

EHS-Net Cooling Study Protocol

1. Title

EHS-Net Cooling Study

2. Research abstract

Improper temperature control of potentially hazardous foods is among the leading causes of foodborne illness in foodservice establishments. Improper cooling significantly contributes to the overall temperature abuse opportunities. The purpose of this study is to collect descriptive data on cooling policies and practices in restaurants.

Only restaurants that cool potentially hazardous foods to refrigerated temperatures will be included in the study. Cooling is defined as the reduction in food temperature from 135°F or above to 41°F or below. The data collected from this study will describe the methods restaurants used to cool foods. While the intent of this study is not to *validate* cooling procedures, this study will collect data that will provide information on the effectiveness of cooling procedures based on cooling standards well recognized in the foodservice environment.

This is an Environmental Health Specialist Network (EHS-Net) special study. EHS-Net is a collaboration involving the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and nine state and local health department sites (California, Connecticut, Georgia, Iowa, Minnesota, New York, Oregon, Rhode Island and Tennessee); these partners have come together in an effort to better understand the contributing factors that lead to foodborne illness.

3. Background

Improper cooling of potentially hazardous foods may lead to contamination and subsequent foodborne illness. Historically, improper cooling has been recognized as one of the leading causes of foodborne illness. From 2001 to 2005, improper cooling was identified as a contributing factor in over 500 confirmed foodborne outbreaks in the US (unpublished FoodNet data). These data clearly indicate that restaurants often cool food improperly; however, relatively little data exists on the methods restaurants use to cool food. This information is needed for the development of effective intervention programs.

4. Objectives

The primary purpose of this study is to collect descriptive data on cooling procedures of potentially hazardous foods. Specifically, we will collect data on:

- rapid cooling procedures employed,
- types of cooling equipment used,
- beginning and ending food temperatures, and
- types of foods being cooled.

A secondary purpose of this study is to determine whether establishment characteristics, such as manager food safety knowledge, restaurant ownership (chain versus independent), and kitchen manager certification, are related to proper cooling procedures.

Only restaurants that cool potentially hazardous foods will be included in this study. Cooling is defined as the reduction in temperature of potentially hazardous foods from 135°F or above to a refrigerated temperature of 41°F or below. Potentially hazardous food is defined as any food of animal origin and heat processed vegetables.

5. Design

This study will use a cross-sectional design to collect information about cooling practices in restaurants. Information will be collected through an interview with the kitchen manager and through observations in the restaurant kitchen. The study will be performed by EHS-Net environmental health specialists (EHSs) who work in state and health departments.

Data Collection

The EHS-Net specialists will contact randomly selected restaurants by telephone to determine their interest in participating in the study (See Appendix A for Recruiting Script). If the restaurant is willing to participate, the EHS-Net specialists will inquire about cooling procedures and arrange a mutually convenient time to conduct the survey. For the interview portion of the study, the EHS-Net specialist will conduct a face-to-face interview with a manager with authority over the kitchen (See Appendix B). For the observation portion of the survey, the EHS-Net specialist will observe the activity in the restaurant kitchen and observe cooling processes (See Appendix C). The manager interview will take approximately 15 minutes to complete. Observations will be limited to approximately 1.5 hours.

Participation by the kitchen manager will be voluntary. The data collection will be anonymous. Although specialists will keep a list of establishments in which they have collected data, no identifying information on restaurants will be stored with the data. Thus, it will not be possible to link the study data with specific restaurants. Additionally, any information used to schedule visits, such as call logs, will be destroyed once data collection is complete.

Data Entry and Management

Data will be entered into a web-based information system designed specifically for this project. User accounts will be issued to the EHS-Net specialist in each state. Account privileges identify the data each specific user is authorized to access and the functions they are authorized to perform. Each EHS-Net specialist is responsible for the administration of the system for his or her own state, and includes user administration, correction and deletion of records capabilities. All data records are owned by the state entering the data. Each state has authority over its records and must grant permission to other states or agencies that would like to use the data.

Refusal Component

Not all restaurants contacted agree to participate in EHS-Net studies- EHS-Net's refusal rate across studies is approximately 30%. To begin to assess response bias in this study, we will determine if refusing restaurants differ from participating restaurants on several descriptive measures. If a manager refuses to participate in this study during the telephone recruitment phase, the recruiter will ask permission to ask three short questions about the establishment by telephone. Participating managers will answer these same questions during the manager interview, and responses for refusing and participating managers will be compared to determine if differences exist.

Study Timeline

Activity	Time schedule
Conduct pilot	2 weeks after HS Administrator concurs with IRB exemption
Submit IRB amendments	1-2 months after exemption received
Conduct study	3-7 months after exemption received
Analyze data collected	8-12 months after exemption received

6. Research Subjects

Number and description of subjects

The study population will include all restaurants that cool potentially hazardous foods in the EHS-Net catchment area. The catchment area for this study includes all or some counties in each of the following nine states: California, Connecticut, Georgia, Iowa, Minnesota, New York, Oregon, Rhode Island, and Tennessee. Each state will recruit establishments for participation in this study through telephone calls to the managers of restaurants on their list. Only restaurants that meet the EHS-Net definition of a restaurant and cool potentially hazardous foods will be included in this study. A restaurant is defined as an establishment that prepares and serves food or beverages to customers but is not an institution, food cart, mobile food unit, temporary food stand, supermarket, restaurants in a supermarket, or caterer.

The sites will enroll a target of 50 establishments per site, and the data collection will be completed within 4 months. Each catchment area will include only one restaurant from each regional or national chain in its study population.

Method of selection/recruitment of subjects

CDC will randomly select samples from lists of restaurants in each state's catchment area. Enrollment will be attempted for all selected restaurants, until the target number of establishments has been enrolled. Establishments will be excluded if they do not cool potentially hazardous food, another restaurant of the same

chain has already been enrolled in the study, or no kitchen manager is employed who speaks English well enough to complete the interview.

Compensation

No compensation will be provided.

7. Analysis

The analysis of the data will proceed in several stages. The first stage of analysis will involve data cleaning, editing, and recoding. A frequency response will be done for each variable to examine item non-response and extraneous responses. Variables with high item non-response or of poor quality will be discarded. The second stage will involve a descriptive analysis of the dataset by running univariate frequencies and cross-tabulations for selected variables by demographic variables (e.g. Independent vs. Chain restaurants). Tests for association will be done using chi-square and t-tests. Analysis may also involve regression modeling of the data to examine any multivariate relationships and to control for confounding. A sub-analysis of establishment characteristics of participants versus refusers will be performed using chi-square analyses.

Analysis Software

SAS system for Windows version 9.1 will be used to analyze data

Study Limitations

Data will be collected in those states participating in EHS-Net (California, Connecticut, Georgia, Iowa, Minnesota, New York, Oregon, Rhode Island, and Tennessee). Given the nature of the study, the data are subject to interviewer bias and recall bias on the part of the interviewee. Therefore, findings may not be assumed to apply to the U.S. restaurant population as a whole.

8. Materials

The data collection consists of a semi-structured, face-to-face establishment manager interview and an observation of cooling practices. These materials, as well as the informed consent, are attached.

9. Risks Summary

Current Risks

This study presents no more than minimal risk of harm to participants as the probability and magnitude of harm or discomfort anticipated in answering these questions are not greater in and of themselves than those ordinarily encountered in daily life. Participants in this study will not provide personally identifiable information.

Future Risks

No future risks exist since call logs will be destroyed once data collection is complete. These materials will be secured in a locked cabinet until destruction.

10. Benefits

To Subjects

Subjects may benefit from a better understanding of cooling procedures. In addition, subjects may benefit from a better understanding of the effectiveness of their cooling procedures.

To Humankind

Humankind may benefit from fewer cases of illness caused by improper cooling of potentially hazardous foods.

To Regulatory Agencies

State and local food protection agencies may use the information learned from this study to assist the restaurant industry implement better cooling practices.

11. Informed Consent

A waiver of documentation of informed consent is requested in accordance with 45 CFR 46.117(c)(2). The proposed research meets the first criteria for the waiver, as it presents no more than minimal risk of harm to participants as the probability and magnitude of harm or discomfort anticipated in answering these questions are not greater in and of themselves than those ordinarily encountered in daily life. Additionally, as participants in this study will not be providing personally identifiable information, activities for which written consent is not normally required outside the research context, the study also meets the second criteria for waiver.

Before conducting the study, we will obtain verbal informed consent from the restaurant manager (See Appendix B). The EHS-Net specialist will read the manager a short introduction describing the purpose of the study and how the data will be used. The interviewer will then ask the manager if he or she agrees to participate in

the study. If the manager agrees, the interview will proceed; if the manager does not agree, the interview will cease.

As indicated earlier, as part of this study, we will be collecting data about restaurants that refuse to participate in the study. A waiver of informed consent is requested for this portion of the data collection, in accordance with 45 CFR 46.116 (d). This research portion meets the criteria for waiver of informed consent, as 1) the research involves no more than minimal risk to participants (the questions are basic questions about the restaurant, not the manager; and the data will be anonymous), 2) a waiver will not adversely affect the rights and welfare of the participants, and 3) the research could not practicably be carried out without a waiver (refusing restaurants will be unlikely to wait on the telephone to hear the informed consent before answering the questions of interest).

12. Funding Information

This study is funded by the CDC EHS-Net project through a cooperative agreement.

13. Institutional Information

Not applicable.

14. Approvals from other IRBs

IRB approval or deferment will be obtained from CDC and all sites.

EHS-Net Cooling Study

Appendix B: Data Collection Instrument

Hello this is _____ with the _____ Health Department. We are working with the Centers for Disease Control and Prevention (CDC) on a research project that focuses on cooling policies and practices and your location has been randomly selected to participate.

Does this establishment cool any potentially hazardous foods from 135°F or above to refrigerated temperatures? Potentially hazardous foods would include any food of animal origin such as meat, poultry, seafood or dairy as well as cooked vegetables.

No → Thank you for your time. *(end interview)*

Yes ↓ *(Go to next paragraph)*

Great! The study consists of an interview with the manager and observation of cooling practices. Specifically we would like to observe how potentially hazardous foods are cooled to refrigerated temperatures. Please keep in mind this is not an inspection and participation is voluntary but we would really appreciate your participation. Also, if you decide to participate, your name and your restaurant's name will not be recorded on the data collection form, nor will they be included in any reports.

Having said that, I need to let you know that at any time during the survey if I see something that is an imminent health hazard, such as no power, no water or sewage on the floor, I will need to stop the study and report the problem to your local health department.

Could we schedule a time to come out when you will be cooling potentially hazardous food and complete the survey?

No → Thank you for your time. Do you have a moment to answer 3 quick questions before hanging up?

No → Thank you for your time. *(end interview)*

Yes ↓ Great, thanks. *(Ask questions 1-3 below)*

1. Approximately how many meals are served here daily? _____ (# meals)

- Unsure
 Refused

2. Which one of the following options best describes the menu for this establishment- American, Asian, Italian, Mexican, or Other?

- American (non-ethnic)
 Asian
 Italian
 Mexican
 Other
 Unsure
 Refused

3. Does this establishment require kitchen manager food safety certification?

- Yes Unsure
 No Refused

Yes ↓ *(Go to next paragraph)*

Great! I'll visit your restaurant for about an hour and a half. Keeping in mind that a manager responsible for managing the kitchen must be available for the interview, and that we would like to be there when cooling is taking place, when would be a convenient time to schedule the visit?

Date: _____ Time: _____

Please call me at if you need to cancel or re-schedule, or if you have any questions.

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Part I: Manager Interview

Manager Informed Consent

Let me give you a little background on why I'm here and what we are going to be doing. I'm working with _____ (health department) on a research project designed to help us better understand cooling practices within restaurants. Your restaurant was picked at random to be in this project. Participation in this study is voluntary. You can choose to stop at any time. If you don't want to be part of the study or if you change your mind later, nothing will happen to you. Whether you are part of the study or not will not affect your restaurant's score on any health inspection.

Having said that, I need to let you know that if at any time during my visit I see something that is an imminent health hazard, such as no power, no water or sewage on the floor, I will need to stop the study and report the problem to your local health department.

I'm going to ask you some questions about this restaurant's policies and practices. If any of the questions make you uncomfortable you can choose not to answer them. The information I collect today will be combined with information from other restaurants in various states and analyzed. Your name and your restaurant's name will not be linked in any way to the information we collect, nor will they be included in any reports.

The information you provide will be valuable in helping us understand the difficult issues restaurants face, so we ask you to be as open and honest as possible.

After our interview, I'd like observe cooling procedures within your establishment.

Do you have any questions?

If you have any questions at a later time, you can contact: (Local Contact Name). (If have card) My information is on this card.

Do you agree to let me interview you? *(Check appropriate box)*

- Yes (Continue with the interview)
- No (Thank you for your time)

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Public reporting burden for this collection of information is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: CDC/ATSDR Information Collection Review Office, MS D-74; 1600 Clifton Road NE, Atlanta, Ga. 30333; ATTN: PRA (0920-0792)

Part I: Manager Interview

1. Does this establishment cool heat-processed potentially hazardous foods?

- Yes
- No (*End evaluation*)
- Unsure
- Refused

2. Which one of the options below best describes the menu for this establishment?

- American (non-ethnic)
- Chinese
- French
- Italian
- Japanese
- Mexican
- Thai
- Other (*Please describe*): _____

3. Is this an independent establishment or a chain establishment?

- Independent
- Chain
- Unsure
- Refused

4. Approximately how many meals are served here daily? _____ Unsure
 Refused

5. Approximately how long have you been a kitchen manager here? _____ Unsure
 Refused

6. Including yourself, how many kitchen managers do you have? _____ Unsure
 Refused

7. How many managers speak the following languages as their *primary* language?

- English _____
- Spanish _____
- Chinese _____
- Other (*describe*) _____
- Unsure
- Refused

Appendix B- EHS-Net Cooling Study Data Collection Instrument

8. Have any kitchen managers received food safety training? This training can be a course or a class, or it can be training that occurs on the job.
- Yes
 - No (*Skip to # 12*)
 - Unsure (*Skip to # 12*)
 - Refused (*Skip to # 12*)
9. Did the food safety training include information on how to properly cool potentially hazardous foods?
- Yes
 - No
 - Unsure
 - Refused
10. Does this establishment require kitchen manager food safety certification?
- Yes
 - No
 - Unsure
 - Refused
11. Are any kitchen managers food safety certified?
- Yes
 - No
 - Unsure
 - Refused
12. How many food workers do you have total? _____ Unsure
 Refused
13. Do any food workers receive food safety training? This training can be a course or a class, or it can be training that occurs on the job.
- Yes
 - No (*Skip to #16*)
 - Unsure (*Skip to #16*)
 - Refused (*Skip to #16*)
14. How many food workers have had food safety training? _____ Unsure
 Refused
15. Did the food safety training include information on how to properly cool potentially hazardous foods?
- Yes
 - No
 - Unsure
 - Refused
16. How many food workers speak the following languages as their *primary* language?
- English _____
 - Spanish _____
 - Chinese _____
 - Other (*describe*) _____
 - Unsure
 - Refused

Appendix B- EHS-Net Cooling Study Data Collection Instrument

17. What is the language spoken most often in the kitchen?

- English
- Spanish
- Chinese
- Other (*describe*) _____
- Unsure
- Refused

18. Does this establishment use an instrument to check food temperatures?

- Yes
- No (*Skip to # 23*)
- Unsure (*Skip to # 23*)
- Refused (*Skip to # 23*)

19. What type of instrument is used to check food temperatures? (Check all that apply)

- Digital/thermocouple probe thermometer
- Bi-metallic probe thermometer
- Computerized Data logger
- Infrared/laser thermometer
- Other (*describe*) _____
- Unsure
- Refused

20. Is anyone trained to check the accuracy of these instruments?

- Yes
- No
- Unsure
- Refused

21. Who is trained to check the accuracy of these instruments? (Check all that apply)

- Food worker
- Manager
- Other (*describe*) _____
- Unsure
- Refused

22. How often are these instruments checked for accuracy?

- Never
- At least once a day
- At least once a week
- At least once a month
- Other (*Please describe*) _____
- Unsure
- Refused

23. In your state or county, what is the required cooling time and temperature?

- Two-stage (135°F to 70° F in ≤ 2 hours; then 70°F to ≤41° F in 4 additional hours or less)
- Two-stage (140°F to 70° F in ≤ 2 hours; then 70°F to ≤41° F in 4 additional hours or less)
- Single-stage (135° F to 41° F in 4 hours or less)
- Single-stage (140° F to 41° F in 4 hours or less)
- Single-stage (140° F to 45° F in 4 hours or less)
- Other _____
- Unsure
- Refused

Appendix B- EHS-Net Cooling Study Data Collection Instrument

- 24. What types of food are cooled?** *(Check all that apply)*
- | | |
|--|--|
| <input type="checkbox"/> Meat – large cuts | <input type="checkbox"/> Pasta or noodles |
| <input type="checkbox"/> Meat – pieces/grinds | <input type="checkbox"/> Casseroles (such as egg bakes or lasagna) |
| <input type="checkbox"/> Poultry – whole | <input type="checkbox"/> Rice |
| <input type="checkbox"/> Poultry – pieces/grinds | <input type="checkbox"/> Cooked vegetables |
| <input type="checkbox"/> Seafood | <input type="checkbox"/> Beans (whole) |
| <input type="checkbox"/> Soups | <input type="checkbox"/> Beans (refried) |
| <input type="checkbox"/> Stews | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Gravies | <input type="radio"/> Unsure |
| <input type="checkbox"/> Sauces | <input type="radio"/> Refused |
| <input type="checkbox"/> Pudding or custard | |
- 25. Who is responsible for cooling foods?** *(Check all that apply)*
- Food worker
- Manager
- Other *(describe)* _____
- Unsure
- Refused
- 26. Do you have formal procedures or processes for cooling potentially hazardous foods?**
- Yes
- No *(Skip to #30)*
- Unsure *(Skip to #30)*
- Refused *(Skip to #30)*
- 27. Are the procedures or processes written?**
- Yes
- No
- Unsure
- Refused
- 28. Have employees been trained on the procedures or processes?**
- Yes
- No
- Unsure
- Refused
- 29. Are the cooling procedures tested and verified? Testing and verification are the processes of measuring temperatures throughout the cooling cycle to ensure the cooling method works.**
- Yes
- No
- Unsure
- Refused

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Part II: Environmentalist section: Answered by data collector.

1. Establishment Type:

- Prep Serve
- Cook Serve
- Complex

2. Is this establishment

- a. ...a sit down establishment?
Yes No Unsure
- b. ...a buffet establishment?
Yes No Unsure
- c. ...a quick-service or fast-food establishment?
Yes No Unsure
- d. ...a caterer?
Yes No Unsure
- e. ...a banquet hall?
Yes No Unsure
- f. ...an institutional foodservice?
Yes No Unsure

3. What is the requirement for cooling cooked potentially hazardous foods in this county?

- Two-stage (135°F to 70° F in ≤ 2 hours; then 70°F to ≤ 41° F in 4 additional hours or less)
- Two-stage (140°F to 70° F in ≤ 2 hours; then 70°F to ≤ 41° F in 4 additional hours or less)
- Single-stage (135° F to 41° F in 4 hours or less)
- Single-stage (140° F to 41° F in 4 hours or less)
- Single-stage (140° F to 45° F in 4 hours or less)
- Other_____

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Part III: Observation

Are foods being cooled during the observation?

- Yes Unsure
 No (End evaluation) Missing

It is possible that you will observe more than one food item being cooled in a restaurant. If so, you will complete questions 1-4 for each food item observed.

1. What type of food is being observed?

- | | |
|---|---|
| <input type="radio"/> Meat – large cuts | <input type="radio"/> Pasta or noodles |
| <input type="radio"/> Meat – pieces/grinds | <input type="radio"/> Casseroles (egg bakes, lasagna) |
| <input type="radio"/> Poultry – whole | <input type="radio"/> Rice |
| <input type="radio"/> Poultry – pieces/grinds | <input type="radio"/> Cooked vegetables |
| <input type="radio"/> Seafood | <input type="radio"/> Beans (whole) |
| <input type="radio"/> Soups | <input type="radio"/> Beans (refried) |
| <input type="radio"/> Stews | <input type="radio"/> Chili |
| <input type="radio"/> Gravies | <input type="radio"/> Other _____ |
| <input type="radio"/> Sauces | <input type="radio"/> Unsure |
| <input type="radio"/> Pudding or custard | <input type="radio"/> Missing |

2. What time did the observation period begin?

- _____ AM / PM
 Unsure
 Missing

3. What is the temperature of the food at the beginning of observation?

- _____ °F
 Unsure
 Missing

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Complete questions 4a-c for each cooling step you observe. If you observed more than one food item being cooled, you will need to complete this grid for each food item being cooled.

4a. Step number:	4b. Did you observe this step?	4c. Which method was used in this step? (<i>Check all that apply</i>)
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <i>Answer question 20-25</i> <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing
	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Missing	<input type="checkbox"/> Refrigeration <i>Answer questions 5-10</i> <input type="checkbox"/> Ice bath <i>Answer questions 11-13</i> <input type="checkbox"/> Ice wand <i>Answer questions 14-17</i> <input type="checkbox"/> Blast chiller <i>Answer question 18</i> <input type="checkbox"/> Ice as ingredient <i>Answer question 19</i> <input type="checkbox"/> Room temperature <input type="checkbox"/> Other: _____ <input type="checkbox"/> Missing

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Refrigeration

Answer questions 5-10 for each step in which refrigeration was a cooling method. If you observed more than one cooling step with refrigeration, you will need to answer these questions for each refrigeration cooling step.

5. What type of cooling unit was used?

- Walk-in cooler
- Reach-in cooler
- Walk-in freezer
- Reach-in freezer
- Unsure
- Missing

6. What was the ambient temperature of the cooling unit?

- _____ °F
- Unsure
- Missing

7. What was the observed food depth while in cooling?

- ≤ 3 inches
- > 3 inches
- Unsure
- Missing

8. Was the product ventilated (uncovered or loosely covered) during cooling?

- Yes
- No
- Unsure
- Missing

9. Were multiple food containers stacked while in cooling?

- Yes
- No
- Unsure
- Missing

**10. Was open air space provided around the top and sides of the container(s) while in cooling?
(Select Yes if the air space around the entire sides and top the food container is ≥ 3".)**

- Yes
- No
- Unsure
- Missing

Ice Bath

Answer questions 11-13 for each step in which an ice bath was a cooling method. If you observed more than one cooling step with an ice bath, you will need to answer these questions for each ice bath step.

11. Was ice present in the ice bath?

- Yes
- No (Skip to question 13)
- Unsure
- Missing

12. Were ice and water filled to the top level of the food?

- Yes
- No
- Unsure
- Missing

13. Was the food stirred at any time during the observation?

- Yes
- No
- Unsure
- Missing

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Ice Wand

Answer questions 14-17 for each step in which an ice wand was a cooling method. If you observed more than one cooling step with an ice wand, you will need to answer these questions for each ice wand cooling step.

14. Was the ice wand inserted into the food?

- Yes Unsure
 No Missing

15. Was any ice present inside the ice wand during the observation?

- Yes
 No
 There was no liquid in the ice wand while in use.
 Unsure
 Missing

16. Was the food stirred at any time during the observation?

- Yes Unsure
 No Missing

17. Was the ice wand replaced with a new ice wand at any time during the observation?

- Yes Unsure
 No Missing

Blast chiller

Answer question 18 for each step in which a blast chiller was a cooling method. If you observed more than one cooling step with a blast chiller, you will need to answer these questions for each blast chiller step.

18. What was the ambient temperature within the blast chiller at the beginning of the observation period?

- _____ °F
 Unsure
 Missing

Ice or frozen food as an ingredient

Answer question 19 for each step in which ice or frozen food as an ingredient was a cooling method. If you observed more than one cooling step with ice as an ingredient, you will need to answer this question for each ice as an ingredient cooling step.

19. Was ice or frozen food added to the food during the observation?

- Yes Unsure
 No Missing

Appendix B- EHS-Net Cooling Study Data Collection Instrument

Observation Conclusion

Answer questions 20-25 for each food item observed.

20. What was the internal temperature of the food at the end of the observation period?

- _____ °F
 Unsure
 Missing

21. What time did the observation end?

- _____
 Unsure
 Missing

22. During the observation, did the worker(s) monitor cooling time or temperature?

- Yes No (*Skip to question 25*)
 Unsure Missing

23. How did the worker(s) monitor cooling time or temperature?

- Touch only Approximated time w/o using a timer or clock
 Probe thermometer Noted time on clock
 Data logging thermometer Used a timer / alarm
 Other _____
 Unsure Refused

24. Did the worker(s) document/record cooling times or temperatures?

- Yes Unsure
 No Missing

25. List any practices observed that may have limited proper cooling not mentioned or described above.

Cooling Study Manual

I. Study Design

- Study design will be a cross-sectional survey.
- Survey will include 3 sections: data collector questions, manager interview, and cooling practices observation.
- This is research; therefore, data collection will be independent of an inspection.
- Restaurants will be randomly selected from a list supplied by the EHS.
- Data will be anonymous.
- EHS and local partners will collect the data.
- An appointment will be made with the establishment to observe cooling practices.
- The design of this study centers around collecting descriptive data. It is not the primary intent of this study to verify the effectiveness of cooling procedures evaluated. Instead, we want to learn more about practices and policies surrounding cooling processes. From this data, we hope to learn more about cooling practices used and what specific cooling procedures and/or foods may warrant future study.

II. Recruitment

A. Recruiting Procedure

We expect each state to collect data in 50 restaurants. Each state will receive a list of randomly selected restaurants from the CDC and will use this list to obtain restaurant participants for this study. This restaurant list will be inflated by the refusal and ineligible rates from previous studies to ensure that each state will be able to meet the target of 50 restaurants. For example, if the refusal/ineligible rates calculated from past studies was 25% for a state (25% of restaurants refused or were ineligible), we will provide that state with a list of 67 restaurants, expecting that approximately 25% (17) of the 67 would refuse to participate or would be ineligible to participate, and 50 would agree to participate.

When recruiting, please adhere to the guidelines described below.

- 1. Do NOT pick and choose restaurants to contact.** Contact restaurants in the order they are listed. This is important; if you pick and choose restaurants to contact, then we no longer have a randomly selected sample.
- 2. Make multiple attempts to contact restaurants.** Recruiters need to make a concerted effort to establish contact with any restaurant that they initially try to contact. This is important because there may be systematic differences between easy-to-contact restaurants and hard-to-contact restaurants. For example, easy-to-contact restaurants may be less busy, better staffed, or better run than hard-to-contact restaurants. As these systematic differences could impact good handling practices in the restaurant, we want to be sure that hard-to-contact restaurants are represented in our sample as well as easy-to-contact restaurants. To ensure that every effort is made to contact all restaurants in the sample, please do the following:
 - Unanswered calls: For unanswered calls make a minimum of 10 attempts over 5 days to reach an establishment.
 - Answered calls: For an answered call where no response was given (i.e. call back later) a minimum of 5 attempts over a minimum of 4 days should be made to the establishment to attempt to get a response.
- 3. Record all call attempts in the provided Call Tracking Log.** A Call Tracking Log designed to assist in keeping track of your calls is provided at the end of this manual. Please fill out the Call Log with the following information:
 - Call Date
 - Call Time
 - Establishment Information
 - Attempt Number: The number of the attempt to call a particular restaurant
 - Results or Disposition of Call: No answer, Nonworking number, Told to call back, etc.
 CDC will not want to see this log; it is provided to assist you.
- 4. Record the final disposition of all restaurants in the Participation Log.** The Excel file called Cooling Study Participation Log should be used to keep track of the responses of the restaurants. Once you have made a final determination about a restaurant, fill out the Participation Log with the following information.
 - Sample ID #: Sample ID number from the restaurant selection list

- Response Code: Indicate the response you received from the restaurant using the following codes.
 - **UNABLE TO CONTACT (U):** Use this response code if you followed the protocol above for unanswered calls and do not ever make contact with a restaurant. Also use this code if you cannot find a working number for a restaurant.
 - **CLOSED (CL):** Use this code if you determine that the restaurant is closed.
 - **CHAIN (C):** Use this code if a restaurant on your list is part of chain, and you have already collected data (or you are scheduled to collect data) from a restaurant in that chain.
 - **REFUSED (R):** Use this code if you followed the protocol above for answered calls and make contact with a restaurant, but do not ever get a definitive response on participation. You will also use this code if you do make contact but the manager/owner declines to participate.
 - **PARTICIPATING (P):** Use this code if you are able to contact a restaurant, it meets the EHS-Net definition of a restaurant, it is not part of an already participating chain, it cools food, and the restaurant agrees to participate.
 - **INELIGIBLE RESTAURANT- NOT EHS-NET (I1):** Use this code if you determine that the restaurant does not meet the EHS-Net definition of a restaurant. The following is the EHS-Net definition of a restaurant: An establishment that prepares and serves food to customers; institutions, food carts, mobile food units, temporary food stands, restaurants in supermarkets, and establishments that only cater are not included. You may be able to determine this without having to call the restaurant; you may have to call the restaurant and ask questions about it before you can make this determination.
 - **INELIGIBLE RESTAURANT-COOL (I2):** Use this code if you are able to contact a restaurant and it is not part of an already participating chain but it does not cool potentially hazardous foods.
 - **INELIGIBLE RESTAURANT- LANGUAGE (I3):** Use this code if you are able to contact a restaurant and it is not part of an already participating chain, but there are no managers who speak English well enough to complete the interview.
 - **INELIGIBLE RESTAURANT- SCHEDULE (I4):** Use this code if you are able to contact a restaurant and it is not part of an already existing chain, but it only cools foods during periods outside of your approved workday.
 - **OTHER (O):** Something that does not fall into any of the other categories.
- Reasons for refusal/comments: Any information they may provide on the reasons for refusal, or other comments.

For all participating and refusing restaurants, also enter in the appropriate spaces:

- The answers to the following 3 questions:
 3. Is this an independent or chain establishment?
 4. How much difficulty did you have communicating with the person who gave you your answer on participation?
None A little Some A lot
 5. How many calls did you make before receiving an answer?
- The above questions should be answered by you, not the respondent.
- Regarding question 4, 'some' is more than 'a little', but less than 'A lot'. These types of questions are intended to be subjective, so use your intuition when answering.

For all refusing restaurants, also enter in the appropriate spaces:

6. Whether they agreed to answer the 3 refuser questions.
If so, the respondent's answers to the 3 refuser questions:
7. Approximately how many meals are served here daily?
8. Which one of the following options best describes the menu for this establishment- American, Asian, Italian, Mexican, or Other?
9. Does this establishment require kitchen manager food safety certification?

4. **Stop collecting data once you have collected data in 50 restaurants.** When you have collected data in 50 restaurants, you do not have to collect any more data, even if you have restaurants on the list that you have not yet contacted.

B. Recruiting Script

Hello this is _____ with the _____ Health Department. We are working with the Centers for Disease Control and Prevention (CDC) on a research project that focuses on cooling policies and practices and your location has been randomly selected to participate.

Does this establishment cool any potentially hazardous foods from 135°F or above to refrigerated temperatures? Potentially hazardous foods would include any food of animal origin such as meat, poultry, seafood or dairy as well as cooked vegetables.

- No → Thank you for your time. (end interview)
 Yes ↓ (Go to next paragraph)

Great! The study consists of an interview with the manager and observation of cooling practices. Specifically we would like to observe how potentially hazardous foods are cooled to refrigerated temperatures. Please keep in mind this is not an inspection and participation is voluntary but we would really appreciate your participation. Also, if you decide to participate, your name and your restaurant's name will not be recorded on the data collection form, nor will they be included in any reports.

Having said that, I need to let you know that at any time during the survey if I see something that is an imminent health hazard, such as no power, no water or sewage on the floor, I will need to stop the study and report the problem to your local health department.

Could we schedule a time to come out when you will be cooling potentially hazardous food and complete the survey?

- No → Thank you for your time. Do you have a moment to answer 3 quick questions before hanging up?
 No → Thank you for your time. (end interview)
 Yes ↓ Great, thanks. (Ask questions 1-3 below)

1. Approximately how many meals are served here daily? _____ (# meals)
 Unsure
 Refused

2. Which one of the following options best describes the menu for this establishment- American, Asian, Italian, Mexican, or Other?
 American (non-ethnic)
 Asian
 Italian
 Mexican
 Other
 Unsure
 Refused

3. Does this establishment require kitchen manager food safety certification?
 Yes Unsure
 No Refused

- Yes ↓ (Go to next paragraph)

Great! I'll visit your restaurant for about an hour and a half. Keeping in mind that a manager responsible for managing the kitchen must be available for the interview, and that we would like to be there when cooling is taking place, when would be a convenient time to schedule the visit?

Date: _____ Time: _____

Please call me at if you need to cancel or re-schedule, or if you have any questions.

C. Scheduling

All surveys must be scheduled in advance. Eligible locations should be scheduled at times that allow the most data to be collected within the limited time allowed for data collection.

Data collection should begin at or near the beginning of a cooling process. If locations cool multiple foods, schedule your evaluation around the specific food or food type that best represents the majority of foods cooled by the establishment. For example, if a restaurant cools chili every day but occasionally cools baked potatoes, schedule the evaluation to include chili. You may collect data on the baked potatoes or any other food being cooled if present during the evaluation. However, data collection on the chili should be priority.

If no clear distinction can be made between volumes of different food types being cooled, choose a food that provides the most convenient observation.

Observations may be completed at any time of the day or week. However, we understand approved work hours may vary among different participating states. Locations that only cool all foods during periods outside of your approved workday should be coded as ineligible.

III. Data Collection

In the Field. When going into the restaurant you will need to bring one copy of the data collection questions, informed consent, and the manager interview. You should bring several copies of the Observation section to the restaurant, as they may need to be completed several times- for multiple food items, and multiple cooling steps.

To help make more efficient use of your time at each facility, you may begin your evaluation with the first part of the observation followed by the manager interview and concluded with the end of the observation.

Choose the primary food and cooling process when scheduling evaluations. Document other cooling processes if present during the observation.

Observation should begin at the beginning of or during the cooling process. This may include ambient cooling or a more rapid cooling process. Evaluations should be scheduled accordingly. Time and temperatures should be recorded at the beginning and end of the observation.

Organizing Forms. We are keeping the data collected in this study anonymous, meaning that we do not want to be able to link any data collected to the restaurant from which the data came. Thus, once you complete your data collection, you will need to separate any identifying information on the restaurant from the restaurant's data.

A. Informed Consent

Once at the restaurant, you will meet with the manager and obtain their informed consent. This script is included in the protocol.

Note: Throughout the data collection instrument, boxes (☐) indicate that there could be multiple answers to the question, while circles (○) indicate that there should be only one answer to the question.

B. Manager Interview

After obtaining informed consent, you will interview a manager with authority over the kitchen. Please use the following guidelines.

1. General Guidelines

- For each survey question, you will read each question aloud and mark the appropriate response. Note that words that should be read aloud are in bold, while words you should not read aloud are not bolded.
- Answer choices should not be read aloud unless specifically noted.
- When reading answer choices, do not read the responses of “Unsure” or “Refused.”
- Questions that allow more than one answer will be followed by “Check all that apply.”
- Please note and follow skip patterns.

- You should attempt to obtain an answer to each question in the interview; however, if you believe that the establishment manager is unaware or unsure of the answer to a question, the response should be recorded as “Unsure,” and if the manager refuses to answer a question, the response should be recorded as “Refused.”

2. Specific Questions

- Question 1: Review “cooling” and “potentially hazardous food” definitions before answering.
- Questions 2-3: No additional explanation needed.
- Question 4: The number provided should be a daily average of meals from a 7-day period. Meals may be represented by ticket orders and/or customers served.
- Question 5: These data will be reported in the information system in terms of years. For example, if the manager’s answer is 6 months, the information will be reported in the system as .5. You will not need to make this conversion until data entry.
- Questions 6-9: No additional explanation needed.
- Questions 10-11: For the purposes of this study, food safety certified/certification will include any formal food safety training where participants received a certificate upon completion of the training.
- Questions 12: Food workers do not include wait or steward staff who have very limited to no food handling responsibilities. See “food worker” definition.
- Questions 13-18: No additional explanation needed.
- Question 19: See thermometer type definitions.
- Questions 20-23: No additional explanation needed.
- Question 24: Select the most appropriate type(s) from the list. Meat would include all animals excluding poultry or seafood. “Large cuts” include ribs, roasts, steaks, fillets, drums, wings and breasts that whole and intact. “Pieces” would include any chopped, pulled, sliced or ground product.
- Question 25: No additional explanation needed.
- Question 26: “Formal procedures or processes” include any method of cooling that has been established by the firm as a standard practice. Formal procedures or processes may be written or unwritten.
- Question 27-29: No additional explanation needed.
- Question 30: See definitions for various types of methods. If multiple methods are used for an individual food item, select combination method by listing in order the methods used. For example, if a food item is cooled by ambient, ice bath and cooler the proper selection would be “K, F, A.” Note: If cooling by refrigeration is indicated, be sure to probe further to better document product depths.
- Questions 31-36: No additional explanation needed.

C. Environmentalist Section

This section contains several questions that the data collector should answer.

For question #1, take care in reviewing the menu. Ask questions about the ingredients of all the menu items. Do not make assumptions about the ingredients used or the process used to prepare them. Upon completion of the menu review determine the Establishment Type using the most complex process that occurs in this establishment and using the following definitions:

- **Prep Serve Establishment** – An establishment where all food items are prepared and served without a kill step. Some food on the menu that is a commercially prepared, ready-to-eat food, may be heated for service.
- **Cook Serve Establishment** – An establishment where at least one food item is prepared for same day service and involves a kill step. The menu may include prep serve items or have some food on the menu that is commercially prepared and heated for service.
- **Complex Establishment** – An establishment where at least one food item requires a kill step and holding beyond same day service or a kill step and some combination of holding, cooling, re-heating, and freezing. The menu may include any combination of prep serve, cook serve, and complex food items.

D. Observation of Cooling Practices

1. General Guidelines

The observation section is designed to capture one food at a time. For each food observed in the cooling process, record all methods used in the order in which they were observed. Data should be collected by observation only. Complete questions 1-27 for each food observed.

2. Specific Questions

- *Note: Questions 1-3 will be answered for each food item observed.*
- Question 1: See question 26 of manager interview instructions.
- *Note: Observation should begin during the cooling process(es) as defined in this manual and indicated by kitchen staff.*
- Question 2: Document start time in any format you wish; however, start (and end times) will be coded in 24-hour standard time when entering into the database.
- Question 3: Document the internal temperature at the centermost area of the food being observed.
- *Note: Questions 4a-4c will be answered for each cooling step.*
- Questions 4a-4c: The purpose of the column is to organize the order of various cooling procedures observed. Each step (method) should be numbered in the order at which they were observed. Steps not observed (previous or subsequent to your observations) should be numbered accordingly and documented; however, no additional interview data will be collected for steps not observed. **Note: Complete subsequent questions for only those methods observed.**
- *Note: Questions 5-10 will be answered for each refrigeration step observed.*
- Question 5: See definitions section for different refrigeration types.
- Question 6: Cooler temperature should be measured at the center-most section of the unit.
- Question 7: This should be an estimate of the food depth, not container depth.
- Question 8: Select "Yes" if any form of ventilation is observed. This would include perforations or holes in covering.
- Question 9: Select "Yes" if the food container being cooled is stacked with one or more additional containers of food. Additional container(s) may or may not be in the cooling process.
- Question 10: Select "Yes" only if the area surrounding and above the cooling food is free of other equipment and food. The cleared areas around the sides and top of the container should be at least 3 inches.
- *Note: Questions 11-13 will be answered for each ice bath step observed.*
- Question 11: Select "Yes" if any ice is present in the ice bath during the observation.
- Questions 12: No additional explanation needed.
- Question 13: Select "Yes" if the food was stirred using the ice wand or an additional utensil (spoon, spatula, etc.)
- *Note: Questions 14-17 will be answered for each ice wand step observed.*
- Question 14-15: No additional explanation needed.
- Question 16: Select "Yes" if the food was stirred using the ice wand or an additional utensil (spoon, spatula, etc.)
- Question 17: No additional explanation needed.
- *Note: Question 18 will be answered for each blast chiller step observed.*
- Question 18: Ambient temperatures may be obtained from either positioning a working thermometer inside the unit or observing an existing ambient thermometer built into the blast chiller. Tumble chill devices may not facilitate ambient recordings. Units where ambient temperatures are impossible to measure should be coded as "Unsure."
- *Note: Question 19 will be answered for each ice or frozen food as an ingredient step observed.*
- Question 19: Select "Yes" if ice or frozen food is added directly to the food and the ice/water become an ingredient.
- *Note: Questions 20-25 will be answered for each food item observed.*
- Question 20: Internal temperatures must be taken at the center-most point of the food being observed.
- Questions 21-25: No additional explanation needed.

IV. Definitions

“Bi-metallic probe thermometer” is a device designed to measure internal food temperatures by way of transducing element(s) that deformed with temperature. For purposes of this study, these devices will have no electrical components and will have a dial display.

“Blast chiller” is defined as a cupboard specifically engineered to rapidly chill hot food.

“Cooling” is defined as the reduction in internal temperature of *cooked* or *heat-treated* food from 135° F to refrigerated temperatures.

“Computerized data logger” and **“data logging thermometer”** are digitally programmed devices designed to automatically record internal food temperatures.

“Digital/thermocouple probe thermometer” is an electronic device with digital display designed to measure internal food temperatures.

“Food depth” is the measured height of food within or upon a container. Food depth does not include the container. For purposes of this study, the food depth will be approximated in inches.

“Food safety certified/certification” will include any formal food safety training where participants received a certificate upon completion of the training.

“Food workers” are defined as those individuals employed by the firm who are involved in food preparation. This does not include wait staff with very limited food handling responsibilities such as garnishing, drink preparation and serving.

“Freezer” is defined as a refrigeration unit designed to keep food temperatures below freezing. For purposes of this study, there is no distinction between reach-in, walk-in or deep-freeze refrigeration units.

“Ice bath” is defined as a rapid cooling method in which foods are placed into an ice and water mixture. Water and ice do not come in direct contact with food.

“Ice or frozen food added as an ingredient” is the process of adding ice or other frozen food to hot food to facilitate cooling. Ice and/or frozen food are considered ingredients of the finished product.

“Ice wand” is defined as an instrument that is frozen and inserted into food to facilitate rapid cooling.

“Infrared/laser thermometer” is a device that uses an infrared light beam to measure the surface temperature of food.

“Leaving food at room/ambient temperature” is the process of decreasing food temperatures by storing or holding food at room temperatures.

“Monitoring temperature” is the process of observing and/or recording food temperatures at any point during the cooling process.

“Potentially hazardous food” will include any raw or heat-treated food of animal origin and heat-treated vegetables. This does not include air-cooled hard-boiled egg with shell intact or any food where preservatives have been added making the food shelf-stable.

“Product ventilated” describes foods that have any form of ventilation during the cooling process. Food that are entirely covered and/or sealed during cooling are not considered ventilated.

“Reach-in cooler” is defined as a refrigeration unit accessible by hand only and is designed to maintain food temperatures above freezing.

“Walk-in cooler” is defined as a refrigeration unit with an entrance that will allow employee to enter and is designed to maintain food temperatures above freezing.

“Water and/or ice used as a cooling medium” is the process of applying water or ice to hot food to facilitate cooling. Ice and/or water serve as a cooling medium only and are not considered ingredients before or after the cooling process. A common example is hot pasta being cooled under running water where the water is continuously drained from the product while cooling.

V. Observation Example

Please review the following example as it will likely answer many questions you may have regarding coding foods and data collection.

During the observation, five different containers of foods are being cooled. Container 1 has chili, containers 2, 3 and 4 all have cooked ground beef, and container 5 has pork ribs. Cooling methods for each container are as follows:

Container 1: Ambient, ice bath, shallow container/walk-in cooler (K, E, A)

Container 2 and 3: Shallow container/ walk-in cooler (A)

Container 4: Ambient, ice bath, shallow container/walk-in cooler (K, E, A)

Container 5: Deep container/walk-in cooler (B)

Container 1 should be coded as “chili”. It follows a combination of cooling methods (K, E, A) and data should be collected for each of the methods observed during the observation period. Your available time during observation may limit data collection for all methods. Therefore, if time does not permit you to observe cooling in the walk-in cooler, you will only collect data for methods K and E. Regardless of where you end your observation, questions 20-25 must be collected for **all** foods observed.

Containers 2-4 should be coded “Meat – pieces/grinds.” Containers 2 and 3 follow a single cooling method (A). Since the type of food and cooling process are identical, choose only one container to evaluate. However, if the containers were filled to noticeably different levels (use our 3” criteria as a gauge) then we would consider this to be two different methods of cooling (method A and method B) and we should collect data for each.

Although container 4 contains ground beef from the above batch, it is cooled using different methods and data should be collected for each method observed.

Container 5 should be coded “Meat – large cuts” and like the above examples should be observed through each cooling process. Again, with all foods observed, questions 20-25 must be answered.

VI. Other

A. Answers to possible questions.

- “What are you doing?”
- “Why are you watching me?”
- “What are you looking for?”

We are trying to learn more about how food is prepared in restaurants. So we are watching food workers prepare food, and taking notes on what they do.

- “Why?”

In the long run, we hope to figure out how to make it easier for food workers to do what they need to do.

- “What are you going to do with your notes?”

They will be entered into a computer and analyzed along with other responses. We are not collecting any information that might identify you in any way.

