are socioeconomic position, sex, race and/or ethnicity, milk feeding practices (human milk, infant formula, or both), gestational age, and baseline anthropometry. The confounders may impact the relationships of interest.

**Figure 1. Analytic framework for the systematic review question: What is the relationship between complementary feeding and growth, body composition, and risk of obesity?**

<b>Population</b>	<b>Intervention/exposure</b>	<b>Comparator</b>	<b>Outcomes</b>	<b>Key confounders</b>
Infants and toddlers (birth up to 24 months)	Timing of the first introduction of <i>any</i> complementary food or beverage (CFB)	Different timing of the first introduction of <i>any</i> CFB	Growth (in infants, toddlers, children, adolescents) <ul style="list-style-type: none"> <li>• Height, length/stature-for-age</li> <li>• Weight, weight-for-age</li> <li>• Stunting, failure to thrive, wasting</li> <li>• BMI-for-age, weight-for-length/stature</li> <li>• Body circumferences (arm, neck, thigh)</li> <li>• Head circumference</li> </ul>	<ul style="list-style-type: none"> <li>• Socioeconomic position</li> <li>• Sex</li> <li>• Race and/or ethnicity</li> <li>• Milk feeding practices (human milk, infant formula, or both)</li> <li>• Gestational age</li> <li>• Baseline anthropometry</li> </ul>
	Timing of the first introduction of a <i>specific type</i> of CFB: <ol style="list-style-type: none"> <li>1) Fruit, including 100% fruit juice</li> <li>2) Vegetables</li> <li>3) Grains</li> <li>4) Protein foods</li> <li>5) Dairy and fortified soy alternatives</li> <li>6) Food/beverage sources of added sugars</li> <li>7) Other CFB</li> </ol>	Different timing of the first introduction of a <i>specific type</i> of CFB	Body composition (in infants, toddlers, children, adolescents, adults, older adults) <ul style="list-style-type: none"> <li>• Skinfold thickness</li> <li>• Fat mass, ectopic fat</li> <li>• Fat-free, lean mass</li> <li>• Waist circumference, waist-to-hip ratio</li> </ul>	
	Types and amounts of CFB: <ol style="list-style-type: none"> <li>1) Fruit, including 100% fruit juice</li> <li>2) Vegetables</li> <li>3) Grains</li> <li>4) Protein foods</li> <li>5) Dairy and fortified soy alternatives</li> <li>6) Food/beverage sources of added sugars</li> <li>7) Other CFB</li> </ol>	Different amount of the same CFB  Different type of CFB	Risk of obesity (in children, adolescents, adults, older adults) <ul style="list-style-type: none"> <li>• BMI</li> <li>• Overweight and obesity</li> <li>• Underweight</li> <li>• Normal/healthy weight</li> </ul>	

**Synthesis organization:**

- I. **Intervention/exposure:** Timing of the first introduction of any complementary food or beverage
  - a. **Outcome:** Growth; Body composition; Risk of obesity
  
- II. **Intervention/exposure:** Timing of the first introduction of a specific type of complementary food or beverage: 1) Fruit, including 100% fruit juice; 2) Vegetables; 3) Grains; 4) Protein foods; 5) Dairy and fortified soy alternatives; 6) Food/beverage sources of added sugars; 7) Other CFB

- a. **Outcome:** Growth; Body composition; Risk of obesity
- III. **Intervention/exposure:** Types and amounts of complementary food or beverage: 1) Fruit, including 100% fruit juice; 2) Vegetables; 3) Grains; 4) Protein foods; 5) Dairy and fortified soy alternatives; 6) Food/beverage sources of added sugars; 7) Other CFB
  - a. **Outcome:** Growth; Body composition; Risk of obesity

**Key definitions:**

Complementary feeding: The process that starts when human milk or infant formula is complemented by other foods and beverages. The complementary feeding period typically continues to 24 months as the young child transitions to family foods.

Complementary foods and beverages (CFB): Foods and beverages (liquids, semisolids, and solids) other than human milk or infant formula provided to an infant or young child to provide nutrients and energy.



## Develop inclusion and exclusion criteria

The inclusion and exclusion criteria provide an objective, consistent, and transparent framework for determining which articles to include in the systematic review (see **Table 2**). These criteria ensure that the most relevant and appropriate body of evidence is identified for the systematic review question, and that the evidence reviewed is:

- Applicable to the U.S. population of interest
- Relevant to Federal public health nutrition policies and programs
- Rigorous from a scientific perspective

**Table 2. Inclusion and exclusion criteria**

Category	Inclusion Criteria	Exclusion Criteria
Study design	<ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials*</li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul>	<ul style="list-style-type: none"> <li>• Uncontrolled trials†</li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> </ul>
Publication date	<ul style="list-style-type: none"> <li>• January 1980 – May 2023‡</li> </ul>	<ul style="list-style-type: none"> <li>• Before January 1980, after May 2023</li> </ul>
Population: Study participants	<ul style="list-style-type: none"> <li>• Human</li> </ul>	<ul style="list-style-type: none"> <li>• Non-human</li> </ul>
Population: Life stage	<ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Infants and toddlers (birth up to 24 months)</li> </ul> </li> <li>• At outcome:                             <ul style="list-style-type: none"> <li>○ Infants and toddlers (birth up to 24 months)</li> <li>○ Children and adolescents (2 up to 19 years)</li> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Children and adolescents (2 up to 19 years)</li> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> </ul>

\* Including quasi-experimental and controlled before-and-after studies

† Including uncontrolled before-and-after studies

‡ This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to July 2016

Category	Inclusion Criteria	Exclusion Criteria
Population: Health status	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants not diagnosed with a disease*</li> <li>• Studies that enroll <u>some</u> participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;</li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>○ born preterm,<sup>†</sup> with low birth weight,<sup>‡</sup> and/or small for gestational age</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;<sup>§</sup></li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>○ born preterm,<sup>**</sup> with low birth weight,<sup>††</sup> and/or small for gestational age;</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul>
Intervention/ exposure	<ul style="list-style-type: none"> <li>• Timing of the first introduction of <i>any</i> complementary food or beverage (CFB)**</li> <li>• Timing of the first introduction of a <i>specific type</i> of CFB</li> <li>• Types and amounts of CFB</li> </ul>	<ul style="list-style-type: none"> <li>• Isolated consumption of human milk, infant formulas (e.g., milk-based, soy, partially hydrolyzed, extensive-hydrolyzed, amino acid based), or vitamin and mineral supplements (e.g., iron drops)</li> <li>• For timing of the first introduction of a specific type of CFB and types and amounts of CFB:                             <ul style="list-style-type: none"> <li>○ Dietary patterns</li> <li>○ Type and/or amount of food or beverage not described</li> </ul> </li> </ul>
Comparator	<ul style="list-style-type: none"> <li>• Different timing of the first introduction of <i>any</i> CFB</li> <li>• Different timing of the first introduction of a <i>specific type</i> of CFB</li> <li>• Different types and amounts of CFB                             <ul style="list-style-type: none"> <li>○ Consumption of a different amount of the same CFB</li> <li>○ Consumption of a different type of CFB</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• No comparator</li> </ul>

\* Studies that enroll participants who are at risk for chronic disease will be included

† Gestational age <37 weeks and 0/7 days

‡ Birth weight <2500g

§ Studies that exclusively enroll participants with obesity will be included

\*\* Complementary foods and beverages (CFB) are defined as foods and beverages (liquids, semisolids, and solids) other than human milk or infant formula provided to an infant or young child to provide nutrients and energy

Category	Inclusion Criteria	Exclusion Criteria
Outcomes	<p>Growth (in infants, toddlers, children, adolescents)</p> <ul style="list-style-type: none"> <li>• Height, length/stature-for-age</li> <li>• Weight, weight-for-age</li> <li>• Stunting, failure to thrive, wasting</li> <li>• BMI-for-age, weight-for-length/stature</li> <li>• Body circumferences (arm, neck, thigh)</li> <li>• Head circumference</li> </ul> <p>Body composition (in infants, toddlers, children, adolescents, adults, older adults)</p> <ul style="list-style-type: none"> <li>• Skinfold thickness</li> <li>• Fat mass, ectopic fat</li> <li>• Fat-free mass, lean mass</li> <li>• Waist circumference, waist-to-hip ratio</li> </ul> <p>Risk of obesity (in children, adolescents, adults, older adults)</p> <ul style="list-style-type: none"> <li>• BMI</li> <li>• Overweight and obesity</li> <li>• Underweight</li> <li>• Healthy/normal weight</li> </ul>	<ul style="list-style-type: none"> <li>• Not applicable</li> </ul>
Publication status	<ul style="list-style-type: none"> <li>• Peer-reviewed articles published in research journals</li> </ul>	<ul style="list-style-type: none"> <li>• Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings</li> </ul>
Language	<ul style="list-style-type: none"> <li>• Published in English</li> </ul>	<ul style="list-style-type: none"> <li>• Not published in English</li> </ul>
Country*	<ul style="list-style-type: none"> <li>• Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	<ul style="list-style-type: none"> <li>• Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>

\* The classification of countries on the Human Development Index (HDI) is based on the UN Development Program Human Development Report Office (<http://hdr.undp.org/en/data>) for the year the study intervention occurred or data were collected. If the study does not report the year(s) in which the intervention/exposure data were collected, the HDI classification for the year of publication is applied. Studies conducted prior to 1990 are classified based on 1990 HDI classifications. If the year is more recent than the available HDI values, then the most recent HDI classifications are used. If a country is not listed in the HDI, then the current country classification from the World Bank is used (The World Bank Country and Lending Groups, available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)

## Search for and screen studies

NESR librarians, in collaboration with NESR analysts and the Committee, will use the analytic framework and inclusion and exclusion criteria to develop a comprehensive literature search strategy. The literature search strategy will include selecting and searching the appropriate bibliographic databases, translating search using syntax appropriate for the databases being searched, and employing search refinements, such as search filters. For existing reviews, search strategies will be updated, as appropriate, for each database. The full literature search will be available upon request and will be fully documented in the final review.

The results of all electronic database searches, after removal of duplicates, will be screened independently by two NESR analysts using a step-wise process by reviewing titles, abstracts, and full-texts to determine which articles meet the inclusion criteria. Manual searching will be conducted to find peer-reviewed published articles not identified through the electronic database search. These articles will also be screened independently by two NESR analysts at the abstract and full-text levels.

## Extract data and assess the risk of bias

NESR analysts will extract all essential data from each included article to describe key characteristics of the available evidence, such as the author, publication year, cohort/trial name, study design, population life stage at intervention/exposure and outcome, intervention/exposure and outcome assessment methods, and outcomes. One NESR analyst will extract the data and a second NESR analyst will review the extracted data for accuracy. Each article included in the systematic review will undergo a formal risk of bias assessment, with two NESR analysts independently completing the risk of bias assessment using the tool that is appropriate for the study design.\*†‡

## Synthesize the evidence

The Committee will describe, compare, and combine the evidence from all included studies to answer the systematic review question. Synthesis of the body of evidence will involve identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors impact the relationships being examined. The first level of synthesis organization will be by intervention/exposure (timing of the first introduction of any complementary food or beverage; timing of the first introduction of a specific type of complementary food and beverage; types and amounts of complementary foods and beverages). For timing of the first introduction of a specific type of complementary food and beverage and types and amounts of complementary foods and beverages, the evidence will be further organized by food and/or beverage groups (fruit, including 100% fruit juice; vegetables; grains; protein foods; dairy and fortified soy alternatives; food/beverage sources of added sugars; other complementary foods or beverages). Then, within each of the intervention/exposure groups, the evidence will be organized by similar outcomes (growth; body composition; risk of obesity) based on the available evidence. Depending on the available evidence for types and amounts of complementary foods and beverages, a final level of organization will be according to age at intervention/exposure.

In addition to the present systematic review on complementary feeding, two systematic reviews with meta-analysis will be conducted on the related topics of sugar-sweetened beverage intake and growth, body

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\* Sterne JAC, Savovic J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. Aug 28 2019;366:I4898.doi:10.1136/bmj.I4898

† Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. Oct 12 2016;355:i4919.doi:10.1136/bmj.i4919

‡ ROBINS-E Development Group., Higgins J, Morgan R, et al. Bias In Non-randomized Studies - of Exposure (ROBINS-E). 2022. <https://www.riskofbias.info/welcome/robins-e-tool>

composition, and risk of obesity\* and 100% juice intake and growth, body composition, and risk of obesity† across the lifespan, including infants and toddlers. Results of the meta-analyses that are relevant to complementary feeding in infants and toddlers will be considered during the synthesis of the evidence and documented in the complementary feeding and growth, body composition, and risk of obesity systematic review.

## Develop conclusion statements and grade the evidence

After the Committee synthesizes the body of evidence, they will draft a conclusion statement or conclusion statements. A conclusion statement is one or more summary statements carefully constructed to answer the systematic review question. It reflects the evidence reviewed, as outlined in the analytic framework (e.g., PICO elements) and synthesis plan, and does not take evidence from other sources into consideration. The Committee will review, discuss, and revise the conclusion statement until they reach agreement on wording that accurately reflect the body of evidence.

The Committee will then assign a grade to each conclusion statement (i.e., strong, moderate, limited, or grade not assignable). The grade communicates the strength of the evidence supporting a specific conclusion statement to decision makers and stakeholders. NESR has predefined criteria, based on five grading elements that the Committee will use to evaluate and grade the strength of the evidence supporting each conclusion statement. The five grading elements are: consistency, precision, risk of bias, directness and generalizability of the evidence. Study design will also be considered during the grading process.

## Recommend future research

The Committee will identify and document research gaps and methodological limitations throughout the systematic review process. These gaps and limitations will be used to develop research recommendations that describe the research, data, and methodological advances that are needed to strengthen the body of evidence on a particular topic. Rationales for the necessity of additional or stronger research may also be provided with the research recommendations.

## Acknowledgments and funding

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The Committee members are involved in: establishing all aspects of the protocol, which presents the plan for how they are planning to examine the scientific evidence, including the inclusion and exclusion criteria; reviewing all studies that meet the criteria the Committee sets; deliberating on the body of evidence for each question; and writing and grading the conclusion statements. The NESR team, with assistance from Federal staff from HHS and USDA (Dennis Anderson-Villaluz, MBA, RD, LDN, FAND; Hazel Hiza, PhD; Tessa Lasswell, MPH, RDN; TusaRebecca Pannucci, PhD, MPH, RD; Elizabeth Rahavi, RD; Kelley Scanlon, PhD, RD; Colleen Sideck, MPH, RDN) and Project Leadership (HHS: Janet de Jesus, MS, RD; USDA: Eve Stoodly, PhD), supports the Committee by facilitating, executing, and documenting the work necessary to ensure the reviews are completed in accordance with NESR methodology. Contractor support was also provided by

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\* Hoelscher DM, Anderson CAM, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Cole NC, Kingshapp BJ, Nevins J, Webster A, Becker B, Higgins M, Bokay K, Butera G, Terry N. Sugar-Sweetened Beverages and Growth, Body Composition, and Risk of Obesity: A Systematic Review with Meta-Analysis Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/protocols>

† Hoelscher DM, Anderson CAM, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Cole NC, Kingshapp BJ, Nevins J, Webster A, Becker B, Higgins M, Bokay K, Butera G, Terry N. 100% Juice and Growth, Body Composition, and Risk of Obesity: A Systematic Review with Meta-Analysis Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/protocols>

Panum Telecom (Emily Madan, PhD).

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# Appendix

## Appendix 1: Inclusion and exclusion criteria comparison between existing<sup>††</sup> and updated systematic reviews for the research question: What is the relationship between complementary feeding and growth, body composition, and risk of obesity?

Category	Existing Reviews	Updated Review	Change and Rationale
Study design	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials</li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Case-control studies</li> <li>• Pre/post studies with a control</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Cross-sectional studies</li> <li>• Uncontrolled studies</li> <li>• Pre/post studies without a control</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials<sup>‡</sup></li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Uncontrolled trials<sup>§</sup></li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> </ul>	<p>Criteria for study design were updated (inclusion of nested-case control studies and exclusion of case-control studies) to strengthen the body of evidence</p>

<sup>†</sup> English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Timing of Introduction of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0305>.

<sup>††</sup> English LK, Obbagy JE, Wong YP, Psota TL, Nadaud P, Johns K, Terry N, Butte NF, Dewey KG, Fleischer DM, Fox MK, Greer FR, Krebs NF, Scanlon KS, Casavale KO, Spahn JM, Stoody E. Types and Amounts of Complementary Foods and Beverages and Growth, Size, and Body Composition: A Systematic Review. April 2019. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.PB242018.SR0306>.

<sup>‡</sup> Including quasi-experimental and controlled before-and-after studies

<sup>§</sup> Including uncontrolled before-and-after studies

Category	Existing Reviews	Updated Review	Change and Rationale
Publication date	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>January 1980 – July 2016</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Before January, after July 2016</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>January 1980 – May 2023*</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Before January 1980, after May 2023</li> </ul>	Not Applicable
Population: Study participants	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Human subjects</li> <li>Males</li> <li>Females</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Hospitalized patients, not including birth and immediate post-partum hospitalization of healthy babies</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Human</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Non-human</li> </ul>	No change other than formatting

\* This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to July 2016



Category	Existing Reviews	Updated Review	Change and Rationale
Population: Life stage	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Infants (0-12 months)</li> <li>○ Toddlers (12-24 months)</li> </ul> </li> <li>• At outcome:                             <ul style="list-style-type: none"> <li>○ Infants (0-12 months)</li> <li>○ Toddlers (12-24 months)</li> <li>○ Child (2-5 years)</li> <li>○ Child (6-12 years)</li> <li>○ Adolescents (13-18 years)</li> <li>○ Adults (19 years and older)</li> <li>○ Older adults (65-79 years)</li> <li>○ Older adults (80+ years)</li> </ul> </li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Child (2-5 years)</li> <li>○ Child (6-12 years)</li> <li>○ Adolescents (13-18 years)</li> <li>○ Adults (19 years and older)</li> <li>○ Older adults (65-79 years)</li> <li>○ Older adults (80+ years)</li> </ul> </li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Infants and toddlers (birth up to 24 months)</li> </ul> </li> <li>• At outcome:                             <ul style="list-style-type: none"> <li>○ Infants and toddlers (birth up to 24 months)</li> <li>○ Children and adolescents (2 up to 19 years)</li> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Children and adolescents (2 up to 19 years)</li> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> </ul>	No change other than formatting

Category	Existing Reviews	Updated Review	Change and Rationale
Population: Health Status	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Studies done in generally healthy populations</li> <li>• Studies done in populations where infants were full term (≥37 weeks gestational age)</li> <li>• Studies done in populations with elevated chronic disease risk, or that enroll some participants with a disease or with the health outcome of interest</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Studies that exclusively enroll subjects with a disease or with the health outcome of interest</li> <li>• Studies done in hospitalized or malnourished subjects</li> <li>• Studies of exclusively pre-term babies (gestational age &lt;37 weeks) or babies that are small for gestational age (&lt;2500g)</li> <li>• Studies of subjects with infectious diseases (e.g. HIV/AIDS) (or with mothers diagnosed with an infectious disease)</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Studies that exclusively enroll participants not diagnosed with a disease*</li> <li>• Studies that enroll some participants: <ul style="list-style-type: none"> <li>○ diagnosed with a disease;</li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting.</li> <li>○ born preterm,<sup>†</sup> with low birth weight,<sup>‡</sup> and/or small for gestational age</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Studies that exclusively enroll participants: <ul style="list-style-type: none"> <li>○ diagnosed with a disease,<sup>§</sup></li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>○ born preterm,<sup>†</sup> with low birth weight,<sup>‡</sup> and/or small for gestational age;</li> <li>○ and/or hospitalized for an illness, injury, or surgery</li> </ul> </li> </ul>	No change other than formatting

\* Studies that enroll participants who are at risk for chronic disease will be included

† Gestational age <37 weeks and 0/7 days

‡ Birth weight <2500g

§ Studies that exclusively enroll participants with obesity will be included

Category	Existing Reviews	Updated Review	Change and Rationale
Intervention/exposure	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Timing of introduction of complementary foods and beverages (CFB)*</li> <li>• Types and amounts of CFB consumed</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Isolated consumption of human milk, infant formulas (e.g., milk-based, soy, partially hydrolyzed, extensive-hydrolyzed, amino acid based), fluid cow’s milk before 12 months of age, or vitamin and mineral supplements (e.g., iron drops)</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Timing of the first introduction of <i>any</i> complementary food or beverage (CFB)*</li> <li>• Timing of the first introduction of a <i>specific type</i> of CFB</li> <li>• Types and amounts of CFB</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Isolated consumption of human milk, infant formulas (e.g., milk-based, soy, partially hydrolyzed, extensive-hydrolyzed, amino acid based), or vitamin and mineral supplements (e.g., iron drops)</li> <li>• For timing of the first introduction of a specific type of CFB and types and amounts of CFB: <ul style="list-style-type: none"> <li>○ Dietary patterns</li> <li>○ Type and/or amount of food or beverage not described</li> </ul> </li> </ul>	<p>Criteria for the intervention/exposure were updated to:</p> <p>identify specific interventions/exposures of interest for clarity;</p> <p>include intervention/exposures of fluid cow’s milk before age 12 months;</p> <p>exclude intervention/exposures of dietary patterns to prevent duplication of effort across NESR reviews;</p> <p>and exclude interventions/exposures for the timing of the first introduction of a specific type of CFB and types and amounts of CFB where the type and/or amount of food or beverage is not described for clarity</p>
Comparator	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Different timing of introduction of CFB</li> <li>• Different types and amounts of CFB</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Not applicable</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Different timing of the first introduction of <i>any</i> CFB</li> <li>• Different timing of the first introduction of a <i>specific type</i> of CFB</li> <li>• Different types and amounts of CFB <ul style="list-style-type: none"> <li>○ Consumption of a different amount of the same CFB</li> <li>○ Consumption of a different type of CFB</li> </ul> </li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• No comparator</li> </ul>	<p>Criteria for the comparator were updated to identify specific comparisons of interest for clarity</p>

\* Complementary foods and beverages (CFB) are defined as foods and beverages (liquids, semisolids, and solids) other than human milk or infant formula provided to an infant or young child to provide nutrients and energy

Category	Existing Reviews	Updated Review	Change and Rationale
Outcomes	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Weight and length/height</li> <li>• BMI, BMI percentile for age and z-score</li> <li>• Waist circumference</li> <li>• Weight change</li> <li>• Weight status change</li> <li>• Weight-for-age, length/stature-for-age, weight-for-length, head, arm, and thigh circumference for age</li> <li>• Change across more than one time point of weight-for-age, length-for-age, weight-for-length, head, arm, and thigh circumference for age</li> <li>• % fat mass, % fat free mass</li> <li>• Skinfold thickness</li> <li>• Incidence of healthy weight, overweight, obesity</li> <li>• Incidence of underweight or failure to thrive, stunting, and wasting in infants and children</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Not applicable</li> </ul>	<p><u>Included</u></p> <p>Growth (in infants, toddlers, children, adolescents)</p> <ul style="list-style-type: none"> <li>• Height, length/stature-for-age</li> <li>• Weight, weight-for-age</li> <li>• Stunting, failure to thrive, wasting</li> <li>• BMI-for-age, weight-for-length/stature</li> <li>• Body circumferences (arm, neck, thigh)</li> <li>• Head circumference</li> </ul> <p>Body composition (in infants, toddlers, children, adolescents, adults, older adults)</p> <ul style="list-style-type: none"> <li>• Skinfold thickness</li> <li>• Fat mass, ectopic fat</li> <li>• Fat-free mass, lean mass</li> <li>• Waist circumference, waist-to-hip ratio</li> </ul> <p>Risk of obesity (in children, adolescents, adults, older adults)</p> <ul style="list-style-type: none"> <li>• BMI</li> <li>• Overweight and obesity</li> <li>• Underweight</li> <li>• Healthy/normal weight</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Not applicable</li> </ul>	No change other than formatting
Publication status	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Studies published in peer-reviewed journals</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Grey literature, including unpublished data, manuscripts, reports, abstracts, conference proceedings</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>• Peer-reviewed articles published in research journals</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>• Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings</li> </ul>	No change other than formatting

Category	Existing Reviews	Updated Review	Change and Rationale
Language	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Studies published in English</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Studies published in languages other than English</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Published in English</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Not published in English</li> </ul>	No change other than formatting
Country*†	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Studies conducted in Very High or High Human Development Countries</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Studies conducted in Medium or Low Human Development Countries</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	NESR began applying the Human Development Index classification from the year in which the intervention/exposure data were collected to account for changes in Human Development Index rankings of countries over time

\* Updated Review: In order to determine the inclusion-exclusion criteria for country, the Human Development classification was used. This classification is based on the Human Development Index (HDI) ranking from the year the study intervention occurred or data were collected (UN Development Program. HDI 1990-2017 HDRO calculations based on data from UNDESA (2017a), UNESCO Institute for Statistics (2018), United Nations Statistics Division (2018b), World Bank (2018b), Barro and Lee (2016) and IMF (2018). Available from: <http://hdr.undp.org/en/data>). If the study did not report the year in which the intervention occurred or data were collected, the HDI classification for the year of publication was applied. HDI values are available from 1980, and then from 1990 to present. If a study was conducted prior to 1990, the HDI classification from 1990 was applied. If a study was conducted in 2018 or 2019, the most current HDI classification was applied. When a country was not included in the HDI ranking, the current country classification from the World Bank was used instead (The World Bank. World Bank country and lending groups. Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)

† Existing Review: This classification was based on the Human Development Index (HDI) ranking from the year 2014. When a country was not included in the Human Development Report 2014 ranking, country classification from the World Bank was used instead.