NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

0920-0237

(expiration date Nov. 30, 2009)

83-C Change Package

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This request is for approval of three changes to the recently approved National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0237), conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC). 1. Information on iodine has been collected through the laboratory component in past NHANES and was inadvertently left off of the list of laboratory assessments. 2. The Office of Management and Budget, in conjunction with the Interagency Working Group on Perchlorate, has requested NHANES to continue collecting information on thyroid function in the laboratory assessments. After discussions with the National Center for Environmental Health (NCEH), CDC, 8 new serum thyroid tests are being added. 3. NCEH requested analyses of urinary nitrate and thiocyanate, potential confounders for the effects of perchlorate exposure.

There will be no change to the burden for any of these changes.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Iodine. Iodine was inadvertently left off of the list of laboratory assessments. It has now been included in the list of environmental analytes by survey year, updated Attachment 12b (attached).

Thyroid function. NHANES 2007-2008 includes assessment of exposure to perchlorate in the US population. The thyroid function can be affected by exposure to perchlorate. The thyroid is the target tissue for health effects from perchlorate exposure. To properly evaluate the potential health effects from exposure to perchlorate in the US, it is important to include measures of thyroid function in the survey. Therefore, after discussion with OMB, the NHANES program initiated a plan to include 8 serum measures of thyroid function in the 2007-2008 survey. An updated Attachment 12a is attached.

After a series of discussions, NCEH and NCHS agreed to share the funding to conduct the laboratory tests. A contract is now in place with a laboratory to conduct the tests. Additionally, Ethics Review Board (human subjects) approval was obtained; reporting of abnormal thyroid function results will be incorporated into the protocol for reporting findings to survey participants; and an addendum to the informed consent documents is being developed.

Nitrate and Thiocyanate. Nitrate and thiocyanate are potential confounders in assessing the effect of perchlorate exposure on thyroid function. Therefore, after discussion with OMB and in conjunction with the Interagency Working Group on Perchlorate the NHANES program has included nitrate and thiocyanate in the 2007-2008 protocol.

2. Purpose and Use of Information Collection

Thyroid Function

The following information would be added to section A. 2. e -- Other laboratory:

Thyroid function: NHANES will resume assessment of thyroid function, an assessment that was included in NHANES 1999-2002. Thyroid stimulating hormone (TSH) and total T4 were measured in the 1999-2002 survey. NHANES 2007-2008 will include

Thyroid stimulating hormone (TSH)
Total thyroxine (TT4)
Free thyroxine (FT4)
Thyroid peroxidase antibodies (TPO-Ab)
Total Triiodothyronine (T3),
Free Triiodothyronine (T3),
Thyroglobulin, (hTg)
Antibody to thyroglobulin (Anti-Tg)

Thyroid function is crucial for maintaining normal metabolic function in adults and for proper neurological development of the fetus. Thyroid function depends on adequate iodine intake, and can be impaired by environmental toxicants such as perchlorate. The measures of thyroid function will be assessed in the one-third subsample of persons 12 years and older for whom urinary perchlorate and urinary iodine are measured.

Potential confounders with perchlorate

Nitrate and thiocyanate are polyatomic anions that can disrupt thyroid function by competitively inhibiting iodide uptake, similar to the action of perchlorate. Nitrate, thiocyanate, and perchlorate can reversibly bind to the sodium-iodide symporter (NIS) protein resulting in reduced iodine absorption by the thyroid. Nitrate, thiocyanate and perchlorate interact additively to impair iodide uptake by the thyroid. By assessing exposure to each of the three physiologically relevant NIS-inhibitors, the relative impact of each chemical on thyroid function can be estimated.

The prevalence of nitrate exposure is likely due to nitrate intake from both food and drinking water, with foods (e.g. vegetables, milk, dairy products) thought to account for the majority of nitrate intake for typical American adults. Nitrate anion can also form endogenously. Thiocyanate is a biomarker of cyanide exposure from tobacco smoke or diet. Thiocyanate primarily forms in the body as a metabolite of cyanide from tobacco smoke or cyanogenic foods such as cassava. Lower levels of thiocyanate can also be found in milk, dairy products and some vegetables. The measurement of these chemicals will provide reference ranges for nitrate and thiocyanate for the U.S. population.