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November 30, 2017

Congressional Committees

WIC: USDA's Review of Vegetables Available under the Program Followed Leading Research Practices

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides supplemental foods, nutrition education, including breastfeeding promotion and support, and health and social service program referrals to low-income pregnant, breastfeeding, and postpartum women, infants, and children up to age 5 who are found to be at nutritional risk. In fiscal year 2016, WIC provided food and services to about 7.7 million participants, and the federal government spent approximately \$6 billion on the program. The U.S. Department of Agriculture's (USDA) Food and Nutrition Service oversees WIC at the federal level and provides grants to state agencies which, in turn, provide food benefits and services to participants through 1,900 local agencies in 10,000 clinic sites.

The federal law authorizing WIC specifies that the supplemental foods provided through the program contain nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding, and postpartum women, infants, and children, and promote the health of the population served by the program. As such, the foods available under WIC are designed to supplement participants' diets with specific nutrients. USDA regulations establish the types and maximum amounts of supplemental food participants may receive. Further, federal law requires USDA to conduct a scientific review of the foods available under WIC at least once every 10 years and amend the foods available, as necessary, to reflect nutrition science, public health concerns, and cultural eating patterns.² USDA contracted with the National Academies of Sciences, Engineering, and Medicine (National Academies) for several recent reviews.³ Among other changes, the 2005 review recommended that fruits and vegetables, with the exception of the white potato, be made available under WIC to better address participants' nutritional needs.⁴ The National Academies recommended excluding the white potato based on food intake data for women and young children that showed white potatoes were the most frequently consumed vegetable and average consumption of starchy vegetables met or exceeded recommended

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¹WIC is authorized by section 17 of the Child Nutrition Act of 1966, as amended, codified at 42 U.S.C. § 1786. Federal regulations implementing the program may be found at 7 C.F.R. pt. 246.

²42 U.S.C. § 1786(f)(11)(C).

³In July 2015, the Institute of Medicine changed its name to the National Academy of Medicine as part of a broad reorganization of the National Academies of Sciences, Engineering, and Medicine (National Academies). The Institute of Medicine is the author of the reports published before that date, and the National Academies is the author of the reports published after that date, although for ease of reference we generally refer only to the National Academies. The mission of the National Academies is to provide independent, objective analysis and advice to inform public policy decisions.

⁴Institute of Medicine, WIC Food Packages: Time for a Change (Washington, D.C.: 2005).

amounts.⁵ The National Academies' most recent review of WIC foods culminated in three reports, which were issued in 2015 and 2017.⁶ The 2015 report that focused on white potatoes recommended that they be available under WIC, in part because nutrients found in white potatoes, such as potassium and fiber, were lacking in WIC participants' diets, and white potatoes can be considered a major source of fiber and other nutrients.⁷

The Consolidated and Further Continuing Appropriations Act of 2015 included a provision for GAO to audit the USDA's most recent review of the supplemental foods available under the program, including the scientific research and data used to conduct USDA's review.⁸ This report assesses the extent to which leading research practices were followed in USDA's most recent review of vegetables available under WIC.

To address this objective, we reviewed relevant federal laws, regulations, and guidance, and the three National Academies' reports that comprise USDA's latest review of foods available under WIC. We also reviewed leading research practices identified in our past work, guidance for federal agencies from the Office of Management and Budget (OMB), and reports from other relevant organizations and individuals with expertise in research design (see enclosure I for additional details). For example, the guidance developed by OMB defines professional research principles and practices that should be followed in order to ensure the quality, objectivity, usefulness, and integrity of information disseminated by the federal government. From these sources, we identified eight leading research practices and key components within those practices that are relevant to the three reports that comprise USDA's review of foods available under WIC, and we assessed the extent to which the research conducted for each report

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⁵Based largely on this recommendation, under an interim rule, USDA allowed fruits and vegetables, except white potatoes, to be purchased with WIC food vouchers in certain WIC food packages, effective October 1, 2009. See Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages, 72 Fed. Reg. 68,966 (Dec. 6, 2007) and Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Delay of Implementation Date, 73 Fed. Reg. 14,153 (Mar. 17, 2008). The final rule, published in 2014, continued to exclude white potatoes. See Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages, 79 Fed. Reg. 12,274 (Mar. 4, 2014). The Consolidated and Further Continuing Appropriations Act of 2015 prohibited USDA from using federal funding to exclude or restrict the eligibility of any variety of fresh, whole, or cut vegetables (except for vegetables with added sugars, fats, or oils) from being provided under WIC. The act further directed USDA to commence the next regular review of the supplemental foods available under the program within 90 days of enactment, and provided that the funding restriction would expire if that review concluded that any vegetable shall not be available for purchase under the program, based upon the nutritional content of the vegetable and the nutrition needs of WIC participants. Pub. L. No. 113-235, § 753, 128 Stat. 2130, 2171-72 (2014).

⁶Institute of Medicine, *Review of WIC Food Packages: An Evaluation of White Potatoes in the Cash Value Voucher: Letter Report* (Washington, D.C.: 2015); National Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Proposed Framework for Revisions: Interim Report* (Washington, D.C.: 2015); National Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Improving Balance and Choice: Final Report* (Washington, D.C.: 2017). For the purposes of this report, we refer to these three reports collectively as "USDA's review."

⁷This report also found that because the recommended levels of starchy vegetables had increased, intakes of such vegetables no longer met or exceeded recommended levels; therefore the basis for excluding white potatoes no longer applied.

⁸Pub. L. No. 113-235, § 753(g), 128 Stat. 2130, 2171-72 (2014).

followed the identified practices. We also interviewed officials from USDA and the National Academies who were responsible for the recent review of foods available under WIC.

We conducted this performance audit from July 2017 to November 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Established as a national program in the mid-1970s, WIC is intended to improve the health of low-income pregnant and postpartum women, infants, and children by providing supplemental foods, nutrition education, including breastfeeding promotion and support, and referrals to healthcare and social services programs. Pregnant, breastfeeding, and post-partum women, infants, and children under age 5 who are determined to be at nutritional risk and who have incomes below certain thresholds are eligible for WIC.

USDA has established seven food packages that are designed for different categories and nutritional needs of WIC participants. ¹⁰ Supplemental foods such as vegetables, fruits, cereal, bread, and infant formula may be included in a package (see fig. 1). Families may receive more than one food package if multiple members are eligible to receive WIC benefits. Participants typically receive food benefits in the form of vouchers or checks that they can redeem to obtain approved foods from authorized retailers. ¹¹ The average amount of monthly food benefits provided under WIC was about \$43 per participant in fiscal year 2016.

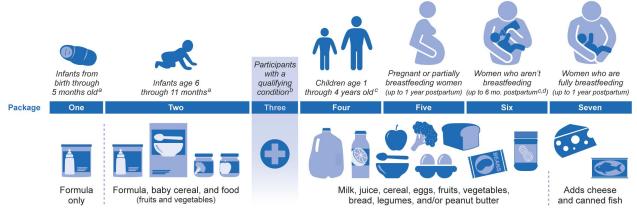
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⁹In this report, we did not review or assess USDA's contract requirements for the National Academies, USDA's oversight of the contract, or the National Academies' implementation of the contract. Our work focused solely on whether the three resulting reports followed the identified leading research practices.

¹⁰7 C.F.R. § 246.10(e).

¹¹In addition, some states issue benefits through a card instead of through paper checks or vouchers in a system called electronic benefit transfer (EBT). State agencies will be required to implement WIC EBT systems by October 1, 2020, unless exempted by USDA. 42 U.S.C. § 1786(h)(12).

Figure 1: Categories of Foods Available under the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Food Packages



Source: GAO analysis of US Department of Agriculture regulations. | GAO-18-125R

Package open to	One Infants from birth through 5 months old ^a	Two Infants age 6 through 11 months ^a	Three Participants with a qualifying condition	Four Children age 1 through 4 years old ^c	Pregnant or partially breastfeeding women (up to 1 year postpartum)	Six Women who aren't breastfeeding (up to 6 mo. Postpartum ^{c,d}	Seven Women who are fully breastfeeding (up to 1 year postpartum)
What package contains	Formula only	Formula, baby cereal, and food (fruit and vegetable)	Participants with a qualifying condition ^b	Milk, juice, cereal, eggs, fruits, vegetables, bread, legumes, and/or peanut butter	Milk, juice, cereal, eggs, fruits, vegetables, bread, legumes, and/or peanut butter	Milk, juice, cereal, eggs, fruits, vegetables, bread, legumes, and/or peanut butter	Adds cheese and canned fish

Note: The authorized supplemental foods must be prescribed from food packages according to the category and nutritional needs of the participants. For the complete food package requirements, including which participants are eligible for each package and maximum monthly allowances, see 7 C.F.R. § 246.10(e).

USDA's Review of Vegetables Available under WIC Generally Followed Leading Research Practices for Designing Studies, Identifying and Analyzing Data, and Developing Statistical Estimates

USDA's review of vegetables available under WIC followed leading research practices for designing studies, according to our analysis of the three reports that comprise its review (see fig. 2). As we noted in our prior work, evaluations should develop clear and specific research questions and select approaches that enable evaluators to address those questions. ¹² In the three reports that comprise USDA's review, which was conducted by the National Academies,

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^aFully breastfed infants from birth through 5 months do not receive infant formula. Fully breastfed infants age 6 through 11 months may receive meats in addition to baby cereal, fruits, and vegetables.

^bFood Package Three is reserved for participating women, infants, and children with qualifying conditions, such as premature birth, low birth weight, metabolic disorders, gastrointestinal disorders, or immune system disorders. Authorized staff at local agencies determine nutritional risk and prescribe supplemental foods for individuals receiving Food Package Three according to medical documentation provided by health care professionals.

^cFood Packages Four and Six include the option of legumes or peanut butter, but not both. Food Packages Five and Seven include both legumes and peanut butter.

^dBread is not a category of supplemental food under Food Package Six.

¹²GAO, Designing Evaluations: 2012 Revision, GAO-12-208G (Washington, D.C.: January 2012).

the researchers developed clear research questions to examine the food and nutritional needs of the WIC-eligible population. To answer these questions, the researchers used several methodologies and data sources. These included a literature review about diet quality among WIC participants, as well as national survey data on nutrients and types of foods consumed by WIC participants and WIC-eligible nonparticipants, which were compared to levels recommended by the most recent nutritional guidelines.¹³ Additionally, the three reports clearly stated limitations in the approaches the researchers used, another research practice we have previously identified as important.¹⁴ For example, the reports noted that the sizes of some subgroups, such as low-income women who were pregnant, were small in the survey data used, and to address this limitation, researchers combined multiple years of data to obtain an adequate number of participants for analysis.

Figure 2: GAO Analysis of the Extent to Which USDA's Review of Vegetables Available under the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Followed Leading Practices for Designing Studies

Reports That Comprise USDA's Review of Vegetables Available under WIC Food Packages

Leading Practices	An Evaluation of White Potatoes ^a	Proposed Framework for Revisions ^b	Improving Balance and Choice ^c
1. Develop useful research questions			
a. Are the research questions clear and specific?	✓	✓	✓
b. Do the research questions contain terms that can be readily defined and measured?	✓	<u> </u>	<u> </u>
c. Are the research questions objective, fair, and neutral?	\checkmark	\checkmark	✓
2. Select methodologies to address the key questions			
a. Does the study methodology address all key questions?	✓	✓	✓
b. Does the study methodology provide the precision, completeness, and conclusiveness of the information needed to answer the questions?	✓	✓	V
3. Select data sources to address key questions			
a. Is the data free of bias or other significant errors that could lead to inaccurate conclusions?	✓	✓	V
b. Is the data sufficient to persuade a knowledgeable person that the findings are reasonable?	✓	✓	✓
c. Is the data relevant, valid, and reliable?	✓	✓	✓
4. Document methodologies and limitations	•	•	
a. Does the study describe the data sources used?	✓	✓	✓
b. Does the study document assumptions and procedures?	✓	✓	✓
c. Are limitations clearly stated about what the study can and cannot address?	✓	✓	✓
d. Are the strengths and weaknesses that are embedded in the methodology clearly stated?	✓	✓	✓

= Followed = Yes

Source: GAO analysis of studies conducted by National Academies of Sciences, Engineering, and Medicine for the U.S. Department of Agriculture. | GAO-18-125R

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¹³The *Dietary Guidelines for Americans* are nutritional guidelines for the general public. These guidelines are required to be updated by the U.S. Department of Health and Human Services and USDA at least every 5 years based on the preponderance of current scientific and medical knowledge. See 7 U.S.C. § 5341(a). There have been various changes to these guidelines over the years. For example, the most recent guidelines (2015-2020) identified nine nutrients, including potassium, for which many Americans are falling short of recommended amounts. ¹⁴GAO-12-208G.

Reports That Comprise USDA's Review of Vegetables Available under WIC Food Packages

Leadin	g Practices	An Evaluation of White Potatoes ^a	Proposed Framework for Revisions ^b	Improving Balance and Choice ^c
1. Deve	elop useful research questions	Followed	Followed	Followed
	Are the research questions clear and cific?	Yes	Yes	Yes
term	Do the research questions contain ns that can be readily defined and asured?	Yes	Yes	Yes
	Are the research questions objective, and neutral?	Yes	Yes	Yes
	ct methodologies to address the estions	Followed	Followed	Followed
	Does the study methodology address ey questions?	Yes	Yes	Yes
the p	Does the study methodology provide precision, completeness, and clusiveness of the information needed nswer the questions?	Yes	Yes	Yes
3. Sele questic	ct data sources to address key ons	Followed	Followed	Followed
sign	Is the data free of bias or other ificant errors that could lead to curate conclusions?	Yes	Yes	Yes
knov	Is the data sufficient to persuade a wledgeable person that the findings are sonable?	Yes	Yes	Yes
3c. I	s the data relevant, valid, and reliable?	Yes	Yes	Yes
4. Doci limitati	ument methodologies and ions	Followed	Followed	Followed
	Does the study describe the data rces used?	Yes	Yes	Yes
	Does the study document assumptions procedures?	Yes	Yes	Yes
	Are limitations clearly stated about tthe study can and cannot address?	Yes	Yes	Yes
	Are the strengths and weaknesses that embedded in the methodology clearly ed?	Yes	Yes	Yes

Note: The leading research practices identified in this figure are based on guidance for federal agencies from the Office of Management and Budget and reports from other relevant organizations and individuals with expertise in research design. alnotitute of Medicine, *Review of WIC Food Packages: An Evaluation of White Potatoes in the Cash Value Voucher: Letter Report* (Washington, D.C.: 2015).
bNational Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Proposed Framework for Revisions: Interim Report* (Washington, D.C.: 2015).

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^cNational Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Improving Balance and Choice: Final Report* (Washington, D.C.: 2017).

In addition to following leading research practices for designing studies, USDA's review of vegetables available under WIC followed leading practices for identifying and analyzing data, according to our analysis of the three reports that comprise its review (see fig. 3). For example, in the reports, the researchers clearly documented the criteria they used to identify and include studies in the literature review, as well as the databases and search words they used. Further, OMB guidance notes that agencies should take sufficient steps to develop statistical estimates that apply to a larger population, not just the subset of individuals for which they have information. Such steps may include adjusting an agency's analysis to more accurately reflect the general population. In the three reports that comprise USDA's review, researchers followed this leading practice. For example, in their analysis of the National Health and Nutrition Examination Survey (NHANES), they developed statistical estimates that applied to WIC participants generally, not just those who were part of the survey. We also found that all three reports followed leading research practices for developing economic analyses. For example, the researchers analyzed the costs of the current foods available under WIC and compared those to various alternatives.

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¹⁵Office of Management and Budget, *Standards and Guidelines for Statistical Surveys* (Washington, D.C.: September 2006).

¹⁶NHANES is a survey conducted by the Centers for Disease Control and Prevention that consists of questionnaires as well as a standardized health examination. It provides information on the health and nutritional status of adults and children in the United States.

Figure 3: GAO Analysis of the Extent to Which USDA's Review of Vegetables Available under the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Followed Leading Practices for Identifying and Analyzing Data

Reports That Comprise USDA's Review of Vegetables Available under WIC Food Packages

Leading Practices	An Evaluation of White Potatoes ^a	Proposed Framework for Revisions ^b	Improving Balance and Choice ^c
1. Developing literature reviews		•	
a. Does the literature review clearly state its criteria?	✓	✓	✓
b. Were the studies in the literature review assessed for their strengths and weaknesses?	✓	✓	V
2. Developing statistical estimates	•	•	
a. Are sufficient steps taken to make estimates to a larger population (i.e., the overall population of individuals to which the conclusions are to be applied)?	<u> </u>	<u> </u>	✓
b. Are estimates based on generally accepted methods (e.g., sampling errors that are associated with the estimates due to sampling some but not all of the individuals)?		~	V
B. Making comparisons	0		
a. Does study test and report only the differences that are statistically significant (i.e., differences that are not a result of chance alone)?		✓	V
I. Developing economic analysis		•	
a. Does economic analysis include a statement of what action is being examined and the timeframe of the analysis?	✓	✓	✓
b. Does economic analysis identify alternatives (e.g., analysis of change compared to no change)?	✓	✓	✓
c. Does analysis include economic effects?	✓	✓	✓
d. Does economic analysis include a sensitivity analysis (i.e., how possible changes impact the outcome)?	✓	✓	✓
e. Does the economic analysis include adequate documentation and transparency (e.g. cites data sources, discloses limitations and contributors, etc.)?	✓	✓	✓

Source: GAO analysis of studies conducted by National Academies of Sciences, Engineering, and Medicine for the U.S. Department of Agriculture. | GAO-18-125R

Reports That Comprise USDA's Review of Vegetables Available under WIC Food Packages

Leading Practices	An Evaluation of White Potatoes ^a	Proposed Framework for Revisions ^b	Improving Balance and Choice ^c
1. Developing literature reviews	Followed	Followed	Followed
1a. Does the literature review clearly state its criteria?	Yes	Yes	Yes
1b. Were the studies in the literature review assessed for their strengths and weaknesses?	Yes	Yes	Yes
2. Developing statistical estimates	Partially followed	Followed	Followed
2a. Are sufficient steps taken to make estimates to a larger population (i.e., the overall population of individuals to which the conclusions are to be applied)?	Yes	Yes	Yes

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Leading Practices	An Evaluation of White Potatoes ^a	Proposed Framework for Revisions ^b	Improving Balance and Choice ^c
2b. Are estimates based on generally accepted methods (e.g., sampling errors that are associated with the estimates due to sampling some but not all of the individuals)?	No	Yes	Yes
3. Making comparisons	Did not follow	Followed	Followed
3a. Does study test and report only the differences that are statistically significant (i.e., differences that are not a result of chance alone)?	No	Yes	Yes
4. Developing economic analysis	Followed	Followed	Followed
4a. Does economic analysis include a statement of what action is being examined and the timeframe of the analysis?	Yes	Yes	Yes
4b. Does economic analysis identify alternatives (e.g., analysis of change compared to no change)?	Yes	Yes	Yes
4c. Does analysis include economic effects?	Yes	Yes	Yes
4d. Does economic analysis include a sensitivity analysis (i.e., how possible changes impact the outcome)?	Yes	Yes	Yes
4e. Does the economic analysis include adequate documentation and transparency (e.g. cites data sources, discloses limitations and contributors, etc.)?	Yes	Yes	Yes

Note: The leading research practices identified in this figure are based on guidance for federal agencies from the Office of Management and Budget and reports from other relevant organizations and individuals with expertise in research design.

^aInstitute of Medicine, *Review of WIC Food Packages: An Evaluation of White Potatoes in the Cash Value Voucher: Letter Report* (Washington, D.C.: 2015).

USDA's review of vegetables available under WIC also generally followed leading practices for developing statistical estimates and making comparisons between subgroups. OMB guidance recommends that agencies should provide additional information about the range of possible estimates that may also be valid due to selecting some but not all individuals in a population. As previously noted, for the reports that comprise USDA's review, the researchers used food consumption data obtained from NHANES, which gathered information from a subset of individuals. From these data, statistical estimates were made that were relevant to a larger population. However, NHANES gathered information from one of multiple possible subsets of relevant individuals, and each of these subsets could have produced different estimates. Leading research practices indicate that this variation in possible estimates should be noted,

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^bNational Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Proposed Framework for Revisions: Interim Report* (Washington, D.C.: 2015).

^cNational Academies of Sciences, Engineering, and Medicine, *Review of WIC Food Packages: Improving Balance and Choice: Final Report* (Washington, D.C.: 2017).

such as by indicating upper and lower bounds on each estimate.¹⁷ Such information is included in two of the three reports that comprise USDA's recent review of foods available under WIC, but it is not included in the 2015 report on the white potato. An official from the National Academies told us that this information was not included because it was not requested in USDA's technical proposal for that study. Similarly, the 2015 report on the white potato did not include sufficient information for making comparisons between relevant subgroups. OMB guidance notes that agencies should provide information on the significance of differences between subgroups.¹⁸ As previously noted, all three reports provided estimates on nutritional intake for WIC participants and eligible non-participants. However, the 2015 report on the white potato did not include the additional information necessary to determine if differences in the estimates for the subgroups were significant.¹⁹ The report notes that, for some of the subgroups, the sample sizes were too small to make statistical comparisons.

Agency Comments

We provided a draft of this report to USDA for review and comment. USDA provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and the Secretary of the U.S. Department of Agriculture. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact us at (202) 512-7215 or larink@gao.gov or kingsburyn@gao.gov Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report include Rachel Frisk (Assistant Director), Hedieh Fusfield (Analyst in Charge), and Jean McSween (Analyst in Charge). Additional assistance was provided by Susan Aschoff, Kate Blumenreich, Sarah Cornetto, Barbara El Osta, Gina Hoover, Mimi Nguyen, Dae Park, and Elaine Vaurio.

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¹⁷Additional information on the variation in possible estimates may be presented as upper and lower bounds, standard errors, or margin of errors. For example, an estimate for one sample may be 56 percent while estimates for different samples from the same population might be 50 percent, 55 percent, 60 percent or 62 percent. For the 56 percent estimate, a leading research practice is to note that it has a margin of error of plus or minus 6 percent with a lower bound of 50 percent and an upper bound of 62 percent.

¹⁸Specifically, this guidance states that agencies should report only the differences that are large enough to be substantively meaningful, even if other differences are also statistically significant.

¹⁹Although this information would have been useful in determining the extent diets differ between WIC participants and WIC-eligible nonparticipants, the evaluation found that both of these groups have inadequate levels of certain nutrients, such as potassium and fiber, and that some of these nutrients are provided by the white potato.

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Enclosures-1

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List of Committees

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The Honorable John Hoeven

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The Honorable Jeff Merkley

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Subcommittee on Agriculture, Rural Development,

Food and Drug Administration, and Related Agencies

Committee on Appropriations

House of Representatives

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Enclosure I: Sources Used to Develop List of Leading Research Practices

GAO. *Designing Evaluations: 2012 Revision*. GAO-12-208G. Washington, D.C.: January 2012. GAO. *Assessing the Reliability of Computer-Processed Data*. GAO-09-680G. Washington, D.C.: July 2009.

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