



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention

[30Day-20-1198]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Use of the Cyclosporin National Hypothesis Generating Questionnaire during Investigations of Foodborne Disease Clusters and Outbreaks" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on February 25, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding

the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks (OMB Control No. 0920-1198, Exp. 9/30/2020) - Revision - Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

An estimated one in six Americans per year becomes 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. During the intervening years (i.e. 2015-2019), the numbers of reported cases have steadily increased and larger multistate outbreaks have been reported. For example, there were an estimated 2,299 laboratory-confirmed, domestically acquired cases among persons who became ill during May to August (the typical timeframe of the cyclosporiasis "season" in the United States) reported in 2018. This was markedly higher than the numbers of cases reported for the same time period in 2016 (174) and 2017 (623). In 2019, as of November 13, there were an estimated 2,408 laboratory-confirmed cases reported for the same time period.

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) (see OMB No. 0920-0997). 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, in consultation with public health partners at the local, state, and federal level, CDC developed the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) using core data elements from the SNHGQ and incorporating modifications pertinent to Cyclospora. The CNHGQ facilitates data collection about exposures of potential relevance that an individual had during the period of interest (typically, for ill persons, the two week period before onset of symptoms). The CNHGQ also facilitates information collection about other factors that may be pertinent to multistate outbreaks of cyclosporiasis, including the individual's travel history, hospitalization status, consumption of fresh produce, and points of service for food items consumed at home or away from home. Use of the CNHGQ reduces delays in information collection that would occur if state and local health departments had to develop new forms for each outbreak investigation. The CNHGQ also promotes a common data framework for analysis of pooled data across jurisdictions and better understanding of potential vehicles/sources of Cyclospora infection.

The CNHGQ has been designed for administration over the telephone by public health officials. State or local health

departments may use a web-based version of the CNHGQ to facilitate information collection and transmission to CDC. Health departments that prefer to complete a fillable PDF version of the CNHGQ may submit forms to CDC by email.

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). In some circumstances, a parent, guardian, household member or other proxy may participate in the interview on behalf of the case-patient.

OMB approval is requested for three years. There are no changes to data collection content, data collection procedures, or the estimated burden per response of 45 minutes per interview. The only change is an increase in the estimated number of respondents based on projected use of the CNHGQ. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,875.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Ill individuals identified as part of an outbreak investigation	Cyclosporiasis National Hypothesis Generating Questionnaire	2,500	1	45/60

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[FR Doc. 2020-11798 Filed: 6/1/2020 8:45 am; Publication Date: 6/2/2020]