

Attachment 15b - Federal Register Notice Responses - 24-Hour Urine Revision

Public Comment

From: jean public [<mailto:jeanpublic1@gmail.com>]

Sent: Monday, July 22, 2013 7:28 PM

Subject: public comment on federal register Re: these stats are collected in a lax and negligent manner - causes of deaths need to be kept too because of the crap food usda is giving us

Subject: these stats are collected in a lax and negligent manner - causes of deaths need to be kept too because of the crap food usda is giving us

these stats are unreliable. the people selected to participate probably are relatives of the federal bureaucrats. the usa could use reliable indicators of cause of death for 325 million americans so we can get some real idea of health. why not have every citizen write in on computer. simple questions. are you healthy. who died in your family this past year. of what cause? this kind of question could bring up statistics that could truly help america. such a question would show cancer deaths in a specific area, but then the govt probably doesn't want the people to get that information this present collection must be what was done in 1930 and hasn't updated. we have computers now you now. it doesn't have to be done on paper. this comment is for the public record. please acknowledge receipt. jean public

[Federal Register Volume 78, Number 140 (Monday, July 22, 2013)]
[Notices] [Pages 43883-43885] From the Federal Register Online via the
Government Printing Office [www.gpo.gov] [FR Doc No: 2013-17481]

Agency Response

From: On Behalf Of OMB-Comments (CDC)

Cc: OMB-Comments (CDC)

Hello,

Thank you for your comments concerning the CDC 60 Day Federal Register Notice for OMB No. 60 Day-13-0950, National Health and Nutrition Examination Survey. We have given the concerns you described careful consideration. For further information regarding the unique mission of CDC, please refer to our website at www.cdc.gov.

Thank you for your interest.

CDC

Public Comment



GENERAL MILLS

September 6, 2013

LeRoy Richardson
Centers for Disease Control and Prevention
1600 Clifton Road, MS-D74
Atlanta, GA 30333

Submitted by email:
omb@cdc.gov

RE: Proposed Data Collections Submitted for Public Comment and Recommendations; Submission for Office of Management and Budget Review; Comment Request; The National Health and Nutrition Examination Survey (NHANES) OMB No. 0920-0950, expires 11/30/2015)-revision-National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) 78 Fed. Reg. 43883 (July 22, 2013)

Dear Mr. Richardson:

General Mills (GMI) is an international packaged food manufacturer of products such as ready-to-eat cereal, flour, refrigerated dough, soups, vegetables, snacks, and numerous other products. GMI appreciates the opportunity to offer written comments concerning the Center for Disease Control's (CDC) request for comments on proposed data collection projects. GMI commends CDC on their efforts to seek comments on the utility of this program and strongly recommends the continuation of The National Health and Nutrition Examination Survey (NHANES) program.

GMI supports and encourages funding of The National Health and Nutrition Examination Survey (NHANES) because of its practical utility and the wealth of information it provides regarding the on-going status of public health:

- NHANES is invaluable in providing both the public and private sectors with current and continuous measures of both food and nutrient intakes for the U.S. population as well as vital health tracking data regarding important and emerging long-term public health concerns, such as obesity rates and food insecurity. NHANES data are used to establish, monitor, and/or evaluate recommended dietary intake recommendations, food fortification policies, environmental exposures, immunization guidelines and health education and disease prevention programs. It identifies research needs, informs public policy, like dietary recommendations, and enables changes to support public health needs.
- The CDC NCHS NHANES Web Site and the USDA Beltsville Human Nutrition Research Center/ Food Surveys Research Group Web Site are of enormous value in making the NHANES data and related research timely, accessible and affordable for researchers around the world; this monitoring system serves as the gold standard for other countries. The universal access to NHANES data facilitates the study of relationships between nutrition and many health outcomes in a nationally representative sample of the United States. The data also provides insights into specific subgroups of the population,

including vulnerable groups, like the aging population and children, and can provide insights into dietary needs to be addressed or monitored given the growing diversity of the population, as well as the effect of changes over time. This model is instrumental in tracking progress and identifying new areas of opportunity in our dynamic system.

- NHANES continuous monitoring of the prevalence of chronic conditions and risk factors related to health and diet provides an invaluable national resource. This continuous monitoring is increasingly more important as the food supply continues to change at a rapid pace, and the population and related food patterns become more diverse.

GMI supports the improvement of collection methods to allow the NHANES data to remain relevant with advances in biomarkers and health reporting.

- Retaining the two-day collection method is of significant importance for calculating usual intake and dietary patterns and should be retained. It should not be compromised as improvements to data collection are considered. Significant statistical measures that were both costly and time-consuming have validated the prevalence of inadequacy with this collection method.
- The 24-hour urine collection and analysis would be a valued improvement to the study. At this time, it is the best biomarker to assess sodium and potassium intake (baseline and change over time).
- In the future, other biomarkers should be considered to give us greater insights into assessment of public health status.

NHANES informs the food industry on public health needs. As part of our mission to nourish lives, General Mills is committed to delivering healthy food products and contributing to consumer understanding of health and nutrition.

- One example of this is was the conversion of all General Mills' Big G cereals in 2005 to contain at least 8 grams of whole grain per serving. NHANES data combined with data from My Pyramid showed 9 out of 10 people were not meeting the whole grain recommendations. Since that time, General Mills has delivered millions of servings of whole grain to Americans through our cereals.
- General Mills has used NHANES data since the 1970s in a wide variety of applications: inform product reformulation and new product development, communicate to consumers, identify nutrients of need and food sources, develop informed fortification practices, assess changing dietary patterns, and to address regulatory issues.

We appreciate the opportunity to comment on this very important topic and hope these comments are useful as the CDC assesses the value and need for this program.

Respectfully submitted,



Ann M. Albertson, MS, RD
Senior Nutrition Research Scientist
General Mills Bell Institute of Health and Nutrition

Agency Response

Ann M. Albertson, MS, RD
Senior Nutrition Research Scientist
General Mills Bell Institute of Health and Nutrition
Minneapolis, MN 55427

Dear Ms. Albertson:

Thank you for your kind words concerning the National Health and Nutrition Examination Survey (NHANES). It is gratifying to learn of the many ways you use NHANES data. Our goal is to continue to produce information that is relevant to our data users. Thank you again for taking the time to write us.

Sincerely,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention

Public Comment

September 19, 2013

LeRoy Richardson
Centers for Disease Control and Prevention
1600 Clifton Road, MS-D74
Atlanta, GA 30333

Submitted by email:
omb@cdc.gov

RE: Proposed Data Collections Submitted for Public Comment and Recommendations; Submission for Office of Management and Budget Review; Comment Request; The National Health and Nutrition Examination Survey (NHANES) OMB No. 0920-0950, expires 11/30/2015)-revision-National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) 78 Fed. Reg. 43883 (July 22, 2013)

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) submits the following comments on the above-referenced study.

Based in Washington, D.C., GMA is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies, and a trusted source of information

GROCERY MANUFACTURERS ASSOCIATION

1350 I Street, NW :: Suite 300 :: Washington, DC 20005 :: ph 202-639-5900 :: fx 202-639-5932 ::
www.gmaonline.org

about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle. The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

Importance of NHANES to nutrition and health

GMA supports the ongoing monitoring of the dietary intake and health status of the U.S. population. The wealth of population-based data generated through the NHANES process is used by a broad range of constituencies (government, academia, consumer groups and the private sector) to monitor and identify opportunities for improvement of public health. The data have far-reaching and diverse applications including: identifying research needs and at-risk subpopulations, tracking vulnerable demographic groups, informing policy documents such as the Dietary Guidelines for Americans, and estimating the exposure of population groups to nutrients, foods and food ingredients. Furthermore, this data has been instrumental in helping U.S. food and beverage companies develop improved and fortified products to better meet nutrient needs for optimum health and conduct risk assessments of new innovative foods and food ingredients. Therefore, continuation of this national survey is an important cornerstone for ongoing improvements to the nutrition and health of the population.

Comments on proposed changes

Many uses of the NHANES data involve tracking changes over time. Therefore, it is important that this ability not be compromised by any changes to the data collection method.

GMA fully supports the addition of a 24-hour urine collection to the program, provided that it is not added at the expense of other critical components. Analysis of these samples for sodium, potassium and perhaps other nutrients is an important addition to better estimate intakes of nutrients that are ubiquitous in the diet, establish a baseline and track changes.

GMA is concerned about the proposed deletion of collection of genetic specimens for future testing. Genetics is critical for a better understanding of links between dietary intakes of population subgroups and health. Although this is an emerging area of research, elimination of the sampling program at this time will jeopardize future applications.

Additional proposed improvements

The 2-day dietary recall is particularly important for calculating usual intake and should be retained at a minimum. Nevertheless, the collection of dietary intake over a longer period of time would enhance the quality of the data from NHANES. The inclusion of weekends deserves special attention, as weekend dietary patterns often differ from those during the week.

Longitudinal data are increasingly viewed as more credible than cross-sectional data for population assessments. NHANES is currently cross-sectional, but tracking a subset of participants through multiple cycles would greatly improve the reliability and predictive power of the data and provide a sounder basis for the development of public health recommendations.

The USDA food composition data base used with the NHANES survey data has a limited number of food products. The inclusion of more foods, particularly branded food products, in the data base is necessary to better reflect changes in dietary intakes. GMA encourages ongoing efforts to expand the food composition data base.

GMA commends progress made in releasing NHANES data in a timely manner. We encourage you to continue finding ways to improve data release so that stakeholders can more rapidly be aware of and respond to shifts in dietary patterns and health.

Use of the NHANES data is currently limited by the need to export and manipulate the data using SAS proprietary software that is not universally available. GMA encourages exploration of other data formats that may be more readily utilized by all stakeholders.

In conclusion, NHANES is a valuable public health tool with many diverse applications by both private and public sectors that should be maintained and developed. Continuous improvement and refinement of the program will only enhance the ability of this remarkable tool to play a central role in public health assessments and improvement.

Thank you for the opportunity to comment on the importance of continued funding for NHANES.

Sincerely,

Leon Bruner, DVM, PhD
Senior Vice President
for Scientific and Regulatory Affairs
and Chief Science Officer
Grocery Manufacturers Association

Agency Response

Leon Bruner, DVM, PhD
Grocery Manufacturers Association
The Association of Food, Beverage and Consumer Products Companies
1350 Eye (I) Street NW
Washington, DC 20005

Dear Dr. Bruner:

Thank you for your kind comments concerning the National Health and Nutrition Examination Survey (NHANES). It is gratifying to learn of the contribution of NHANES data to your industry. Our goal is to continue to produce information that is relevant to our data users.

We would like to meet with you in person or via a conference call to provide more details about some of the items you commented on and to hear more about your suggested improvements. Please contact Vicki L. Burt, ScM RN, Chief of the Planning Branch for the NHANES survey at 301-458-4127 or vburt@cdc.gov.

Thank you again for taking the time to write us.

Sincerely,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention

Public Comment

September 20, 2013

LeRoy Richardson
1600 Clifton Road, MS-D74
Atlanta, GA 30333

Re: 60-Day 13-0950 (Proposed Data Collection re the National Health and Nutrition Examination Survey)

Dear Mr. Richardson:

The Academy of Nutrition and Dietetics (the “Academy”) is pleased to comment on the proposed data collection for the National Health and Nutrition Examination Survey (NHANES) published in the Federal Register. The Academy is the world’s largest organization of food and nutrition professionals, with more than 75,000 members comprised of registered dietitian nutritionists (RDNs), registered dietitians (RDs), dietetic technicians, registered (DTRs), and advanced-degree nutritionists. Every day we work with Americans in all walks of life—from prenatal care through old age—providing nutrition care and conducting nutrition research. We are committed to evidence-based strategies for improving the nation’s health and meeting nutrition needs through the lifecycle.

Nutrition monitoring and research is a public policy priority of the Academy. We **enthusiastically support** the Centers for Disease Control and Prevention’s (CDC’s) work conducting the critical NHANES and urge the CDC to continue to request funding sufficient to continue this important work.

Collected data are essential for informing policymakers, researchers, the private sector, and the public on the health and nutrition status of American children and adults and the effectiveness of food and nutrition programs. Knowing what Americans eat and how their diets directly affect their health provides valuable information to guide policies on food safety, food labeling, food assistance, military rations, and dietary guidance. NHANES has helped inform research and policy related to sodium reduction strategies, celiac disease, diabetes risk, obesity, and many other pressing public health issues. The national nutrition monitoring system is our nation’s best and most comprehensive method of assessing nutritional health, because the survey continuously collects usual dietary and supplement intake and laboratory indicators of nutrition status from a nationally representative U.S. sample.

The Academy appreciates the opportunity to comment on the proposed data collection and emphasizes the practical utility of the NHANES. We hope you will look towards the Academy and our members’ expertise as you develop future survey questions. Please contact either Jeanne Blankenship at 202-775-8277 ext. 1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS RDN

Pepin Tuma

Jeanne Blankenship, MS RDN
Vice President, Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics
Dietetics

Pepin Andrew Tuma, Esq.
Director, Regulatory Affairs
Academy of Nutrition and

Agency Response

Jeanne Blankenship, MS RDN
Vice President, Policy Initiative and Advocacy
Academy of Nutrition and Dietetics
1120 Connecticut Avenue NW, Suite 480
Washington, D.C. 20036

Dear Ms. Blankenship:

Thank you for your kind comments concerning the National Health and Nutrition Examination Survey (NHANES). It is gratifying to learn of the contribution of NHANES data to nutrition policy and research. Our goal is to continue to produce information that is relevant to our data users.

Thank you for your offer to provide your members' expertise in developing future survey questions. Vicki L. Burt, ScM RN, Chief of the Planning Branch for the NHANES survey will contact you at the numbers provided to discuss this at greater length. If you wish to initiate a conversation related to future NHANES questions feel free to contact Vicki at 301-458-4127 or vburt@cdc.gov.

Thank you again for taking the time to write us.

Sincerely,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention

cc: Pepin Andrew Tuma, Esq.

Pepin Andrew Tuma, Esq.
Director, Regulatory Affairs
Academy of Nutrition and Dietetics
1120 Connecticut Avenue NW, Suite 480
Washington, D.C. 20036

Dear Mr. Tuma:

Thank you for your kind comments concerning the National Health and Nutrition Examination Survey (NHANES). It is gratifying to learn of the contribution of NHANES data to nutrition policy and research. Our goal is to continue to produce information that is relevant to our data users.

Thank you for your offer to provide your members' expertise in developing future survey questions. Vicki L. Burt, ScM RN, Chief of the Planning Branch for the NHANES survey will contact you at the numbers provided to discuss this at greater length. If you wish to initiate a conversation related to future NHANES questions feel free to contact Vicki at 301-458-4127 or vburt@cdc.gov.

Thank you again for taking the time to write us.

Sincerely,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention

cc: Jeanne Blankenship, MS RDN

Public Comment



September 20, 2013

LeRoy Richardson
Centers for Disease Control and Prevention
1600 Clifton Road, MS-D74
Atlanta, GA 30333

Unilever
800 Sylvan Ave.
Englewood Cliffs, NJ
USA 07632

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www.unilever.com

Submitted by email:
omb@cdc.gov

RE: Proposed Data Collections Submitted for Public Comment and Recommendations; Submission for Office of Management and Budget Review; Comment Request; The National Health and Nutrition Examination Survey (NHANES) OMB No. 0920-0950, expires 11/30/2015)-revision-National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) 78 *Fed. Reg.* 43883 (July 22, 2013) [60-Day 13–0950]

Dear Sir or Madam:

Unilever respectfully submits comments to the Centers for Disease Control and Prevention (CDC) in response to the Request for Comments on the National Health and Nutrition Examination Survey (NHANES).

Unilever is one of the world’s largest consumer product companies with \$69.4 billion (€50 billion) in global sales. Our foods, home and personal care brands are trusted the world over since 1890. Our food and beverage products include many leading brands in the U.S., such as Hellmann’s® mayonnaise; Ragú® sauces; Ben & Jerry’s®, Breyers® and Klondike® ice cream; I Can’t Believe It’s Not Butter® and Country Crock® spreads, Lipton® tea and Slim-Fast® line of ready-to-drink beverages.

In answer to the questions posed in 78 *Federal Register* 43883, July 22, 2013:

Unilever supports the ongoing monitoring of the dietary intake and health status of the US population. The data generated through the NHANES process is used by a broad range of constituencies (government, academia, consumer groups and the private sector) interested in public health improvements. The data is used to identify research needs, identify at-risk subpopulations, track vulnerable demographic groups and inform policy documents such as the Dietary Guidelines for Americans. Additionally NHANES is used for dietary exposure risk assessments used to evaluate potential impact on public health of foods, food components, and various trace materials. Therefore, continuation of this national survey is an important foundation for ongoing improvements to the nutrition and health of the population.

Many uses of the NHANES data involve tracking changes over time. Therefore, it is important that this ability is not compromised by any changes to the data collection method. The 2-day dietary recall is particularly important for data quality and reliability.

Unilever fully supports the planned addition of a 24-hour urine collection to the program, provided that it is not added at the expense of other critical components. Analysis of these samples for sodium, potassium and other nutrients is an important addition to better estimate intakes of ubiquitous dietary nutrients and increase the utility of the NHANES data.

The NHANES data is a critical component in dietary exposure risk assessments conducted by the FDA, EPA, academia, and industry. The NHANES study is considered the global gold standard for dietary consumption patterns evaluation. Marketplace innovation of new foods or food additives require an evaluation of safety for proposed uses through a dietary exposure risk assessment based on NHANES data. Therefore, continuation of this national survey is important for ongoing assessments of potential population health impacts from food innovation.

The utility of the NHANES data would increase if the following areas of limited information were addressed:

- **Multiple Day Food Frequency Patterns:** while 2 days of data is a good start, patterns typically cycle on a weekly basis. Weekend diets often differ from work week diets. Health status is based on the accumulation of many days of dietary choices. 7-day or 14 day food consumption frequency information would capture this needed information E-capture techniques might reduce the burden of these surveys on the participants.
- **Food conversion to commodities and food additives:** recipe conversions to ingredients then to components (such as commodities and food additives) is a critical component of a risk assessment. Current dietary assessments are limited due to broad assumptions being used for these conversions. Accuracy of dietary composition and exposure would greatly increase if 75% of the most frequently consumed foods were converted to components.
- **Link NHANES food codes with USDA National Nutrient Database for Standard Reference's full nutrient data tables.** This would enable extension of dietary assessments for all currently available nutrient, macronutrient, and micronutrient data. For example flavonoids, selenium, or fluoride. This would also provide a harmonized global approach such as provided for dietary intake in the Dutch Food Composition Database NEVO codes.
- **Branded food composition and nutritional profiles:** Accuracy of recipes and nutritional information would significantly increase if a means for capture of branded foods consumed (at home) were included in the dietary survey. UPC code and ingredient list capture by raster or smart phone pictures of labels could potentially make capturing foods by brand a feasible addition to the survey.
- **Improve beverage consumption methodology:** Currently beverage consumption is under-reported in the NHANES survey. Also there is a need for a broader range of beverage types to be reported. For example, ready-to-drink beverages as well as

home-prepared. Better capture of individual beverage consumption in the dietary surveys would increase data utility.

- Food allergy/food sensitivity evaluation: Individuals suffering from consumer- identified food allergies or food sensitivities cover a range of actual physiological conditions, some IgE antibody mediated and others through other immunological or non-immunological means. There are over 15 million Americans that are affected by these conditions.
 - Impact on diet: The diets of these sensitive individual may be skewed to accommodate avoidance to triggering foods. Currently there is limited data – available to evaluate the nutritional status that results. This information is important in assuring appropriate labeling of foods in the marketplace that offers the widest possible “safe” choices of foods for this sensitive population.
 - Biomarker addition to analytical testing: Currently there is no way to estimate incidence between these conditions with similar physiological symptoms. Addition of an IgE blood serum monitor for the top 8 allergens listed under the FALCPA Act, as well as biomarkers of general inflammation or autoimmune disease could potentially help distinguish between the subgroups.
 - Food allergen thresholds: Recently the FDA asked for comments on application of food allergen thresholds to foods. Supporting these discussions with population describing data would be crucial in determining the best policy development with the greatest chance for positive population health benefit.

Thank you for considering our comments on this issue. Sincerely,

Laurel Fix, Ph.D., DABT
Head of Regional Regulatory Affairs Foods North America
Englewood Cliffs, NJ

Agency Response

Laurel Fix, PhD, DABT
Head of Regional Regulatory Affairs Foods North America
Unilever
800 Sylvan Avenue
Englewood Cliffs, NJ 07632

Dear Dr. Fix:

Thank you for your kind comments concerning the National Health and Nutrition Examination Survey (NHANES). It is gratifying to learn of the contribution of NHANES data to your company. Our goal is to continue to produce information that is relevant to our data users.

We would like to meet with you via a conference call to provide more details about some of the items you commented on and to hear more about your suggestions to improve the utility of the NHANES data. Please contact Vicki L. Burt, ScM RN, Chief of the Planning Branch for the NHANES survey at 301-458-4127 or vburt@cdc.gov.

Thank you again for taking the time to write us.

Sincerely,

Kathryn S. Porter, MD, MS, FACPM
Captain, U.S. Public Health Service
Director, Division of Health and Nutrition Examination Surveys
National Center for Health Statistics, Centers for Disease Control and Prevention