

Request for non-substantive changes to the Cyclosporiasis National Hypothesis Generating Questionnaire; OMB Control Number 0920-1198

Cyclosporiasis is a foodborne intestinal illness caused by infection with the parasite *Cyclospora cayetanensis*. *C. cayetanensis* is transmitted through consumption of contaminated fresh produce or water. Cyclosporiasis is a seasonal illness in the United States: cases generally occur during the spring and summer months between May and August with peaks in illness onset typically noted in June and July. Outbreaks have been reported almost every year in the U.S. since it became nationally notifiable in 1999 and have been associated with a variety of produce items, including basil, cilantro, leafy greens, raspberries, and snow peas. Cyclosporiasis is currently reportable in 44 states, New York City, and Washington D.C. State and local health departments use the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) to collect standardized information on produce exposures from cyclosporiasis case-patients.

In the fall of 2021, the CDC Cyclosporiasis Surveillance Team undertook an evaluation of the CNHGQ with the goal of improving data collection. Outbreaks identified in 2020 and 2021 indicated that data collected using the current questionnaire could not adequately differentiate between product types for leafy greens which makes implicating a food vehicle as the cause of illness nearly impossible and precludes traceback investigations by partners at the Food and Drug Administration (FDA). Additionally, a new produce item – one not currently included in the questionnaire – was suspected as the cause of an outbreak. Partners at state health departments who administer the questionnaire to case-patients have also requested several changes since the last update.

The evaluation consisted of semi-structured interviews with the principle foodborne disease epidemiologists at selected state health departments and an analysis of historic response rates for produce items currently in the questionnaire. Based on the outcome of this evaluation, the following changes are recommended for the CNHGQ:

1. Specify the date format as MM/DD/YYYY anywhere a date is requested.
2. Laboratory Information Section
 - a. Eliminate “lab developed test” from the laboratory test method table in the Laboratory Information section. No one understood what might be captured in this category. Additionally, “other test type” would capture anything not covered under the specific test types listed in the laboratory test method table.
 - b. Further specify the difference between “GI PCR Panel” and “PCR, not part of a panel” by adding “standalone PCR test, not part of a panel”.
 - c. Add parent question “Was the patient co-infected with another intestinal pathogen” prior to asking “Specify the name of lab-confirmed co-infection”. If the answer to the parent question is “no” then the sub-question can be skipped. People frequently misunderstood the question “Specify the name of lab-confirmed co-infection” and would either write in the name of the laboratory that performed the testing or write “*Cyclospora cayetanensis*” (which is the primary pathogen in these cases, not a co-infection).
 - d. Remove the question “State Lab Accession Number”. This field is frequently left blank, as state health departments may not have the ID number if the patient was not tested

at a state laboratory and this data element is not currently used by the CDC surveillance team.

3. Add a check box for “Case was lost to follow up” and check boxes for whether information was extracted from the medical record. These questions would indicate to CDC surveillance epidemiologists that it is impossible to obtain additional information on that particular case.
4. Section 1: Demographic Data
 - a. Specify that only the month and year of birth are requested for date of birth.
 - b. Specify “years” as the desired unit for “age”.
5. Section 2: Clinical Information
 - a. Move the parent question “Have you (your child) had any of the following symptoms” for the symptom table out of the table for clarity.
 - b. Add “for example, loss of appetite” to the question about “anorexia”, to help explain what anorexia means in this scenario.
 - c. Remove the question about hospitalization from the symptom table and make it a standalone question with yes/no response options. Hospitalization is not a symptom but an outcome.
6. Section 3: Travel, events, and ill contacts
 - a. Add a parent question at the beginning of this section that asks, “Did you (your child) travel to another state or country during the 14 days before onset of illness?”. If the interviewee answers “No”, then the next 3 questions can be skipped, which reduces the overall number of questions and the length of the interview.
 - b. Move the “Note to Interviewer: To help determine if the interviewee meets the case definition, did the interviewee report international travel outside the U.S. or Canada during the 14 days before onset of illness?” to immediately follow the travel questions rather than at the end of the section. If the interviewee traveled internationally, the interview can be concluded.
 - c. Add a table to the event attendance question to gather more complete and consistent data. The table specifies “Event (e.g., wedding, fairs, concerts, etc.)”, “Date attended”, “Location of event”, and “Foods eaten”. Previously this was a free text field and the level and quality of information provided was variable.
7. Section 4: Sources of produce at home
 - a. Edit the script for clarity and add “grocery order invoices” to prompt people who may purchase groceries online for home delivery, for example through Instacart or other services.
 - b. Edit the question to specify “fresh produce” instead of “foods” and add “Instacart” to the list of examples of home delivery grocery services.
 - c. Specify that a range may be given in the “Date shopped” field, rather than the exact date (which is often unknown by interviewees).
 - d. Add a question requesting consent to use the interviewee’s phone number to look up purchase histories for stores where the phone number is the person’s shopper card. This request was made specifically by state health departments; as they already have the person’s phone number they wanted a mechanism to ask people for permission to use it where applicable.
 - e. Add a specific comments field for this section. Previously there was none.

8. Section 5: Sources of produce outside of the home
 - a. Edit the question for clarity and add “restaurants at airports”.
 - b. Specify that a range may be given in the “Meal date” field, rather than the exact date (which is often unknown by interviewees).
 - c. Add a specific comments field for this section.
 - d. Add a checkbox for “Unknown” to the response options for the question: “Is this case associated with a cluster?”. State health department interviewers may not know whether a case is associated with a cluster at this point in the investigation.
9. Section 6: Fresh herbs
 - a. Add “or dried” to the list of herb preparation types in the script that we are not interested in; this was requested since dried herbs are the most common form of herb used by most people. Dried herbs do not pose a risk for cyclosporiasis. We are only interested in fresh herbs.
10. Section 7: Fresh berries and fruit
 - a. Add “or dried” to the list of fruit preparation types in the script that we are not interested in; dried fruits do not pose a risk for cyclosporiasis.
 - b. Move “fresh black raspberries” to the “other fresh berries” question. This item is very infrequently reported by interviewees and does not need to be a standalone question. If the answer to “Did you (your child) eat any other fresh berries” is no, then these items can be skipped which will reduce the overall number of questions asked.
 - c. Move “fresh golden raspberries” to the “other fresh berries” question. This item is very infrequently reported by interviewees and does not need to be a standalone question. If the answer to “Did you (your child) eat any other fresh berries” is no, then these items can be skipped which will reduce the overall number of questions asked.
 - d. Add sub-questions to “Did you (your child) eat any fresh strawberries” to gather additional information regarding whether strawberries were eaten at home and what was the brand and purchase place or eaten outside the home and establishment location. Strawberries frequently emerge as a potential signal during the cyclosporiasis season, meaning that cyclosporiasis case-patients are consuming strawberries at higher-than-expected rates. However, without additional information on brand or purchase location there is little that can be done with this information without follow up interviews. Collecting this information at the initial interview could preclude having to call the interviewee back and ask additional questions about their strawberry consumption.
 - e. Add sub-questions to “Did you (your child) eat any fresh blueberries” to gather additional information regarding whether blueberries were eaten at home and what was the brand and purchase place or eaten outside the home and establishment location. Blueberries frequently emerge as a potential signal during the cyclosporiasis season, meaning that cyclosporiasis case-patients are consuming blueberries at higher-than-expected rates. However, without additional information on brand or purchase location there is little that can be done with this information without follow up interviews. Collecting this information at the initial interview could preclude having to call the interviewee back and ask additional questions about their blueberry consumption.

- f. Move “fresh boysenberries” to the “other fresh berries” question. This item is very infrequently reported by interviewees. If the answer to “Did you (your child) eat any other fresh berries” is no, then these items can be skipped which will reduce the overall number of questions asked.
- g. Swap the order of “Did you (your child) eat any tangerines?” with grapefruit so that tangerines immediately follow oranges (a more similar product type).
- h. Add “or clementines” to the tangerine question and provide an example “e.g., Cuties”. This is expected to facilitate recall by prompting people with a familiar name for this produce type.
- i. Add additional explanation to “Did you (your child) eat precut melon or melon salad?” to help clarify the intended product. We recommend adding “e.g., premade, in a container” and “this could also include melon in a fruit cup or fruit salad” to help facilitate recall.
- j. Move “coconut (whole or shredded)” to the “other fruit” question. This item is very infrequently reported by interviewees. If the answer to “Did you (your child) eat any other fresh fruit” is no, then this item can be skipped which will reduce the overall number of questions asked.
- k. Add “bananas” to the “other fruit” question. This is the most frequent response to this question and it is must be written in. Adding a check box will make it easier to collect this data.

11. Section 8: Leafy greens

- a. Add a question “Did you (your child) eat any bagged salad kits (e.g., bagged leafy greens with dressing or toppings like nuts, seeds, croutons, or cheese that need to be mixed in)?” with sub-questions asking for the ingredients in the bagged salad, the brand, and the place of purchase. Outbreaks in 2020 and 2021 were linked to bagged salad kits and there is no question specific to this exposure currently in the questionnaire. Bagged salad kits are different than “pre-made single serving salads” which are currently included in the questionnaire, and the current format of questions for the different lettuce types proved to be insufficient to gather information on bagged salad kits, which often have multiple lettuce types in them. Gathering information on this specific exposure will enhance our ability to identify outbreaks related to this emerging source.
- b. Add additional explanation to the question “Did you (your child) eat any pre-made single serving salads (e.g. ready to eat salads with toppings, meats, and dressing)?” to help further differentiate it from bagged salad kits. Past outbreaks have identified that these are frequently confused with the bagged salad kits. Suggested additional explanation includes identifying the container type (e.g. “in a hard plastic container”) and where a person might find these items (e.g. “These are ‘grab-and-go’ type items you might find in the deli section of a grocery store.”) This additional explanation is expected to facilitate recall.
- c. Modify the response options to the question “Did you (your child) eat any iceberg lettuce” to better differentiate between product types. Outbreaks in 2020 and 2021 linked to leafy greens identified that the current response options are insufficient. We recommend adding specifying details to 1) the response option “prepackaged” to read “prepackaged, precut/shredded in a bag”, 2) the response option “head/loose” to read

“head/loose (not prepackaged)”; and adding a response option to indicate whether that lettuce type was consumed as a part of a pre-made salad or bagged salad kit to further enhance our ability to identify outbreaks linked to these products.

- d. Modify the response options to the question “Did you (your child) eat any romaine lettuce” to better differentiate between product types. Outbreaks in 2020 and 2021 linked to leafy greens identified that the current response options are insufficient. We recommend adding specifying details to 1) the response option “prepackaged” to read “prepackaged, precut/shredded in a bag”, 2) the response option “head/loose” to read “head/loose (not prepackaged)”; and adding a response option to indicate whether that lettuce type was consumed as a part of a pre-made salad or bagged salad kit to further enhance our ability to identify outbreaks linked to these products.
- e. Modify the response options to the question “Did you (your child) eat any mesclun lettuce” to better differentiate between product types. Outbreaks in 2020 and 2021 linked to leafy greens identified that the current response options are insufficient. We recommend adding specifying details to 1) the response option “prepackaged” to read “prepackaged, in a hard plastic container”, 2) the response option “head/loose” to read “head/loose (not prepackaged)”; and adding response options to indicate if the product was prepackaged in a bag (as opposed to a hard plastic container) and whether that lettuce type was consumed as a part of a pre-made salad or bagged salad kit to further enhance our ability to identify outbreaks linked to these products.
- f. Add a question “Did you (your child) eat any butter lettuce (also called Boston or Bibb lettuce)?” with sub-questions asking for the type (red, green, mixed), the packaging (prepackaged in a bag, prepackaged in a hard plastic container, head/loose, and whether the item was part of a pre-made salad or bagged salad kit), if eaten at home what was the brand and place purchase, and if eaten outside the home what was the name and location of the establishment. Butter lettuce was identified as a suspect food vehicle in an outbreak in 2021 and there is no question specific to this exposure on the current questionnaire.
- g. Modify the response options to the question “Did you (your child) eat any fresh cabbage” to better differentiate between product types. Outbreaks in 2020 and 2021 linked to leafy greens identified that the current response options are insufficient. We recommend adding specifying details to 1) the response options “red” and “green” to read “red, head/loose (not prepackaged)” and “green, head/loose (not prepackaged)”; and adding response options to indicate if the product was precut/shredded, prepackaged in a bag (e.g., coleslaw mix) and whether the cabbage was consumed as a part of a pre-made salad or bagged salad kit to further enhance our ability to identify outbreaks linked to these products.
- h. Modify the response options to the question “Did you (your child) eat any fresh spinach” to better differentiate between product types. Outbreaks in 2020 and 2021 linked to leafy greens identified that the current response options are insufficient. We recommend adding specifying details to 1) the response option “prepackaged” to read “prepackaged, in a bag”, 2) the response option “head/loose” to read “head/loose (not prepackaged)”; and adding response options to indicate if the product was prepackaged in a hard plastic container (as opposed to a bag) and whether that lettuce type was

consumed as a part of a pre-made salad or bagged salad kit to further enhance our ability to identify outbreaks linked to these products.

12. Section 9: Other fresh vegetables

- a. Modify the question “Did you (your child) eat any zucchini?” to specify raw, uncooked zucchini: “Did you (your child) eat any raw, uncooked zucchini?”.
- b. Modify the question “Did you (your child) eat any squash?” to specify raw, uncooked squash: “Did you (your child) eat any raw, uncooked squash?”.
- c. Modify the question “Did you (your child) eat any bell peppers?” to specify raw, uncooked bell peppers: “Did you (your child) eat any raw, uncooked bell peppers?”.
- d. Modify the questions “Did you (your child) eat any ‘mini carrots?’” and “Did you (your child) eat any other fresh carrots?” to combine them into one parent question: “Did you (your child) eat any raw carrots” with a response option for “mini” or “baby” carrots and specify other raw carrots, if needed. If the answer to carrots is no, the interviewer can skip to the next question, reducing the overall number of questions. Adding the potentially more familiar “baby carrots” as a synonym for “mini carrots” may enhance recall.
- e. Modify the question “Did you (your child) eat any other raw root vegetables?” to specify raw, uncooked root vegetables: “Did you (your child) eat any other raw, uncooked root vegetables?”.
- f. Modify the question “Did you (your child) eat any raw onions?” to specify raw, uncooked onions: “Did you (your child) eat any raw, uncooked onions?”.
- g. Modify the question “Did you (your child) eat any raw green onions/scallions?” to incorporate it instead as a response option under the parent question “Did you (your child) eat any raw, uncooked onions?” If the answer to onions is “no” the interviewer can skip to the next question, reducing the overall number of questions.
- h. Modify the question “Did you (your child) eat any salsa or pico de gallo (not from a jar)?” to specify fresh made, not commercially prepared salsa: “Did you (your child) eat any fresh made salsa or pico de gallo (i.e., not from a vacuum-sealed jar)?”.
- i. Modify the question “Did you (your child) eat any fresh guacamole (not from a jar)?” to specify fresh made, not commercially prepared guacamole: “Did you (your child) eat any fresh made guacamole (i.e., not from a vacuum-sealed jar)?”.

These changes are recommended to enhance data collection and improve our ability to identify and investigate outbreaks while maintaining the overall length of the questionnaire. Some changes were specifically requested by partners at state health departments, others were identified as opportunities for improvement based on the evaluation. The total number of questions on the updated questionnaire has been reduced from 83 to 80. The updated version was pilot tested amongst staff in the Parasitic Diseases Branch and took between 25 and 45 minutes to administer, depending on individual factors (e.g., travel history and recall ability); the previous version of the questionnaire also took up to 45 minutes to administer, so the overall burden of the questionnaire has not changed.