



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17IM]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) during Investigations of Foodborne Disease Clusters and Outbreaks - New - Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

An estimated 1 in six Americans per year become ill with a foodborne disease. Foodborne outbreaks of cyclosporiasis - caused by the parasite *Cyclospora cayetanensis* - have been

reported in the United States since the mid-1990s and have been linked to various types of fresh produce. During the 15-year period of 2000-2014, 31 U.S. foodborne outbreaks of cyclosporiasis were reported; the total case count was 1,562. It is likely that more cases (and outbreaks) occurred than were reported; in addition, because of insufficient data, many of the reported cases could not be directly linked to an outbreak or to a particular food vehicle.

Collecting the requisite data for the initial hypothesis-generating phase of investigations of multistate foodborne disease outbreaks is associated with multiple challenges, including the need to have high-quality hypothesis-generating questionnaire(s) that can be used effectively in multijurisdictional investigations. Such a questionnaire was developed in the past for use in the context of foodborne outbreaks caused by bacterial pathogens; that questionnaire is referred to as the Standardized National Hypothesis Generating Questionnaire (SNHGQ). However, not all of the data elements in the SNHGQ are relevant to the parasite *Cyclospora* (e.g., questions about consumption of meat and dairy products); on the other hand, additional data elements (besides those in the SNHGQ) are needed to capture information pertinent to *Cyclospora* and to fresh produce vehicles of infection. Therefore, the Cyclosporiasis National Hypothesis Generating Questionnaire

(CNHGQ) has been developed, by using core data elements from the SNHGQ and incorporating modifications pertinent to *Cyclospora*.

The core data elements from the SNHGQ were developed by a series of working groups comprised of local, state, and federal public health partners. Subject matter experts at CDC have developed the CNHGQ, by modifying the SNHGQ to include and focus on data elements pertinent to *Cyclospora*/cyclosporiasis. Input also was solicited from state public health partners. Because relatively few data elements in the SNHGQ needed to be modified, a full vetting process was determined not to be necessary. The CNHGQ has been designed for administration over the telephone by public health officials, to collect data elements from case-patients or their proxies. The data that is collected will be pooled and analyzed at CDC, to generate hypotheses about potential vehicles/sources of infection.

CDC requests OMB approval to collect information via the CNHGQ from persons who have developed symptomatic cases of *Cyclospora* infection during periods in which increased numbers of such cases are reported (typically, during spring and summer months). In part because molecular typing methods are not yet available for *C. cayetanensis*, it is important to interview all case-patients identified during periods of increased reporting, to help determine if their cases could be part of an outbreak(s).

The CNHGQ is not expected to entail substantial burden for respondents. The estimated total annualized burden associated with administering the CNHGQ is 750 hours (approximately 1,000 individuals interviewed x 45 minutes/response). There will be no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Individuals	Cyclosporiasis National Hypothesis Generating Questionnaire	1,000	1	45/60

Leroy A. Richardson,

*Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.*

[FR Doc. 2017-06869 Filed: 4/5/2017 8:45 am; Publication Date: 4/6/2017]