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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17IM]

[Docket No. CDC-2016-0120]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/ or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) during Investigations of Foodborne Disease Clusters and

Outbreaks. CDC seeks to request Office of Management and Budget (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).

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0120 by any of the following methods:

- Federal eRulemaking Portal: [Regulations.gov](http://www.Regulations.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

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 6 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 are 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.)	Total Burden (in hrs.)
Individuals	Cyclosporiasis National Hypothesis Generating Questionnaire	1,000	1	45/60	750
	Total				750

Leroy A. Richardson,
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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