Conference for Food Protection 2023 Issue Form

Issue: 2023 I-022

Council Recommendation:	Accepted as Submitted	Accepted as _Amended	 No Action	
Delegate Action:	Accepted	_ Rejected	_	
All information above the line	e is for conference use only.			
Issue History: This is a brand new Is	ssue.			
Title:				

Issue you would like the Conference to consider:

We propose amending Food Code 3-501.14 to include an option to cool time and temperature control for safety (TCS) foods at a depth of 2 inches or less, uncovered, and refrigerated, without time and temperature monitoring.

Amend Food Code to allow cooling without time and temperature monitoring.

Hot foods should be cooled rapidly to minimize pathogen growth and prevent outbreaks. Unfortunately, rapid cooling is often difficult for restaurants to accomplish and for inspectors to verify. The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures. This monitoring is not always feasible for restaurant operators because of the time required to adequately monitor the cooling process.

The Food Code outlines methods that can promote rapid cooling of TCS foods but does not specify how to apply the methods to various situations or whether some methods are more effective than others. Inspectors and operators are left to evaluate every method, or combination of methods, to determine which meet the time requirement. We recommend that operators and inspectors be allowed to also focus on specified cooling methods that are known to facilitate guick and proper cooling without additional time monitoring.

The recommended solution is intended to reduce the complexities of monitoring cooling time/temperature parameters by offering a safe, simple, and clear alternative: foods can be cooled uncovered, in a refrigerated environment at a depth of 2 inches or less, with no additional time and temperature monitoring required.

Public Health Significance:

Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators. This option is also beneficial to inspectors, as it is easy to verify during an inspection and easy to train new operators on safe cooling methods. Ultimately, this option will potentially reduce operating costs for food establishments and reduce time dedication for operators and inspection staff while providing a more reliable way to reduce foodborne illness.

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen growth factors contributing to restaurant-related outbreaks (Gould *et al.*, 2013).

The FDA Food Code contains specific time and temperature parameters recommended to achieve proper cooling and suggests methods that can promote rapid cooling. Even with these guidelines restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020; Wittry *et. al,* 2022). An FDA study assessing the occurrence of foodborne illness risk factors in retail settings found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018)

Washington State has already adopted this alternative cooling option (in place for 17 years) and it is strongly preferred by operators within the state. Seattle-King County Health Department conducted a risk factor study in 2016, which included 2115 restaurants, and found that 75% of operators reported using the 2-inch cooling option to cool hot foods. Only 12% of operators reported using time and temperature monitoring as outlined by the FDA food code (unpublished data, Seattle-King County Health Department). Since 2-inch cooling without time-temperature monitoring was implemented, no foodborne outbreaks have been associated with this cooling method.

The cooling standard in Washington shows that providing an option to cool at a depth of 2 inches or less, ventilated, and refrigerated provides a solution that is consistently safe and that restaurant operators have adopted enthusiastically.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting 3-501.14 of the current Food Code be amended as specified below:

- 3-501.14 Cooling.
- (A) Except as specified under (B) of this section, Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:
- (1) Within 2 hours from 57°C (135°F) to 21°C (70°F); P and
- (2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. P
- (B) As an alternative to the cooling provisions of subsection A of this section, FOODS that are being continuously cooled must be cooled in a shallow layer of two inches or less, uncovered, in cooling or cold holding EQUIPMENT maintaining an ambient temperature of 5°C (41°F) or less.
- (<u>BC</u>) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. ^P
- (Θ) Except as specified under \P (Θ) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in \P 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. P

(ĐE) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. P

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Supporting Attachments:

- "Summary of Issue to Amend 3-501-14"
- "Supplemental Materials"
- "Supporting Publications"
- "National Restaurant Association Letter of Support"
- "Taco Time Letter of Support"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

The working group for this issue included:

Donald Schaffner, Rutgers University
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Janet Anderberg, Washington State Health Department (Retired)
Nicole Hedeen, Minnesota Department of Health
Susan Shelton, Washington State Health Department
And several other members

Executive Summary:

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012; Hedeen, Schaffner, & Brown, 2022). Hot foods should be cooled rapidly to minimize pathogen growth and prevent outbreaks. Unfortunately, rapid cooling is often difficult for restaurants to accomplish and for inspectors to verify. The FDA Risk Factor study (2018) found that cooling practices did not meet the cooling parameters described in the FDA Food Code at least once in 72% of 273 full-service restaurants where cooling was observed. Although the FDA Food Code provides guidance on possible cooling methods, it does not provide guidance on the specific combinations of cooling methods that will achieve compliance with the time recommendations. Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators and is an effective means of cooling. This option is also beneficial to inspectors, as it is simple to verify during an inspection and easy to train operators on safe cooling methods. Ultimately, this option will potentially reduce operating costs for food establishments and reduce time dedication for operators and inspection staff while providing a more reliable way to reduce illness.

1. Define the problem that needs to be addressed

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen growth factors contributing to restaurant-related outbreaks (Gould *et al.,* 2013), and was identified as a contributing factor in 10% of the 251 outbreaks reported to the National Environmental Assessment Reporting System during 2014-2016 (Lipcsei *et. al,* 2019). Approximately 9% of outbreaks in the United States between 2009 and 2015 were due to bacterial intoxications from pathogens such as *Clostridium perfringens, Bacillus cereus,* and *Staphylococcus aureus* (Dewey-Mattia *et. al,* 2018). These bacteria can multiply to disease-causing levels if foods are cooled improperly (Doyle, 2002). Approximately 10% of foodborne outbreaks in Minnesota each year are also due to bacterial intoxications (Minnesota Department of Health, unpublished data on confirmed foodborne outbreak by etiology, 2018). Bacterial intoxication outbreaks are preventable if time-temperature control measures (including proper cooling) are properly implemented.

The FDA Food Code contains specific time and temperature parameters recommended to achieve proper cooling and suggests methods that can promote rapid cooling. Even with these guidelines restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020; Wittry et. al, 2022). A FDA

study assessing the occurrence of foodborne illness risk factors in retail settings found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018). Evaluation of risk factor data from the City of Minneapolis Environmental Health Department identified compliance with cooling time and temperature parameters as the second most out of compliance risk factor (unpublished data, 2022). This issue is compounded by the fact that it is difficult for inspectors to observe cooling due to the limited amount of time they are in facilities. A study of 420 restaurants conducted by the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net) during 2009-2010 demonstrated that many restaurants were not meeting FDA recommendations for cooling, and about one third of kitchen managers did not know cooling regulations for their jurisdiction (Brown *et. al*, 2014). Modeling conducted in the same study showed that about a third of cooling observations in restaurants had an estimated cooling rate that was slower than the Food Code requirements (Schaffner *et. al*, 2015).

2. Describe the cause of the problem

The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures. This monitoring is not always feasible for restaurant operators because of the time required to adequately monitor the cooling process (Hedeen, Schaffner, & Brown, 2022). Other factors influencing an operator's ability to monitor food temperatures include insufficient staffing, the time-of-day foods are cooled (e.g., early or late shifts), and how busy a restaurant is throughout the day (Green & Selman, 2005). Operators need to know when food reaches 135 °F so they can begin to monitor the cooling process and ensure the time and temperature parameters are met. Since cooling takes many hours and often spans multiple work shifts this further complicates monitoring. Multiple food items may also be cooling at the same time using a variety of methods. Since foods may cool at different rates, this makes it difficult for operators to verify cooling processes and monitor and track each cooling food.

Inspectors also have difficulty verifying if a food has cooled within the Food Code time and temperature parameters. Inspections are snapshots in time that generally last an hour or two whereas cooling takes place over many hours. Foods are also often cooled late into the day or overnight when inspectors are not present in the establishment. Risk factor data from the City of Minneapolis suggests that inspectors were unable to observe active cooling during 72% of retail food inspections. Other jurisdictional data suggests that this number is even higher (77% in one metro-county within Minnesota).

Inspectors may also try to assess proper cooling by discussion with the restaurant manager and by review of temperature logs, if available, to determine the cooling start time. Relying upon conversations with the operator to establish the time food began cooling is difficult because the answer provided is often an estimate, and likely a conservative estimate to avoid negative consequences. If the operator is unsure of the start time the inspector must decide what should be done with the food if it is above 41 °F at the time of inspection.

3. Explain why the current policy is not addressing the problem

Foodborne disease outbreaks resulting from improper cooling continues to occur (Lipcsei et al., 2019; Wittry et. al, 2022). The Food Code recommends that retail food establishments verify that their cooling practices are effective as well as monitor and record food temperatures during the cooling process, but research suggests that many establishments do not always engage in these practices (Brown et al., 2012; Hedeen & Smith, 2020). A study by FDA (2018) found that cooling practices did not meet FDA guidelines in at least one food item in 72% of 273 full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018). Although operators are encouraged to record cooling time and temperatures, the food code does not require them to do so, and studies have found that only about 25% of operators use a log for cooling (Brown et al., 2012; Hedeen & Smith, 2020).

Due to difficulties observing active cooling, inspectors often rely on subjective observations of FDA recommended cooling methods to determine if a food was cooled properly. The Food Code outlines methods that can promote rapid cooling of time and temperature control for safety (TCS) foods but does not specify how to apply the methods to various situations or whether some methods are more effective than others. Inspectors and operators are left to evaluate every method, or combination of methods, to determine which meet the time requirement. Additionally, many of the terms used in the FDA Food Code sections are also ambiguous, such as "shallow," "thinner,", containers that facilitate "heat transfer," and other "effective" methods." Since these terms are not defined within the code, operators and inspectors are left to interpret or guess what they mean.

The FDA Food Code designates cooling time and temperature violations as a priority violation and the use of effective cooling methods as a priority foundation violation. This message that time and temperature monitoring is the best way to determine successful cooling limits inspectors and operators due to difficulties with verification. This message also deprioritizes the focus on specific cooling methods to achieve successful cooling.

We recommend that operators and inspectors be allowed to also focus on specified cooling methods that are known to facilitate quick and proper cooling without additional time monitoring. We specifically propose that if food is uncovered, at a depth or 2-inches or less, and placed in an environment of 41 °F or less that time and temperature monitoring of that food would not be required. This alternative method can help ensure proper cooling and increase verification efficiency for inspectors and operators.

4. Present your policy recommendation and explain how it compares to possible alternatives

The current Food Code recommendations for cooling rely on time and temperature monitoring (cooling foods from 135-70°F within 2 hours and from 135-41°F within 6 hours), which is difficult to do.

We propose adding an option for meeting the requirements of 3-501.14 for cooling foods. This option requires food cooling when all three of the conditions below are true:

- food is in a shallow layer of two inches or less,
- uncovered, and
- in cooling or cold holding equipment that maintains an ambient temperature of 5°C (41°F) or less.

This proposed option provides a clear, safe roadmap for operators and will reduce resource and time demands for monitoring cooling. This option is also beneficial to inspectors and public health as it makes it easier to verify adequate cooling during an inspection. This option will help operators and inspectors identify cooling compliance more quickly and in turn, allow them to intervene when needed.

Why 2 inches?

Two inches has been found to be a depth that facilitates rapid cooling (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Portioning foods at 2 inches or less and ventilating foods during refrigerated cooling are effective and simple ways for operators to promote rapid cooling. Two-inch pans are readily available for purchase and many restaurants already have them on hand.

Why not greater than 2 in?

Research shows that food depth is a main factor in rapid cooling. Cooling foods at a depth of 2 inches or less is conservative and limits the risk of significant *C. perfringens* or *B. cereus* growth. One study found that foods stored at a depth greater than 3 inches were twice as likely to cool more slowly than specified in the Food Code (Schaffner et. al., 2015). Another study found that containers with a food depth of 3 inches or more were more likely to have cooling rates slower than the Food Code cooling rate (Igo, Hedeen, & Schaffner, 2021). Cooling of foods at depths greater than 2 inches creates variability in cooling profiles and even less viscous foods may have a hard time cooling at depths of 3-4 inches (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021).

Why not focus on other methods?

The Food Code outlines several methods that can be utilized during the cooling process to facilitate proper cooling; however, food depth has been shown to be one of the most significant variables that impact cooling rates (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Additionally, "cooling at a depth of 2 inches or less, ventilated, and refrigerated" leaves little room for interpretation whereas other methods (e.g., use of ice) are more difficult to implement. The use of ice baths or ice wands is an active process that requires monitoring and is less predictable (Hedeen & Smith, 2020; Hedeen, Schaffner, & Brown, 2022). Adding ice as an ingredient, to assist with cooling, is a limited option as it is only appropriate for soups and other liquid based foods. Although blast chillers are extremely effective, they are also very expensive and not common in most foodservice kitchens.

Why not look in the Food Code Annex for more detail on how to cool?

The current information in the FDA Food Code Annex 3 – Public Health Reasons/Administrative Guidelines provides subjective guidance to operators and inspectors but is not codified by most states. It discusses the importance of reducing the volume of food to optimize cooling rates but provides no specific details on ideal food volumes. It mentions how foods should be ventilated and that smaller batches should be used to decrease the risk of pathogen growth, but again, provides no specific details. The annex also mentions that blast chillers are ideal for rapid cooling, but these units are not an option for most operators.

Why not just define shallow cooling? Defining "shallow cooling" (which is not currently defined in the Food Code) as food portioned at 2 inches or less would be a limited revision that might improve cooling compliance but would still retain all of the disadvantages of the current code (i.e., operators must still monitor time and temperatures during the cooling process and inspectors would still need to measure temperatures and estimate cooling rate during an inspection). Providing the option of 2-inch cooling,

without time and temperature monitoring, offers operators a less complex and less time-consuming way to cool foods safely.

Describe the intended and/or unintended consequences, positive and negative, that may result from implementing the proposed policy recommendation

Positive: This language gives operators a simpler way to cool foods properly.

The current Code focuses on time and temperature monitoring to determine if food is cooling properly (i.e., within FDA guidelines). The Code offers a list of cooling methods that help facilitate rapid cooling but does not offer guidance on which methods or combination of methods are most effective. Adding the specified performance standard as an option allows for an easy and efficient way for operators and inspectors to verify adequate cooling. The proposed addition clarifies which combination of cooling methods can be used to successfully cool. Note that we are not proposing the removal of the existing time and temperature monitoring requirements, so operators can always choose this option.

Negative: 2 inches isn't a safe enough standard

Cooling studies have shown that reducing food depth to 2 inches and cooling uncovered in a properly functioning refrigeration unit facilitates proper cooling (Schaffner et. al., 2015; Hedeen & Smith, 2020; and Igo, Hedeen, & Schaffner, 2021). Research looking at the cooling curves of foods prepared in retail settings within Minneapolis, MN shows how food depth affects cooling and provides support that foods cooled at a depth of 2-inches or less present negligible risk. We have included a summary of the data in Supplemental Figure S1, which breaks down the depth of the cooling food item and whether the food item cooled within the time and temperature requirements outlined in the Food Code. If the food item did not meet Code requirements, the cooling curve was run through the ComBase perfringens Predictor and the predicted log increases are reported. The data show cooling foods at a depth of 2 inches or less, reliably prevents a 1-log increase in pathogen growth and supports the contention that cooling foods at a depth of 2 inches or less, ventilated, and refrigerated, meet acceptable levels of risk.

There are a few food items that were reportedly cooled at a depth of 2 inches or less but did not cool within the time and temperature parameters outlined in the code (i.e., reached 41 °F in more than 6 hours). These cooling curves were input into the ComBase perfringens Predictor, and the predicted log increases were less than 1, indicating limited potential for significant pathogen growth. Modeling data show that *C. perfringens* growth curves and cooling rates for food cooling may not precisely follow the 6-hour cooling parameters outlined in the Code (See Supplemental Figure S2). The modeling predictions show that while the food code cooling rate is protective of public health, cooling at a slightly slower rate represents a negligible increase in risk.

The state of Washington has provided a natural experiment on the effectiveness of this cooling method for the past 17 years after they revised the model food code to explicitly allow 2 inch cooling without time monitoring (Washington State Health Department, 2022). The state has a robust outbreak detection system and investigates all foodborne outbreaks identified. Since 2-inch cooling without time-temperature monitoring was implemented, no foodborne outbreaks have been associated with this cooling method (See Supplemental Table S1). This option is strongly preferred by operators within the state (See Letter of Support from Taco Time). Seattle-King County Health Department conducted a risk

factor study in 2016, which included 2115 restaurants, and found that 75% of operators reported using the 2-inch cooling option to cool hot foods. Only 12% of operators reported using time and temperature monitoring as outlined by the FDA food code (unpublished data, Seattle-King County Health Department).

The cooling standard in Washington shows that providing an option to cool at a depth of 2 inches or less, ventilated, and refrigerated provides a solution that is consistently safe and that restaurant operators have adopted enthusiastically.

Negative: The Food Code isn't meant to be a prescriptive document.

This proposed language is not prescriptive, rather it provides an option other than time and temperature monitoring for those who want it. In a survey of 43 Minneapolis restaurant operators, 81.4% were supportive of a standardized definition of shallow as it pertains to shallow depth cooling. Operators can choose which option works best for their establishment. This language will allow a clear option that is safe and easy to follow.

Negative: Use of 2-inch pans will require more space for cooling and for operators to purchase more pans.

Cooling in deeply filled containers comes with its own costs and burden, including costs of staff and labor for monitoring, ice wands, ice, prep sinks, blast chillers, and other materials and equipment needed to properly cool. Shallow pans cost much less than these items. Pans already come in 2- or 4-inch depths and only cost around \$15. Food only needs to be kept at a 2 inch depth during the cooling process. Once cooled it can be transferred to other containers so additional cooling space is only needed for a short period. Restaurants could also consider small-batching recipes, re-organizing their shelving systems, or using speed racks in walk-in coolers to help alleviate space constraints.

References:

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Figure S1. Analysis of Cooling Data with a Focus on Food Depth

The table below presents an analysis of the cooling data collected by the City of Minneapolis in retail restaurants. The temperature of each cold-holding unit was captured at one point in time during the cooling process and ranged from 34-40°F (average 38.1° F). The data are sorted in order of decreasing food depth. The second column indicates whether the cooling profile met the FDA Food Code or not. In those cases where the answer was "almost" or "no" we ran these data through the ComBase perfringens Predictor and the predicted log increases are shown in the third column. Where the predicted log increase was greater than one, this text has been indicated in bold. The name of the food is shown in the fourth column.

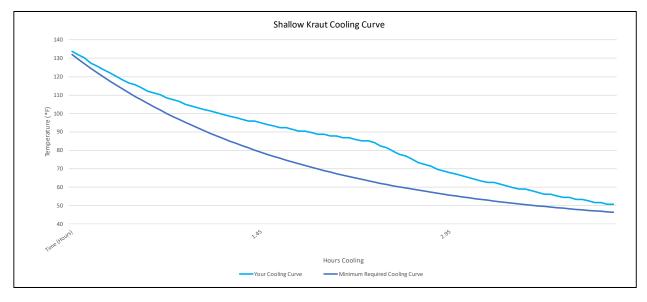
There are two instances where 2-inch cooling would appear be "risky" but are explained by mitigating circumstances. These two instances are for Sausage Gravy and Shallow Kraut. The cooling curve for Shallow Kraut is biphasic, which indicates that the ambient temperature changed during the cooling process. The cooling curve is pictured below, and we have included notes from the inspector on what may have happened. The Sausage Gravy was cooled with the ambient temperature of the cooler at 45.2° F, which would not be compliant with cooling in cold holding equipment maintaining an ambient temperature of 41°F or less. All other food items at a depth of 2 inches would result in a less than 1 log increase of *Clostridium perfringens*.

Food Depth (Inches)	Meets code	Perf predictor	Recipe
		Log Increase	
2.5	Yes	0.029	Chicken Wings
2.5	Almost*	0.241	Shallow Potatoes
2.5	No	1.332	Deep Kraut
2.5	Almost	0.559	Cheese Sauce Deep
2.5	Almost	0.271	Squash Soup Deep
2.5	Almost	0.576	Spinach in Metal Pan
2.5	No	1.094	Spinach in Plastic Pan
2.5	Yes	0.019	Tomato Sauce
2.5	Yes	0.004	Diced Chicken
2.5	No	0.942	Chili Verde
2.5	No	1.181	Refried Beans 2.5-inch pan
2.25	No	1.374	Chicken Pot Pie Mix
2.25	Yes	0.038	Chicken Breasts
2	No	1.870	Sausage Gravy
2	Almost	0.652	Garden Veggie Soup
2	Yes	0.180	Chicken Curry Walk-In 2 Inches
2	Yes	0.081	Tomato Soup 2 Inch Metal Walk-In
2	Almost	0.242	Corn Chowder Plastic No Cover 2"
2	Almost	0.479	Chorizo 2"
2	Yes	0.028	Cherry Compote
2	Yes	0.028	Black Beans
1.75	Almost	0.110	Chicken Rice
1.5	Yes	0.020	Empanadas
1.5	Yes	0.011	Ground Beef
1.5	Yes	0.018	Mushroom Sauce Bottom Pan
1.5	Yes	0.013	Mushroom Sauce Top Pan
1.5	No	1.280	Shallow Kraut*

1.5	Yes	0.138	Marinara 1.5" V1
1.5	Yes	0.202	Marinara 1.5" V2
1.5	Almost	0.123	Au Jus
1.5	Almost	0.115	Cheese Sauce Shallow
1.5	Almost	0.089	Squash Soup Shallow
1.5	Yes	0.008	Butternut Squash Soup
1.5	Yes	0.005	Mashed Potatoes
1.5	Almost	0.004	Turkey Chili
1.5	Almost	0.167	Refried Beans 1.5 Inch Pan

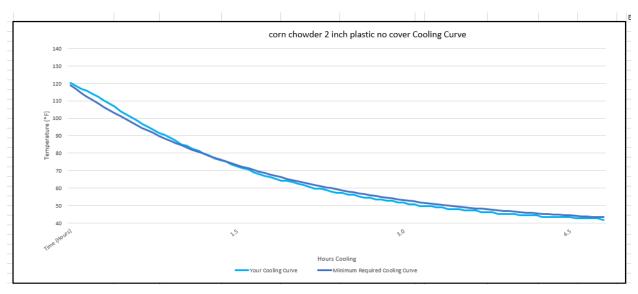
^{*} The determination of cooling curves that "almost" meet the food code is somewhat subjective but these are curves where (a) the first phase of cooling happens more rapidly than the food code allows while the second part happens more slowly, (b) where the first part of the curve matches the food code and the second part more cools more slowly, or (c) where the entire curve is just slightly slower than the food code recommendation.

Shallow Kraut Cooling Curve:



The overall shape of the curve (a spike increase in the middle of the curve) suggests that the cooling method measurements were not maintained for the duration of the cooling curve. It is likely that the operator removed the data logger mid cooling, or the food was re-panned.





This food item didn't meet the FDA minimum time and temperature parameters for adequate cooling, and was labeled "almost" on the table above. You can see how close the curve is to the minimum required cooling curve. When this curve was run through the ComBase perfringens Predictor, there was only a 0.22 log increase.

Figure S2. Summary of Cooling Rates in relation to Food Code Requirements

The temperature change of cooling foods is not linear. Hot foods cool faster at first then more slowly as the temperature difference with the environment (and thus the driving force) is less.

The FDA Food Code recommends that hot foods be cooled 135 °F to 70 °F within two hours and then from 70 °F to 41 °F within another four hours, for a total cooling time of six hours.

According to Newtons law of cooling, the rate of cooling of an object can be described by a linear relationship if the logarithm of the difference between the object and the environment is plotted versus cooling time.

If we use the time and temperature parameters from the FDA Food Code and assume and an environmental temperature of 37°F this gives the highest R² value for cooling rate. The slope of this log linear plot is -0.23.

We also have validated computer models for predicting the growth rate of the two most likely spore forming pathogens found in cooling foods (*C. perfringens* and *B. cereus*). Those models are Perfringens Predictor https://browser.combase.cc/Perfringens Predictor.aspx and Juneja, et al 2019 (Predictive model for growth of *Bacillus cereus* during cooling of cooked rice). The predictions below use pH 7, 0.5% salt for Perfringens Predictor, and assume cooked rice for *B. cereus*.

The predicted log increases assuming a food code cooling rate are 0.33 for *C. perfringens* and 0.10 for *B. cereus* and are shown in the table below. It is commonly accepted that a less than one logarithm increase for either of these pathogens constitutes a tolerable risk given the typical levels found in food and the levels needed to cause illness for these pathogens.

Linearized rate	C. perfringens	B. cereus
	log CFU ind	crease
-0.30	0.15	
-0.23	0.35	0.10
-0.20	0.56	0.16
-0.15	1.27	0.37
-0.10		1.13

This shows that the food code cooling rate is protective of public health, and that slightly slower cooling rates might also represent a negligible risk. For example, if we assume a log linear cooling rate of 0.20, this also results in less than a one logarithm increase for either pathogen.

If we convert this cooling rate back to an arithmetic scale this represents a food that is cooled according to this profile:

time (hr)		temp °F
	0	135.0
	1	98.8
	2	76.0
	4	52.5

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6	43.2
12	37.4

As shown in the first table, a cooling rate of 0.15 would result in an unacceptable (1.26 log) increase in the concentration of *C. perfringens*.

If we convert this cooling rate back to an arithmetic scale this represents of food that is cooled according to this profile:

time (hr)	te	emp °F
	0	135.0
	1	106.4
	2	86.1
	4	61.6
	6	49.3
	12	38.6

The slowest cooling rate which results in an acceptable (e.g., approximately 0.99 log) increase in the concentration of *C. perfringens* is 0.165, which corresponds to a food cooled according to this profile:

time (hr)		temp °F
	0	135.0
	1	104.0
	2	82.8
	4	58.4
	6	47.0
	12	38.0

Thus, if the "2 inch food depth uncovered" protocol results in cooling slower than what is specified in the FDA Food Code this does not necessarily result in a risk to public health.

Table S1. Summary of Washington State Outbreak Data

When Washington state adopted the FDA Food Code in 2005, it added language allowing for 2 inch cooling as an alternative to time and temperature monitoring. From 2010-2021 there were 408 foodborne disease outbreaks of all types reported in Washington State.

Some of these outbreaks, 42 of 408 (10.2%) were listed as *Clostridium perfringens*, *Bacillus cereus*, or other bacterial toxin, and thus could have been caused by cooling deficiencies.

- 4/42 Laboratory confirmed outbreak
 - o All C. perfringens
- 38/42 Suspected outbreak
 - o 8/38 B. cereus
 - o 19/38 C. perfringens
 - 11/38 Bacterial toxin

Cooling method utilized in outbreaks from 2010 - 2021

Grouping	Category	*Deep Pan Cooling	2 Inch Cooling, Uncovered	Room Temperature Storage	Deep Pan & Room Temperature Storage	Unknown Methods	Total
By agent status	Confirmed	1	0	1	1	1	4
	Suspected	21	0	5	7	5	38
	Total	22	0	6	8	6	42
By agent type	B. cereus	4	0	1	1	2	8
	C. perfringens	13	0	3	5	2	23
	Bacterial toxin	5	0	2	2	2	11
	Total	22	0	6	8	6	42

^{*}Deep Pan cooling is cooling foods at a depth of greater than 2 inches.

In summary, 30/42 (71%) of the above outbreaks had Deep Pan Cooling listed as the primary Contributing Factor. Fewer 6/42 (14%) listed Room Temperature Storage as the Primary Contributing Factor. The same number 6/42 (14%) listed either Hot-holding or Cold-holding as the Primary Contributing Factor and the cooling method was not identified/evaluated. **None of 42 outbreaks was linked to use of 2 inch cooling.**

Restaurant Food Cooling Practices[†]

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ABSTRACT

Improper food cooling practices are a significant cause of foodborne illness, yet little is known about restaurant food cooling practices. This study was conducted to examine food cooling practices in restaurants. Specifically, the study assesses the frequency with which restaurants meet U.S. Food and Drug Administration (FDA) recommendations aimed at reducing pathogen proliferation during food cooling. Members of the Centers for Disease Control and Prevention's Environmental Health Specialists Network collected data on food cooling practices in 420 restaurants. The data collected indicate that many restaurants are not meeting FDA recommendations concerning cooling. Although most restaurant kitchen managers report that they have formal cooling processes (86%) and provide training to food workers on proper cooling (91%), many managers said that they do not have tested and verified cooling processes (39%), do not monitor time or temperature during cooling processes (41%), or do not calibrate thermometers used for monitoring temperatures (15%). Indeed, 86% of managers reported cooling processes that did not incorporate all FDA-recommended components. Additionally, restaurants do not always follow recommendations concerning specific cooling methods, such as refrigerating cooling food at shallow depths, ventilating cooling food, providing open-air space around the tops and sides of cooling food containers, and refraining from stacking cooling food containers on top of each other. Data from this study could be used by food safety programs and the restaurant industry to target training and intervention efforts concerning cooling practices. These efforts should focus on the most frequent poor cooling practices, as identified by this study.

Improper cooling of hot food by restaurants is a significant cause of foodborne illness. In the United States between 1998 and 2008, improper cooling practices contributed to 504 outbreaks associated with restaurants or delis (1). These findings suggest that improvement of restaurant cooling practices is needed. The U.S. Food and Drug Administration (FDA) Food Code, which provides the basis for state and local food codes that regulate retail food service in the United States, contains guidelines for food service establishments, aimed at reducing pathogen proliferation during food cooling (4). Specifically, the Food Code states that cooked potentially hazardous food (foods that require time-temperature control to keep them safe for consumption) should be cooled "rapidly," i.e., from 135 to

The Food Code also states that procedures in the food preparation process that are critical to food safety (critical control points), such as cooling, should be tested and verified and then monitored to ensure that they work properly (5). Testing and verification occurs during initial development of the cooling process; it involves measuring time and food temperatures throughout the process to ensure that the process cools effectively. Monitoring involves measuring time and temperature during the cooling process on a routine basis—again to ensure that the process continues to cool effectively. The Food Code also recommends that thermometers used to measure food temperatures be calibrated as necessary to ensure their accuracy. Finally, the Food Code recommends that temperature data obtained from monitoring critical control points be recorded so that managers can verify that cooling processes are cooling effectively.

 $^{70^{\}circ}F$ (57.2 to 21.1°C) in 2 h or less, and from 70 to 41°F (21.1 to 5°C) in 4 additional h or less. Thus, according to the FDA, proper cooling is cooling that minimizes the amount of time that food is in the temperature "danger zone" of 41 to $135^{\circ}F$ (5 to $57.2^{\circ}C$), the temperature range in which foodborne illness pathogens grow quickly.

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Further, the Food Code recommends the use of one or more of the following methods to facilitate cooling: (i) placing food in shallow pans and refrigerating it at the maximum cold holding temperature of 41°F [5°C]; (ii) separating food into smaller or thinner portions and refrigerating it at the maximum cold holding temperature of 41°F [5°C]; (iii) stirring the food in a container placed in an ice water bath; (iv) using rapid cooling equipment, such as ice wands (containers filled with ice and placed inside food) and blast chillers (a type of rapid cooling equipment); (v) adding ice as an ingredient to the food; and (vi) using containers that facilitate heat transfer. The Food Code also states that cooling food should be arranged to provide conditions for maximum heat transfer through food container walls (e.g., by not placing containers of cooling food close to each other) and be ventilated (e.g., uncovered, if protected from overhead contamination, or loosely covered) during the cooling period to facilitate heat transfer from the surface of the food. The Food Code also recommends that the person in charge of the food service establishment (e.g., manager) ensure that food is being properly cooled through routine monitoring of food temperatures during cooling.

In one of the few existing studies containing information on restaurant food cooling, the FDA found that improper cooling was a frequent foodborne illness risk factor observed in full-service restaurants. In 79% of observations, food was not cooled to the proper temperatures quickly enough to meet FDA recommendations (6). Although this study provides valuable information on the prevalence of restaurants' failure to meet cooling time and temperature guidelines, it does not provide any data on restaurants' cooling practices, such as whether cooling processes are tested and verified. It also does not provide any data on the methods restaurants use in their attempts to cool food (e.g., shallow pans). Knowledge about these issues is essential to the development of effective cooling interventions. For this reason, the purpose of this study was to collect data on these topics. This study focuses on describing restaurants' food cooling practices and on the methods restaurants use to cool food (e.g., refrigeration, ice baths). Where appropriate, the study assesses the frequency with which restaurants meet FDA recommendations concerning cooling practices.

MATERIALS AND METHODS

This study was conducted by the Environmental Health Specialists Network (EHS-Net), a network of environmental health specialists and epidemiologists focused on the investigation of factors contributing to foodborne illness. EHS-Net is a collaborative project of the Centers for Disease Control and Prevention, the FDA, the U.S. Department of Agriculture (USDA), and state and local health departments. At the time this study was conducted, the EHS-Net sites were in California, Connecticut, New York, Georgia, Iowa, Minnesota, Oregon, Rhode Island, and Tennessee.

Data were collected from July 2009 through March 2010. The study protocol was cleared by the CDC Institutional Review Board and the appropriate institutional review boards in the participating sites. All data collectors (EHS-Net environmental health special-

ists) participated in training designed to increase data collection consistency.

Data collectors collected data in approximately 50 restaurants in each EHS-Net site. "Restaurants" were defined as establishments that prepare and serve food or beverages to customers but that are not institutions, food carts, mobile food units, temporary food stands, supermarkets, restaurants in supermarkets, or caterers. Data collectors contacted randomly selected restaurants in predefined geographical areas in each site via telephone to request their participation in the study and arrange for an on-site interview with a "kitchen manager" (defined as a manager with authority over the kitchen) and an observation of cooling practices. Data collectors attempted to schedule restaurant visits to coincide with the beginning of the restaurants' cooling processes, although this was not always possible. Only one restaurant from any given regional or national chain was included per EHS-Net site. For example, if chain A had three restaurants in an EHS-Net site, only one of those restaurants would be eligible to participate in the study in that site. Only English-speaking managers were interviewed. Data collection was anonymous; that is, no data were collected that could identify individual restaurants or managers.

Restaurant visits lasted an average of 80 min. Data collectors interviewed the manager about restaurant characteristics (e.g., chain versus independent ownership, number of meals served daily), food handling and cooling policies and practices (e.g., whether thermometers were used to check temperatures, whether temperatures of cooling food were monitored), and local regulations concerning cooling.

When possible, data collectors also recorded observation data on cooling practices occurring during their visit. For each food being cooled during the observation, data collectors recorded data on the type of food being cooled, the number of cooling steps involved in the cooling of the food, and the method used in each step to cool the food (refrigerating food at or below 41°F [5°C], ice bath, ice wand, blast chiller, ice or frozen food as an ingredient, room temperature cooling). For example, if a cooling food was first observed in an ice bath and was moved to a refrigerator later in the observation, the data collector would record an ice bath step and a refrigeration step. Additional observation data were collected on the methods of refrigeration, ice bath, and ice wand (Table 1).

In some restaurants, multiple food items were being cooled, and as described above, the cooling process for some of these food items involved multiple cooling steps. We collected data on each food item being cooled and each cooling step involved in the cooling process of each food item. Thus, the denominators for the observation data vary, and are described in the "Results" section.

Data collectors also recorded whether workers monitored the temperatures of the cooling foods during the observation period and took temperatures of cooling food at the beginning and at the end of the observation period. These temperature data are not discussed here.

RESULTS

Restaurant demographics. Four hundred twenty restaurant managers agreed to participate in the study. The restaurant participation rate was 68.4% (this rate is based on data from eight of the EHS-Net sites; participation rate data were unavailable for one site). According to interviewed managers, most restaurants were independently owned and served an American menu (see Table 2). The median number of meals served daily in these restaurants was 150 (25th percentile = 80, 75th percentile = 300, minimum = 7, maximum = 7,700).

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TABLE 1. Description of additional observation data collected on the cooling methods of refrigeration, ice bath, and ice wand

Refrigeration

Type of cooling unit (walk-in coolers, reach-in coolers, freezers) Ambient temperature of cooling unit

Whether food depth was shallow (no more than 3 in. [7.6 cm] deep) Whether the food was ventilated (uncovered or loosely covered) Whether the containers of cooling food were arranged to allow maximum heat transfer through container walls (containers not stacked on top of one another; at least 3 in. [7.6 cm] of open-air space provided around the top and sides of the containers)

Ice bath

Whether ice was present in the ice bath

Whether ice and water were filled to level of the cooling food Whether food was stirred

Ice wand

Whether ice wand was inserted into the food Whether ice and/or liquid was present in the ice wand Whether food was stirred

Manager interview data on general food safety practices. According to interviewed managers, over 90% of restaurants provided food safety training to managers and workers, and over 75% employed at least one food safety certified manager (Table 3). Over 95% of managers said that they used thermometers to check the temperature of food being prepared in their restaurant. Thermometers used included bimetallic probe thermometers, digital-thermocouple probe thermometers, and infrared-laser thermometers. Over 80% of managers said that someone was trained to calibrate (i.e., check the accuracy of) these thermometers. Of those who said they used thermometers to check food temperatures, about 40% said that they calibrated thermometers at least once a week; others said that they calibrated at least once a day, at least once a month, less than once a month, never, or they were unsure how often thermometers were calibrated.

Twenty percent (20.2% [85]) of managers said the cooling time and temperature regulation in their jurisdiction was the same as the FDA's—135 to 70° F (57.2 to 21.1° C) in 2 h or less and then 70 to 41°F (21.1 to 5°C) in 4 additional h or less. Ten percent (9.5% [40]) said they had a two-stage regulation like the FDA's, but the temperatures differed (140°F [60°C] rather than 135°F [57.2°C]). Two percent (1.7% [7]) said their regulation had the same temperatures as the FDA's but required a single-stage process (135 to 41°F [57.2 to 5°C] in 4 h or less). Ten percent (9.7% [41]) said their regulation had a single-stage process with temperatures that differed from the FDA's (140 to 41°F [60 to 5°C] in 4 h or less: 8.3%; 140 to 45°F [60 to 7.2°C] in 4 h or less: 1.4%). Twenty-three percent (22.6%) [95]) said they had some other regulation, and 36.2% (152) did not know their jurisdiction's cooling regulation.

Manager interview data on cooling practices. Over 90% of managers said that food safety training for managers and workers covered proper cooling (Table 4). Over 85%

TABLE 2. Data on restaurant demographics obtained from interviews with 420 kitchen managers

Demographic	n	%
Restaurant ownership		
Independent	290	69.0
Chain	130	31.0
Menu description		
American	252	60.0
Italian	47	11.2
Mexican	34	8.1
Chinese	21	5.0
Other	66	15.7

said that their restaurant had formal processes (methods of cooling that have been established by the restaurant as a standard practice) for cooling potentially hazardous foods. In these restaurants with formal cooling processes, a third of managers said that the processes were written, and 89% said that food workers had been trained on them. Of managers in restaurants with formal cooling processes, over 60% said their processes had been tested and verified.

Sixty percent of all managers said that food cooling times or temperatures were monitored during routine cooling of foods. Of those managers who said that food cooling times or temperatures were monitored in their restaurants, most said that cooling foods were "always" or "often" monitored. Most managers who said that they monitored food cooling times or temperatures said that they used thermometers to do so. Others reported using time to monitor cooling, both thermometers and time to monitor cooling, the look or feel of the food, or some other method to monitor cooling. Of those who said they used thermometers to monitor cooling, about 50% said that they calibrated thermometers at least once a week; others said that they calibrated at least once a day, at least once a month, less than once a month, never, or they were unsure how often thermometers were calibrated. A quarter of managers said that monitored time or temperature measures were recorded.

Fifty-three percent (52.6% [221]) of managers said that they had formal cooling processes and that they were verified; 46.2% (194) of managers said that they had formal cooling processes, that these processes were verified, and that time or temperature was monitored during these processes; 42.9% (180) said that they had formal cooling processes, that these processes were verified, that time or temperature was monitored during these processes, and that they calibrated thermometers used for monitoring. Not quite 15% (14.5% [61]) of managers said that they had formal cooling processes, that these processes were verified, that time or temperature was monitored during these processes, that thermometers used for monitoring were calibrated, and that measurements from time or temperature monitoring were recorded. Thus, 85.5% (359) of managers reported cooling processes that did not incorporate all FDArecommended components.

Observation data on cooling practices. Data collectors observed 596 food items being cooled during their visit

TABLE 3. Data on restaurant general food safety practices obtained from interviews with 420 kitchen managers^a

Demographic	n	%
Kitchen managers receive food safety traini	ng	-
Yes	401	95.5
No	19	4.5
Food workers receive food safety training		
Yes	390	92.9
No	25	6.0
Unsure	5	1.1
Restaurant has at least one certified kitchen	manager	
Yes	321	76.4
No	97	23.1
Unsure	2	0.5
Thermometer is used to check food tempera	atures	
Yes	400	95.3
No	19	4.5
Unsure	1	0.2
Type of instrument used to check food temp	peratures ($N = 400)^b$
Bimetallic probe thermometer	298	74.5
Digital/thermocouple probe thermometer	184	46.0
Infrared/laser thermometer	16	4.0
Someone is trained to calibrate thermometer	rs(N = 4)	00)
Yes	331	82.7
No	61	15.3
Unsure	8	2.0
Frequency with which thermometer is calib	rated (N =	= 400)
At least once a day	57	14.3
At least once a week	152	38.0
At least once a month	76	19.0
Less than once a month	17	4.3
Never	58	14.5
Other	9	2.2
Unsure	31	7.7

 $^{^{}a}$ N values vary throughout the table because of skip patterns in the interview; N = 420 unless otherwise noted.

in 410 restaurants (10 of the 420 restaurants in the study were not actively cooling foods at the time of the visits). Seventy-one percent (291 of 410) of these restaurants were cooling one food item during the visit, but others were cooling several food items during the visit (the number of food items observed in each restaurant ranged from 1 to 6). Of the 596 food items observed being cooled, soups, stews, and chilis were the most common food items (29.9% [178]), followed by poultry and meat (25.2% [150]), sauces and gravies (15.4% [92]), cooked vegetables (6.7% [40]), rice (5.7% [34]), beans (5.2% [31]), pasta (3.9% [23]), casseroles (3.2% [19]), seafood (1.2% [7]), pudding (1.0% [6]), and other foods (2.7% [16]).

Workers were observed monitoring cooling food time or temperatures by using one or more methods (e.g., time, temperature) in 39.4% (235 of 592; data were missing for

four observations) of cooling observations. Probe thermometers were most frequently used for this purpose (82.5% [194]), followed by time estimates (e.g., noting cooling time on a clock, approximating cooling time) (23.8% [56]), touching the cooling food or container (6.8% [16]), and "other" methods (3.8% [9]).

Data collectors collected data on 997 discrete cooling steps (the number of cooling steps observed for each food item ranged from 1 to 4). Among these 997 cooling steps, the most common cooling method was refrigeration—46.6% (466) of cooling steps involved refrigeration. Other cooling methods included ice bath (19.4% [195]), ice wand (7.7% [77]), ice or frozen food as an ingredient in the cooling food (2.7% [27]), blast chiller (0.5% [5]), room temperature cooling (16.8% [169]), and "other" types of cooling (6.3% [63]).

Table 5 presents data on the cooling unit types and temperatures observed in the 466 refrigeration step observations. Walk-in coolers were the most commonly used cooling unit for refrigeration, followed by reach-in coolers and freezers. Sixteen percent of cooling unit temperatures were above 41°F (5°C), the FDA-recommended maximum food cold-holding temperature. About 10% of walk-in coolers, a third of reach-in coolers, and less than 1% of freezers were above the FDA-recommended maximum temperature of 41°F (5°C).

In 39.3% (183 of 466) of these refrigeration observations, the food depth was not shallow; in 34.3% (160) of the observations, the cooling food was not ventilated; in 13.7% (64) of the observations, containers of cooling food were stacked on top of each other; and in 23.8% (111) of observations, open-air space was not provided around the top and sides of the food cooling containers (see Fig. 1).

In 1.0% (2) of the 195 ice bath observations, ice was not present in the ice bath; in 32.8% (64) of the observations, ice and water were not filled to the level of the cooling food; and in 28.7% (56) of observations, the food was not stirred during the observation period.

In 100.0% of the 77 ice wand observations, the wands were inserted into the food. In 2.6% (2) of these observations, ice was not present in the ice wand; in 2.6% (2) of observations, no liquid was in the ice wand; and in 13.0% (10) of observations, the food was not stirred during the observation period.

DISCUSSION

This study identifies multiple shortcomings in restaurant cooling practices. The data collected indicate that many restaurants' cooling practices do not meet FDA recommendations aimed at reducing pathogen proliferation during food cooling.

It is encouraging that most managers reported that they had formal cooling processes and that they provided training to food workers on these processes. Additionally, over 90% of managers in restaurants that monitored cooling said that they calibrated the thermometers used for monitoring. However, many managers reported the absence of several FDA-recommended cooling components. For example,

^b Participants were able to provide multiple responses to the question; thus, the numbers add to more than the *N*, and percentages add to more than 100%.

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TABLE 4. Data on restaurant cooling practices obtained from interviews with 420 kitchen managers^a

Cooling practice	n	%
Kitchen manager food safety train $(N = 401)^a$	ning covered pro	oper cooling
Yes	390	97.3
No	7	1.7
Unsure	4	1.0
Food worker food safety training c	overed proper co	pooling ($N = 390$
Yes	356	91.3
No	27	6.9
Unsure	7	1.8
Restaurant has formal cooling pro	ocesses $(N = 4)$	20)
Yes	362	86.2
No	57	13.6
Unsure	1	0.2
Cooling processes are written (N	= 362)	
Yes	123	34.0
No	231	63.8
Unsure	8	2.2
Food workers have been trained	on cooling proc	esses $(N = 362)$
Yes	323	89.2
No	36	10.0
Unsure	3	0.8
Cooling processes have been test	ed and verified	(N = 362)
Yes	221	61.0
No	126	34.8
Unsure	15	4.2
Time or temperature is monitored de	uring cooling pro	cesses ($N = 420$
Yes	250	59.5
No	168	40.0
Unsure	2	0.5
Frequency with which cooling pro		itored ($N = 250$
Always	113	45.2
Often	92	36.8
Sometimes	39	15.6
Rarely Unsure	5 1	2.0 0.4
	_	0.4
Cooling process monitoring meth		
Probe thermometer	225	90.0
Data logging thermometer Time	2 62	0.8 24.8
Thermometer and time	49	19.6
Sight	3	1.2
Touch	11	4.4
Other	16	6.4
Unsure	2	0.8
Frequency with which thermomet calibrated $(N = 226)$	ters used to mor	nitor are
At least once a day	38	16.8
At least once a week	111	49.1
At least once a month	40	17.7
Less than once a month	6	2.7
Never	13	5.7
Other	6	2.6
Unsure	12	5.4

TABLE 4. Continued

Cooling practice	n	%
Cooling time or temperature mea	sures are record	ed $(N = 250)$
Yes	66	26.4
No	183	73.2
Unsure	1	0.4

^a N values vary throughout the table because of skip patterns in the interview.

about half of managers said that they did not have tested and verified cooling processes, and 41% did not monitor time or temperature during cooling processes. Eighty percent of those who monitored cooling processes did not monitor both time and temperature, as recommended by FDA, and 6% of those who monitored cooling food temperatures with a thermometer never calibrated their thermometers. Finally, less than a third of restaurant managers said that they recorded temperature data obtained from monitoring. Lack of testing and verification means that the adequacy of the cooling process was not determined prior to implementation; this absence could result in ineffective cooling. Similarly, lack of monitoring of both time and temperature means that the effectiveness of the cooling process is not assessed on a regular basis. Lack of thermometer calibration can lead to inaccurate temperature readings, and consequently, to inadequate cooling. Lack of recording prevents managers from reviewing the data to verify that their cooling processes are working properly. These deficiencies can cause cooling foods to remain in the temperature danger zone for too long, allowing potentially unsafe pathogen proliferation.

All together, most managers described cooling processes that did not incorporate all FDA-recommended components—testing and verification, time and temperature monitoring, thermometer calibration, and time and temperature measurement recording. These data indicate that most restaurants have cooling deficiencies that should be addressed.

Over a third of interviewed managers did not know their jurisdiction's cooling regulation. If managers do not know the cooling regulations, it seems unlikely that these regulations will be followed. Clearly, more education is needed concerning cooling regulations and practices.

Refrigeration was the most common cooling method used by restaurants. However, 16% of the units used for cooling were observed operating above the FDA-recommended maximum temperature for cold holding of foods. These data are concerning, because food cooling rates decline exponentially as ambient cooling temperatures approach 41°F (5°C) and higher. Additionally, FDA recommendations for facilitating rapid cooling during refrigeration were not always followed. Most frequently, restaurants did not refrigerate food at shallow depths. They also did not always ventilate cooling food, provide open-air space around the tops and sides of food cooling containers,

^b Participants were able to provide multiple responses to the question; thus, the numbers add to more than the N, and percentages add to more than 100%.

1 73

29

466

	T	· , · · · · · · · · · · · · · · · · · · ·		8		
Cooling unit	Median	25th percentile	75th percentile	n	$% > 41^{\circ} F (5^{\circ} C)$	$n > 41^{\circ} \text{F (°C)}$
Walk-in coolers	39.0	36.0	40.0	344	11.6	40
Reach-in coolers	40.0	37.0	44.0	93	34.4	32

TABLE 5. Ambient temperatures taken from the cooling units used in 466 refrigeration steps observed in 410 restaurants

All 39.0 36.0 40.0

and refrain from stacking cooling food containers on top of each other. These practices facilitate rapid cooling; however, depending on the amount of food being cooled, be us

need for more refrigerator space could, at least in part, account for the prevalence of these poor cooling practices. Indeed, qualitative data suggest that food workers view the lack of adequate space as a barrier to proper cooling (3).

The ice bath was the next most frequent cooling method. Again, practices that would best facilitate rapid cooling by use of this method, such as ensuring that the ice and water were filled to the outside top of the food

they could also require considerable refrigerator space. A

method. Again, practices that would best facilitate rapid cooling by use of this method, such as ensuring that the ice and water were filled to the outside top of the food containers and that the food was stirred regularly during the cooling process, were not always followed. These activities are relatively easy to do; it could be that food workers are unaware of their importance to proper cooling.

Although ice wands were used infrequently, they were used correctly for the most part—they were filled with ice and inserted into the cooling food. However, as with the use of ice baths, the cooling foods were not always stirred during the cooling process. The cooling methods of ice as an ingredient and blast chillers were also rarely used. Ice as an ingredient is likely used infrequently because it could affect the quality, taste of the food. Blast chillers, although effective, are expensive, and their cost likely explains the infrequency of their use.

In about a fifth of cooling steps observed, cooling food was kept at room temperature. Because room temperature storage is not a method that facilitates rapid cooling, this practice is not recommended for cooling foods that are in the temperature danger zone. However, this practice might be acceptable for foods that are not in the temperature danger zone. For example, it would be acceptable to cool a hot food at room temperature until the food cooled to 135°F

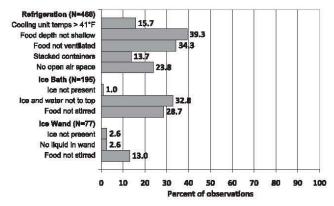


FIGURE 1. Frequencies of improper food cooling practices observed in refrigeration, ice bath, and ice wand steps in 410 restaurants.

(57.2°C; the high point of the temperature danger zone). At that point, however, a rapid cooling method would need to be used. Food temperature monitoring is a particularly important part of any cooling process in which room temperature is used, because it is critical to identify when the food reaches the danger zone so that a rapid cooling method can be implemented.

0.5

15.7

This study had several limitations. First, this study included only English-speaking managers and workers. Second, the study collected self-report data (managers reported on their workers' and their own practices and policies); these data are susceptible to a bias to over-report socially desirable behaviors, such as cooling food properly. Lastly, the study also collected observation data; these data are susceptible to reactivity bias, in that food workers might have reacted to being observed by changing their cooling practices. These last two biases could have led to an underestimation of the prevalence of improper cooling practices.

Our data suggest that many restaurant managers do not understand how to cool food properly. Data from this study can be used by food safety programs and the restaurant industry to target training and intervention efforts to improve cooling knowledge, policies, and practices. An important focus of these efforts would be to emphasize the need for testing, verification, and monitoring to ensure that the cooling process works properly. These fundamental components of a food safety management system control foodborne illness risk factors (5).

Training and intervention efforts should also focus on the most frequent poor cooling practices identified in this study—inadequate cooling unit temperatures, inadequate facilitation of rapid cooling during refrigeration, and inadequate ice baths. Efforts should focus not only on how to cool foods properly but also on why it is important to cool foods properly. Research has indicated that this "why" aspect is an important component of effective training (2, 3). Thus, a focus on the temperature danger zone and how cooling time and temperature requirements are designed to reduce the amount of time that food remains in this zone would be appropriate. Efforts to improve cooling practices should also focus on identifying barriers and facilitators to proper cooling practices and addressing them. For example, if restaurants are implementing refrigeration cooling methods improperly because they do not have the space to do otherwise, food safety programs could work with them to identify alternative methods of cooling.

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Quantitative Data Analysis To Determine Best Food Cooling Practices in U.S. Restaurants[†]

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ABSTRACT

Data collected by the Centers for Disease Control and Prevention (CDC) show that improper cooling practices contributed to more than 500 foodborne illness outbreaks associated with restaurants or delis in the United States between 1998 and 2008. CDC's Environmental Health Specialists Network (EHS-Net) personnel collected data in approximately 50 randomly selected restaurants in nine EHS-Net sites in 2009 to 2010 and measured the temperatures of cooling food at the beginning and the end of the observation period. Those beginning and ending points were used to estimate cooling rates. The most common cooling method was refrigeration, used in 48% of cooling steps. Other cooling methods included ice baths (19%), room-temperature cooling (17%), ice-wand cooling (7%), and adding ice or frozen food to the cooling food as an ingredient (2%). Sixty-five percent of cooling observations had an estimated cooling rate that was compliant with the 2009 Food and Drug Administration Food Code guideline (cooling to 41°F [5°C] in 6 h). Large cuts of meat and stews had the slowest overall estimated cooling rate, approximately equal to that specified in the Food Code guideline. Pasta and noodles were the fastest cooling foods, with a cooling time of just over 2 h. Foods not being actively monitored by food workers were more than twice as likely to cool more slowly than recommended in the Food Code guideline. Food stored at a depth greater than 7.6 cm (3 in.) was twice as likely to cool more slowly than specified in the Food Code guideline. Unventilated cooling foods were almost twice as likely to cool more slowly than specified in the Food Code guideline. Our data suggest that several best cooling practices can contribute to a proper cooling process. Inspectors unable to assess the full cooling process should consider assessing specific cooling practices as an alternative. Future research could validate our estimation method and study the effect of specific practices on the full cooling process.

Improper cooling of hot foods by restaurants is a significant cause of foodborne illness in the United States. Data collected by the Centers for Disease Control and Prevention (CDC) show that improper cooling practices contributed to 504 foodborne illness outbreaks associated with restaurants or delis between 1998 and 2008 (1).

Clostridium perfringens is the pathogen most frequently associated with foodborne illness outbreaks caused by improper cooling of foods. Between 1998 and 2002, 50 (almost 50%) of 102 outbreaks with known etiologies associated with improper cooling were caused by *C. perfringens* (7). *C. perfringens* spores can germinate during cooking, and the resulting cells grow quickly, especially

when foods are cooled too slowly. Bacillus cereus spores can also survive the cooking process and may pose a risk during improper cooling (7). The U.S. Food and Drug Administration (FDA) Food Code provides the basis for state and local codes that regulate retail food service in the United States and contains cooling guidelines for food service establishments. To combat foodborne illness outbreaks associated with improper cooling, the 2009 FDA Food Code (section 3-501.14) states that cooked foods requiring timetemperature control should be cooled "rapidly" (specifically from 135 to 70° F [57 to 21° C]) within ≤ 2 h, and cooled further from 70 to 41° F (21 to 5° C) within an additional ≤ 4 h (14). The U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) has similar cooling requirements for commercially processed cooked meats. These requirements state that the maximum internal temperature of cooked meat should be allowed to remain between 130 and 80° F (54.4 and 26.7°C) for no longer than 1.5 h and then between 80 and $40^{\circ}F$ (26.7 and $4.4^{\circ}C$) for no longer than an additional 5 h (12).

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The Food Code also recommends specific methods to facilitate cooling. Some of these methods include placing food in shallow pans, refrigerating at the maximum cold-holding temperature of $41^{\circ}F$ (5°C), and ventilating (i.e., keeping food uncovered or loosely covered) to facilitate heat transfer from the surface of the food. The Food Code also recommends that the person in charge of the food service establishment (e.g., manager) ensure that workers routinely monitor food temperature during cooling (13).

Little is known about how restaurants cool food, and yet knowledge about these issues is essential to developing effective cooling interventions. Thus, during 2009 to 2010, the CDC's Environmental Health Specialists Network (EHS-Net), a group of environmental health specialists and epidemiologists focused on investigating environmental factors that contribute to foodborne illness, conducted a study designed to describe restaurants' food cooling practices and to assess the effectiveness of these practices.

This work is the second arising from this cooling study. In the first article, we presented descriptive data on restaurant cooling practices (1). In this second article, we present additional quantitative analysis to determine practices that best ensure a proper cooling process. Specifically, we examine how food type, active food temperature monitoring, food pan depth, and food ventilation are related to estimated food cooling rates.

MATERIALS AND METHODS

EHS-Net, a collaborative program of the CDC, FDA, USDA, and state and local health departments, conducted this study in collaboration with Rutgers University. At the time this study was conducted, nine state and local health departments were funded by the CDC to participate in EHS-Net. These state and local health departments, or EHS-Net sites, were in California, Connecticut, New York, Georgia, Iowa, Minnesota, Oregon, Rhode Island, and Tennessee.

Personnel in each of the nine EHS-Net sites collected the data for this study. These data collectors visited approximately 50 randomly selected restaurants in each of the nine EHS-Net sites. Restaurant visits lasted an average of 80 min. Information on data-collection training, Institutional Review Board status, and sample selection for this study is available in a previous publication based on this study (1). In brief, standardized data collection forms, developed by the CDC and EHS-Net site staff, were used. Forms were piloted by EHS-Net data collectors, and revisions were made based on the pilot results. Data collectors also participated in training designed to increase data collection consistency. This training included a written restaurant cooling scenario that data collectors reviewed as a group to ensure consistent interpretation and coding. These personnel were environmental health specialists, experienced and knowledgeable in food safety.

In each restaurant participating in the study, data collectors interviewed a kitchen manager about restaurant characteristics and cooling policies and practices. If food was being cooled during their visit to the restaurant, data collectors also recorded observational data on cooling practices. Data collectors recorded data on the types of food being cooled, the number of steps involved in the cooling process, and the method used in each cooling step to cool the food (refrigeration [keeping food at or below 41°F (5°C)], ice bath, ice wand, blast chiller, adding ice or frozen food as an ingredient, room-temperature cooling). Data

collectors recorded additional observational data on the details of the refrigeration methods, such as whether the food depth was shallow (defined for this study as \leq 7.6 cm [3 in.] deep), whether the food was ventilated (i.e., uncovered or loosely covered), and what the cooling environment temperature was.

Data collectors also recorded whether workers monitored the time or temperature of the cooling foods during the observation period. Worker monitoring actions included taking the temperature of the food with a probe or data-logging thermometer, using a timer or alarm to measure cooling time, or noting food cooling time with a clock.

Data collectors also measured the temperatures of cooling foods at the beginning and end of the observation period by inserting calibrated thermometers into the centermost point of the foods. Those beginning- and ending-point temperatures were taken in similar places in the food and were used to estimate cooling rates according to the procedure outlined in the following text. All data collectors used digital probe thermometers to measure temperatures, and they calibrated their thermometers regularly. Additionally, the method of taking each temperature was specified in the data collection protocol. For example, data collectors were instructed to take the temperature of cooling food at the centermost area of the food. Data collectors used different brands of thermometers.

When foods are cooled in accordance with either the FDA Food Code or the USDA FSIS guidelines, the required change in temperature is nonlinear with respect to time (10). Such nonlinear temperature profiles are also typically observed in practice due to the physical principles that govern cooling. At the start of a cooling process, a large temperature differential, often called the driving force, exists between the food and the cooling environment. A large driving force means a rapid cooling rate. As a food cools, the driving force lessens—a smaller driving force means a slower cooling rate.

Although temperature profiles during cooling are nonlinear, the logarithm of the driving force is linear with time; therefore, cooling rates can be estimated from the beginning and ending points recorded by the data collectors. Thus, the estimated cooling rate as shown by Smith-Simpson and Schaffner (9) was assumed to be $[\text{Log}(T_1 - T_{\text{df}}) - \text{Log}(T_2 - T_{\text{df}})]/t$. T_1 and T_2 are the two temperatures measured during cooling, T_{df} is the driving force temperature, i.e., the temperature of the cooling environment, and t is the time between the two temperature measurements.

If we consider the cooling profile recommended in the 2009 FDA Food Code (from 135 to 70°F [57.2 to 21.1°C] in 2 h, from 70 to 41°F [21.1 to 5°C] in an additional 4 h), assume a driving force temperature of 37°F (2.8°C), and perform simple linear regression, the equation that matches the FDA Food Code cooling profile is $Log(\Delta T) = -0.2312t + 1.9871$. ΔT is the difference between the food temperature and the driving force temperature, 37° F (2.8°C) in this case, and t is the cooling time in h. Although any driving force could be assumed, the driving force that converts the cooling profile recommended in the Food Code (135 to 70°F [57 to 21° C] in 2 h and 70 to 41° F [21 to 5° C] in an additional 4 h) to the straightest possible line (i.e., $R^2 = 0.99994$) is achieved when a driving force temperature of 37°F (2.8°C) is used. Note than 37°F (2.8°C) is actually a more sensible assumption of a driving force when refrigeration is used because, for a food to actually reach 41°F (5°C), the driving force must be less than 41°F [5°C]. Because the data collectors also recorded the environmental temperature (i.e., the driving force temperature, $T_{\rm df}$), this actual value was used to calculate the cooling rate. When cooling with a different method was used, a different driving force temperature was used (e.g., room temperature cooling would be a 70°F [21.1°C] driving force temperature, and ice wand or ice bath cooling would be a 32°F [0°C] driving force temperature).

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The slope of the cooling profile is the coefficient 0.2312 in the previous equation, so any food cooled at this rate can be assumed to comply with the FDA Food Code (i.e., cooling from 135°F [57.2°C] to 41°F [5°C] within 6 h). Foods cooled at a faster rate (>0.2312) cool faster than recommended in the Food Code guidelines, and foods cooled at a slower rate (<0.2312) cool slower than recommended in the Food Code guidelines. This approach does involve making the assumptions that the estimated cooling rate follows the earlier equation and can be predicted using only two points. However, an alternative approach, calling for more temperature measurements during the cooling process, would have required data collectors to be present in the restaurants for a longer period than was feasible. Cooling rate distributions were created using the histogram function of the Data Analysis ToolPak in Excel (Microsoft, Redmond, WA).

RESULTS

Restaurant sample. As noted by Brown et al. (1), 420 restaurant managers agreed to participate in the study, a participation rate of 68.4%. According to manager interview data, 290 (69%) of restaurants in the study were independently owned; the remaining 130 (31%) were chain restaurants. Most restaurants (252 [60%]) served an American menu, 47 (11%) served Italian, 34 (8%) Mexican, 21 (5%) Chinese, and 66 (16%) "other." The median number of meals served daily was 150; the numbers of meals served daily ranged from 7 to 7,700.

Food cooling observation. As noted in Brown et al. (1), data collectors observed 596 food items being cooled during their visits in 410 restaurants. Soups, stews, and chilis were the most common food items being cooled (178 [30%]), followed by poultry and meat (150 [25%]), sauces and gravies (92 [15%]), cooked vegetables (40 [7%]), rice (34 [6%]), beans (31 [5%]), pasta (23 [4%]), casseroles (19 [3%]), seafood (7 [1%]), pudding (6 [1%]), and other foods (16 [3%]). Data collectors observed 1,070 steps used during the cooling of these food items. Because one food might be cooled by at least one step, and by as many as four different steps, the number of steps exceeded the number of foods. The most common cooling method was refrigeration, used in 511 (48%) of the cooling steps. Other cooling methods included ice baths (199 [19%]), room-temperature cooling (182 [17%]), ice-wand cooling (80 [7%]), adding ice or frozen food to the cooling food as an ingredient (27 [2%]), blast chillers (5 [<1%]), and other methods (66 [6%]).

Extraction of EHS-Net data. To determine the overall distribution of estimated cooling rates, we used data from cooling step observations that met key criteria for our analysis. The key criteria required for each cooling step observation were a starting temperature, an ending temperature, the elapsed time between the starting and ending temperature, and the driving force temperature (cooling environment temperature). More than 1,000 (1,014) cooling step observations from the EHS-Net data set met these criteria. For each of these step observations, an estimated cooling rate was calculated using the methods and equations described earlier. We used the same process to examine how food type and active food temperature monitoring by food

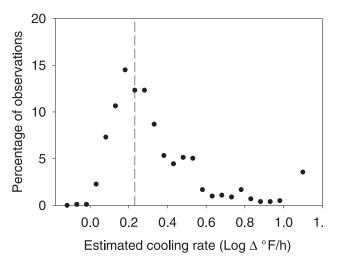


FIGURE 1. Frequency distribution of estimated cooling rates of 1,014 observations of cooling food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.

workers affected estimated cooling rate. Nine hundred thirty (930) step observations had data on food type and 1,014 observations had data on cooling method. Cooling steps involving refrigeration (453) also had data on food depth and ventilation during refrigeration; these data were analyzed further.

Estimated cooling rates. Figure 1 shows the overall distribution of estimated cooling rates, based on beginningand ending-point food temperatures taken by the data collectors. The x axis represents the estimated cooling rate, and the y axis represents the fraction of the number of times a particular estimated cooling rate was observed. The vertical line indicates the Food Code guideline cooling rate of ~ 0.23 (cooling to $41^{\circ}F$ [5°C] in 6 h). Cooling step observations positioned left of this line represent foods that were cooling at rates slower than the Food Code guideline. Observations positioned right of this line represent foods that were cooling at rates as fast as or faster than the Food Code guideline. Of the observations, 660 (65%) had an estimated cooling rate that was as fast as or faster than the Food Code guideline. In 36 (\sim 3%) observations there was a very rapid estimated cooling rate (rate of >1, cooling to $41^{\circ}F$ [5°C] faster than 1.4 h). Conversely, 354 (~35%) observations had an estimated cooling rate slower than the Food Code guideline. One hundred forty-seven (almost 15%) observations had an estimated cooling rate that was only slightly slower than the Food Code guideline (rate of ~ 0.18 , cooling to 41°F [5°C] in 7.7 h); this was the most frequently observed cooling rate. In 108 (~10%) of the observations, the estimated cooling rate was significantly slower than the Food Code guideline (rate of 0.13, cooling to $41^{\circ}F$ [5°C] in 10.7 h). In 9% of observations, the estimated cooling rate was slower than 0.13 (in 74 [7%], rate of 0.08 [cooling to 41°F (5°C) in 17.4 h]; in 23 [2%], rate of 0.03 [cooling to 41° F (5° C) in >24 h]). Finally, two observations showed an estimated cooling rate of less than 0

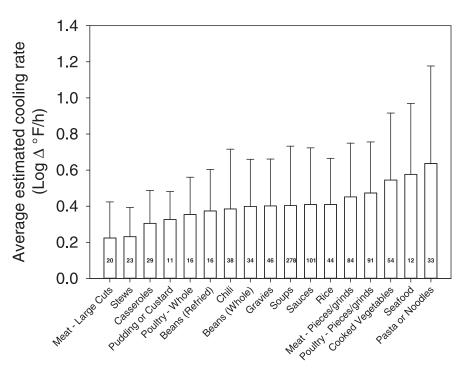


FIGURE 2. Relationship between food type and the average estimated cooling rate. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h). Error bars represent the standard deviation of the cooling rate, and numbers superimposed on the bars represent the number of times each cooling rate was observed.

Food type cooled

(i.e., cooling attempts were made, but the temperatures actually increased slightly).

Estimated cooling rates and food type. Figure 2 shows the relationship between food type and the average estimated cooling rate. The x axis represents the food type for the cooling step observations, and the y axis represents the average estimated cooling rate; the standard deviation of the estimated cooling rate is shown as error bars. The numbers superimposed on the bars indicate the number of observations associated with each estimated cooling rate. Large cuts of meat and stews (in which C. perfringens presents a risk) show the slowest overall estimated cooling rate, a rate approximately equal to the Food Code guideline (rate of 0.23, cooling to 41°F [5°C] in 6 h). Pasta and noodles (in which B. cereus poses the primary risk) were the fastest cooling foods, with an average cooling rate of 0.64, which corresponds to a cooling time of just over 2 h. The large standard deviations show the high variability associated with each food type. Faster cooling rates (e.g., with pasta) were more often associated with higher variability, but even the slowest rates had high variability. Although some of these food types have pH values sufficient to prevent the growth of spore-forming bacteria, pH is seldom used as a control measure in restaurants. In addition, pH data on the products in question were not available.

Estimated cooling rates and time or temperature monitoring. Figure 3 shows the effect of monitoring of cooling food time or temperature by food workers on estimated cooling rates. The x axis represents the estimated cooling rate for the cooling step observations and the y axis represents the fraction of the time (expressed as a percentage) that this particular rate was observed for each

condition (monitored and unmonitored). The vertical line indicates the Food Code guideline cooling rate of ~ 0.23 . Closed circles indicate estimated cooling rates for foods that were monitored; open circles indicate estimated cooling rates for foods that were unmonitored. For estimated cooling rates that were slower than the Food Code guideline (positioned left of vertical line), unmonitored cooling was twice as common as monitored cooling. For estimated cooling rates that were slightly faster than the Food Code guideline (rate of 0.3, positioned slightly right of the dotted line, cooling to 41°F [5°C] in 4.6 h), monitored cooling was twice as common as unmonitored cooling. For faster cooling rates (rate of 0.4 and higher, cooling to 41°F [5°C] in 3.5 h and faster) there was little difference between monitored and unmonitored cooling. Considering all the data together, unmonitored food is more than twice as likely (2.2 times) to cool slower than the Food Code guideline.

Estimated cooling rates and food depth. Figure 4 shows how food depth affects estimated cooling rates. The x axis represents the estimated cooling rate for the cooling step observations, and the y axis represents the frequency of the estimated cooling rates. The vertical line indicates the Food Code guideline cooling rate of \sim 0.23. Closed circles indicate estimated cooling rates for foods that were ≤7.6 cm (3 in.) deep in containers; open circles indicate estimated cooling rates for foods that were >7.6 cm (3 in.) deep. For estimated cooling rates that were slower than the Food Code guideline (i.e., positioned left of the dotted line), cooling in deep pans was observed about twice as often as cooling in shallow pans. For estimated cooling rates that were as fast as or faster than the Food Code guideline (i.e., positioned right of the dotted line), shallow food depths were generally observed more frequently than deep food depths. Considering

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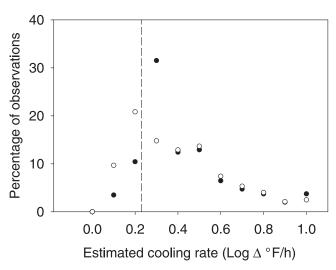


FIGURE 3. Effect of active temperature monitoring by food workers and estimated cooling rate. Closed circles indicate cooling rates for monitored food; open circles indicate cooling rates for unmonitored food. Food Code cooling rate is 0.23 (cooling to 41°F [5°C] within 6 h), indicated by the dotted vertical line.

all the data together, food deeper than 7.6 cm (3 in.) in containers is twice as likely to cool slower than the Food Code guideline.

Estimated cooling rates and ventilation. Figure 5 shows how ventilation affects the estimated cooling rate. The x axis represents the estimated cooling rate for the cooling step observations, and the y axis represents the frequency of the estimated cooling rates. The vertical line indicates the Food Code guideline cooling rate of ~ 0.23 . Closed circles indicate ventilated food cooling rates; open circles indicate unventilated food cooling rates. For estimated cooling rates that were much slower than the

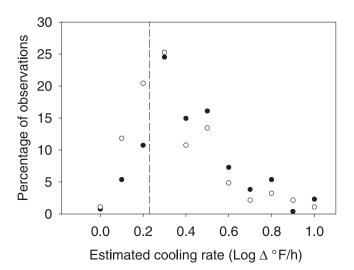


FIGURE 4. Effect of food depth on estimated cooling rate. Cooling rates for food in shallow pans (≤ 3 in. [7.6 cm] deep) indicated by closed circles; cooling rates for food in deep pans (>3 in. [7.6 cm] deep) indicated by open circles. Food Code cooling rate is 0.23 (cooling to 41 °F [5 °C] within 6 h), indicated by the dotted vertical line.

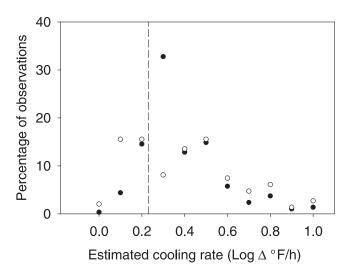


FIGURE 5. Effect of ventilation on estimated cooling rate. Closed circles indicate ventilated food cooling rates; open circles indicate unventilated food cooling rates. Food Code cooling rate is 0.23 (cooling to $41^{\circ}F$ [5 °C] within 6 h), indicated by the dotted vertical line.

Food Code guideline (rate of 0.1, cooling to 41°F [5°C] in \sim 14 h), unventilated cooling was observed more than three times as often as ventilated cooling. When estimated cooling rates were slightly slower than the Food Code guideline (rate of 0.2, cooling to 41°F [5°C] in \sim 7 h), the frequency of ventilated and unventilated cooling was similar. For estimated cooling rates that were slightly faster than the Model Food Code (rate of 0.3, cooling to 41°F [5°C] in 4.6 h), ventilated cooling was observed more than four times as often as unventilated cooling. Considering all the data together, unventilated cooling foods were almost twice (1.7 times) as likely to cool slower than the Food Code guideline.

DISCUSSION

The data from this study indicate that about a third of restaurant cooling step observations had an estimated cooling rate that was slower than the Food Code guideline. These data are concerning because slow cooling can cause foodborne illness outbreaks (5). However, many of these observations showed an estimated cooling rate that was only slightly slower than the Food Code guideline, which suggests that many restaurants may need to make only small changes to their cooling practices to comply with the Food Code guideline.

The data from this study indicate that following the Food Code guidelines concerning the cooling methods examined in this study likely will improve cooling rates and ensure compliance with Food Code guidelines. Following the Food Code guidelines (storing foods at shallow depths, ventilating foods, and actively monitoring cooling food time or temperatures) facilitated faster estimated cooling rates. Our data show that, of the three methods, active monitoring was the most effective (2.2 times more likely to meet Food Code guidelines), followed by shallow food depth (2 times more likely), and ventilation (1.7 times more likely).

Restaurants should be able to boost their cooling rates relatively easily by using one or more of these methods.

The data from this study also show that some foods, particularly large cuts of meat, are harder to cool to the Food Code guideline than other types of foods. These data are not surprising; other researchers have found similar results (6, 11). These data reinforce the need for restaurants to pay particular attention to cooling these types of foods. The data from this study also confirm the difficulties of cooling food stored in deep containers; this circumstance is known to increase the risk of *C. perfringens* proliferation (2–4).

This study is one of few to examine restaurant food cooling practices and processes. This lack of data may stem from the fact that assessing the full 6-h cooling process is time intensive and, thus, difficult to accomplish. The FDA attempted to assess restaurant food cooling processes in their Retail Risk Factor Study but encountered difficulties (15). In that study, cooling was observed in substantially fewer retail establishments than were other food preparation practices, due, in part, to the limited amount of time data collectors had available to spend in establishments.

A limitation of this study is that it included only restaurants with English-speaking managers. Additionally, the data collected were susceptible to reactivity bias (as in any study involving observational activities). For example, food workers were aware that they were being observed and might have reacted to being observed by changing their routine behavior (e.g., monitoring cooling food temperatures more frequently).

Our study did not assess the full cooling process but instead used mathematic modeling to estimate cooling rates. The method, of necessity, had to assume that driving force temperature was constant, and at the single value measured by the data collectors, as explained in the methods above. Our data suggest that several best cooling practices can contribute to a process in which food is cooled properly. Future research could not only validate our estimation method but also further investigate the effect of specific cooling practices on the full cooling process.

It may be useful to frame the findings from this study in terms of contributing factors and environmental antecedents to foodborne illness outbreaks (8). Contributing factors are factors in the environment that cause, or contribute to, an outbreak; environmental antecedents are factors in the environment that lead to the occurrence of contributing factors. In this case, slow or improper cooling is a contributing factor. Cooling practices such as storage of food in deep containers, lack of ventilation, and lack of active monitoring can be environmental antecedents to this contributing factor. Our data suggest that focusing on these environmental antecedents may help reduce outbreaks caused by slow or improper cooling.

Environmental health specialists who are not able to assess the full cooling process during their restaurant inspections may wish to consider assessing the specific cooling practices used in the cooling process (i.e., the environmental antecedents [e.g., food depth]), because these practices can be assessed far more quickly than can the full

cooling process. This assessment will allow environmental health specialists to identify methods to improve the cooling process and educate restaurant managers accordingly. Our data suggest that, in many cases, the changes needed to improve the cooling process may be small and relatively easy to implement.

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Restaurant Practices for Cooling Food in Minnesota: An Intervention Study

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Abstract

Improper cooling of hot foods is a leading contributing factor to foodborne disease. Although the U.S. Food and Drug Administration (FDA) Food Code outlines the cooling parameters and methods to facilitate proper cooling, restaurants continue to have issues. The purpose of this study was to further examine restaurant cooling practices and determine the effect of an educational intervention on 30 Minnesota restaurants, each with a history of cooling violations. Descriptive data on restaurant cooling practices and a cooling curve were collected from each restaurant to determine compliance with the Food Code and to assess which cooling methods work best. Additionally, cooling education was provided to a manager and assessments were conducted preintervention, postintervention, and at the next routine inspection to determine if cooling knowledge improved. Restaurants were evaluated at their next routine inspection to see if cooling practices had changed and if cooling violations were present. Most study restaurants were not using appropriate cooling methods as per the Minnesota Food Code, and 53% of food items observed did not cool within required cooling parameters. Foods cooled in containers <3 inches in depth were significantly more likely to cool properly. Managers scored significantly higher on the postassessment and on the next routine inspection assessment than on the preassessment, suggesting that education on cooling can increase operator knowledge. Postintervention, 20% more kitchen managers reported having written cooling procedures and had verified their cooling process than was reported preintervention. However, the increase in knowledge and reported policy changes did not translate to a reduction in cooling violations at the next inspection. Our findings documented significant food safety gaps in restaurant cooling practices. Translation of knowledge into sustained, improved food safety practices remains a major challenge for the environmental health profession; overcoming this challenge should be a focus for behavioral scientists and others interested in improving practices in restaurants for the long term.

Keywords: restaurants, cooling, cooling methods, intervention, cooling curves

Introduction

MPROPER COOLING OF hot foods is a leading contributing factor to foodborne disease (Gould *et al.*, 2013; Lipcsei *et al.*, 2019). During 2009–2015, ~9% of foodborne outbreaks in the United States were due to bacterial intoxication from pathogens such as *Clostridium perfringens* (Dewey-Mattia *et al.*, 2018); these bacteria can multiply to disease-causing levels if food is cooled improperly (Doyle, 2002). Similarly, ~10% of foodborne outbreaks in Minnesota each year are due to bacterial intoxication (Minnesota Department of Health, unpublished data, 2018), which are preventable if time–temperature control measures are properly implemented, including cooling.

To reduce the risk of foodborne disease, the U.S. Food and Drug Administration (FDA) Food Code (2017) includes

guidelines for retail food service establishments to keep time and temperature control for safety foods. These guidelines state that food must be cooled from 135°F to 70°F within 2 h and from 135°F to 41°F within a total of 6 h (U.S. FDA, "FDA Food Code," 2017). At the time of data collection for this study, the 1998 Minnesota Food Code was in effect, which stated that potentially hazardous foods (PHFs) must be cooled from 140°F to 70°F within 2 h and from 70°F to 41°F within 4 h (MN Dept. of Health, 1998).

The FDA Food Code contains guidelines, consistent with the 1998 Minnesota Food Code, on methods that help facilitate proper cooling, including placing food in shallow pans, using containers that facilitate heat transfer, adding ice as an ingredient, or other effective methods. However, there is no information on what methods or types of containers work best or a definition of "shallow." In addition, the FDA

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recommends that operators monitor times and temperatures for cooling of foods to verify proper cooling (U.S. FDA, "Annex 3," 2017). Recording times and temperatures in a cooling log is one way to provide verification.

Although these guidelines are in place, restaurants continue to struggle with proper cooling. An FDA study found that cooling was out of compliance in 72% (196) of the fullservice restaurants where cooling was observed (U.S. FDA, "Report on the occurrence," 2018). Another study of 420 restaurants concluded that many restaurants are not meeting FDA recommendations for cooling, and about one-third of kitchen managers did not know cooling regulations for their jurisdiction (Brown et al., 2014). Modeling conducted in the same study showed that about a third of restaurant cooling step observations had an estimated cooling rate that was slower than the Food Code guidelines (Schaffner et al., 2015). Restaurants are dynamic and fast-paced, making it difficult to monitor cooling of foods. Additionally, inspectors are only in restaurants for a snapshot of time, so it is difficult to determine Food Code compliance. Training and other intervention efforts are needed to teach restaurant operators how to cool food properly (Brown et al., 2014; Schaffner et al., 2015).

The purpose of this study was to further examine restaurant cooling practices and to determine the effect of an educational intervention on restaurant cooling practices. Specific study objectives were to (1) collect descriptive data on restaurant cooling practices; (2) capture a cooling curve on a PHF in each restaurant to determine compliance with the Food Code and assess which cooling methods work best; and (3) determine if providing cooling education to managers would increase knowledge and result in changes to restaurant cooling practices.

Materials and Methods

Two Minnesota Department of Health (MDH) environmental health specialists, both registered sanitarians, collected data from September 2016 to May 2017 from a convenience sample of 30 restaurants in 5 Minnesota counties. Inspectors in these counties were asked to provide a list of restaurants that had a cooling violation on their last routine inspection. In total, 37 restaurant names were provided to the specialists, of those, three restaurants were excluded because the restaurant manager did not speak English and four refused to participate. The five counties represented both rural and metropolitan areas of the state and are regulated by MDH. A restaurant was 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, or caterer.

Specialists recruited restaurants by telephone. Restaurants were told that data on cooling practices would be collected at three points in time: preintervention, postintervention, and at the next routine inspection. Participating restaurants received a DeltaTrak thermometer (\$50 value) as an incentive to participate. Kitchen managers (defined as a manager with authority over the kitchen) (hereafter referred to as manager) were told that participation was voluntary and nonregulatory and that all data collected would not be identifiable. They were also told that their inspector might accompany the

specialist during the visit and that improperly cooled food could not be served to customers.

Preintervention

The first appointment was scheduled at a time that would coincide with the beginning of the restaurants' cooling processes of at least one PHF (selected by the manager). Specialists placed a data logger in the center of the food item to collect a cooling curve of that product. Observations on the cooling methods were noted. Managers were told to cool the food as they normally would, to keep the probe in the center of the food, and to not turn the probe off or remove it from the food item.

Specialists also interviewed the manager about restaurant characteristics and cooling practices and administered a nine-question multiple-choice assessment (preassessment) (Supplementary Fig. S1). Scoring was out of nine, and there was only one correct answer for each question.

Educational intervention

The specialist returned for a second appointment (often later that same day) to complete cooling observations, collect the data logger, and provide the educational intervention to the manager. The educational intervention took 30–45 min and consisted of verbally explaining an infographic (Supplementary Fig. S2) about cooling, sharing a cooling fact sheet (Supplementary Fig. S3) and a cooling log, and downloading and discussing the cooling curve collected. Specialists had standardized guidelines on how to deliver the educational component. Then, the assessment was conducted again (postintervention assessment) to measure any changes in the manager's knowledge.

Next routine inspection

Cooling practices were assessed again at the restaurants' next routine inspection, which occurred on average 240 d (range: 19–427 d, median: 286 d) after the intervention. Inspectors interviewed managers on cooling practices and provided the same assessment. Due to turnover and scheduling, the manager from the first two appointments was not necessarily the one being assessed during the routine inspection. Specialists reviewed the routine inspection report and noted if cooling violations were written.

To assess the impact of study interventions on the 30 restaurants, specialists reviewed data from 6507 routine restaurant inspections conducted under MDH jurisdiction in 2016 and compiled a list of restaurants with at least one cooling violation (minus the 30 study restaurants). Inspection data on those restaurants' next routine inspection (conducted in 2017 or 2018) were reviewed to see if they had another cooling violation.

DeltaTrak model 20902 data loggers, precalibrated and set to collect time and temperature data in 5-min intervals, were used to capture cooling curves. Temperatures of the refrigerator units were taken with a calibrated thermometer from the area where the food item was cooling. Descriptive and quantitative data analyses were performed with Microsoft Excel 2017 and SAS 9.4. *p*-Values <0.05 were considered statistically significant; associations with *p*-values <0.10 were also noted.

Results

Most of the 30 study restaurants were independent restaurants (83%, 25); the remaining 17% (5) were chains. The majority (53%, 16) of managers interviewed had been working as managers in the restaurants for 2–5 years.

Restaurant cooling practices

Preintervention, 87% (26) of managers self-reported that they had a formal procedure for cooling PHFs (Table 1). Of these, 19% (5) reported that the procedures were written and 62% (16) reported that they had tested and verified the process. Twenty-three percent (7) of managers reported recording times and temperatures in a log, and logs were verified visually by the specialist.

At the routine inspection, all 29 managers interviewed (one restaurant had closed) said that they had a formal procedure for cooling PHFs. Forty-one percent (12) reported that the procedures are written, 83% (24) had tested and verified the process, and 31% (9) said they record times and temperatures in a log (visual verification by inspector). Sixty-two percent (18) of managers reported that they had made changes to their cooling practices since participating in the study. Reported changes included using shallow containers and stainless

TABLE 1. RESTAURANT COOLING PRACTICES (ASCERTAINED BY MANAGER INTERVIEW)

	(n =	$(n = 30)^a$		$(n=29)^{b}$	
	n	%	n	%	
How long have you been a kitche restaurant?	en mana	ager a	t this		
<2 years	2	7	_	_	
2–5 years	16	53		_	
6–10 years		10			
11–20 years	3 5 3	17			
>20 years	3	10			
Refused	1	3			
Does this restaurant have a forma cooling potentially hazardous f	l proce oods?	dure o	or proc	ess for	
Yes	26	87	29	100	
No	3	10	_	_	
Unsure	1	3			
Are the procedures or processes written? (Pre: $n=26$)					
Yes	5	19	12	41	
No	21	81	16	55	
Unsure		_	1	3	
Are the cooling procedures tested	and ve	rified?	(Pre:	n = 26	
Yes	16	62	24	83	
No	9	35	3	10	
Unsure	1	3	2	7	
Do you record times and tempera	tures in	a co	oling l	og?	
Yes	7	23	9	31	
No	22	73	20	69	
Unsure	1	3	_	_	
-					

Cooling logs were also visually verified by specialists and inspectors.

steel containers, using ice wands, and taking temperatures throughout the cooling process.

Cooling methods were observed on 34 food items: in 4 restaurants, 2 food items were observed. Types of PHFs varied and included soups, pasta, rice, meat, and sauces. Fifty-three percent (18) of foods were cooled in a stainless steel container, 35% (12) in a container <3 inches in depth, 35% (12) were stirred at some point during the cooling process, 32% (11) in an ice bath, and 26% (9) with an ice wand. Almost all (94%, 32) food items were ventilated (uncovered or loosely covered) and none were stacked.

Sixty-five percent (22) of foods were cooled using a combination of two or more of the following methods: stainless steel container, depth <3 inches, stirring, ice bath, or ice wand. Eighty-two percent (28) of foods were cooled in a refrigerator, 9% (3) in a freezer, and one in both. Most (86%, 24) refrigerators used to cool food were at or below 41°F. Eleven percent (3) of refrigerators were above 41°F.

Cooling curves

Routine

Thirty-three cooling curves were collected (Supplementary Fig. S4). For one food item, the data logger was not working properly, so start and end times and temperatures were used to determine compliance. Some food items were not completely cooled to 41°F when the specialist returned to collect the data logger. As a result, analysis on the cooling curves was grouped into the two cooling requirements outlined in the Minnesota Food Code: (1) 140°F to 70°F within 2 h and (2) 70°F to 41°F within 4 h. Fifty-nine percent (20) of the 34 foods met the first requirement. Of the 25 foods that had completely cooled, 68% (17) met the second requirement. Overall, 53% (18) of the 34 foods did not meet at least one of the cooling parameters.

Exploratory data analysis of cooling methods

Due to the limited number of food items that had completely cooled by the time data loggers were obtained, only the first cooling requirement (140–70°F within 2 h) was used to assess the effectiveness of the cooling methods (Table 2). Food cooled in containers <3 inches in depth was significantly more likely to meet the first cooling requirement (p=0.035). There was also evidence that food cooled in stainless steel containers (p=0.091) and food cooled in restaurants that had a written cooling procedure (p=0.066) were more likely to meet the first cooling requirement. There were no significant differences in food items that were cooled using an ice bath, an ice wand, or a combination of two or more cooling methods.

Manager assessment scores

There was a significant increase in managers' scores from pre- to postintervention (p < 0.0001) (Table 3). There also was a significant increase in managers' scores from pre-intervention to the routine inspection (p = 0.01). However, postintervention scores were significantly better than scores at the next routine inspection (p < 0.001).

Postintervention inspection data

Of the 6507 restaurants at which a routine inspection was conducted by MDH in 2016, 472 (7%) had one or more cooling violations. Of those, 18% (84) had one or more

^aPre means preintervention.

^bAt the next routine inspection (routine), one restaurant had closed, n=29.

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Table 2. Contingency Table of Cooling Methods and Achieving the First Parameter of Cooling Criteria

	First gi		
	Cooling fr to 70°F v		
Cooling method	Yes	No	Sig.a
<3 Inches			_
Yes	10	2	0.035
No	10	12	
Written procedures			
Yes	7	1	0.067
No	13	13	
Stainless steel			
Yes	13	5 9	0.091
No	7	9	
>2 Methods			
Yes	15	7	0.128
No	5	7	
Ice bath			
Yes	7	4	0.495
No	13	10	
Ice wand			
Yes	5	4	0.736
No	15	10	

n = 34.

cooling violations on their next routine inspection. In the study population, of the 29 establishments still in operation, 31% (9) had one or more cooling violations on their next routine inspection. When using a chi-square goodness-of-fit test, the difference between the baseline group and study group was not statistically significant (p=0.07).

Discussion

Many managers were not following Food Code guidelines to facilitate proper cooling. Most managers reported that they had a formal procedure for cooling, but many had not verified that their cooling process worked, and few had written procedures or recorded temperatures in a log. These findings were almost identical to the manager-reported practices reported by Brown *et al.* (2012).

After the intervention, 20% more managers reported that their procedures had been verified, and an additional two restaurants were recording times and temperatures in a log. Although these changes were small, they could result in better practices. Testing and verification of times and temperatures are recommended best practices in the Food Code. The likelihood of temperature abuse is reduced when employees are monitoring food temperatures (U.S. FDA, "Annex 3," 2017). Similarly, by not having written procedures for cooling, food workers may deviate from the establishment's cooling process or use methods that hinder cooling. Additional research looking into the social and behavioral factors affecting policy and procedure compliance would be beneficial.

The majority of restaurants were not utilizing proper cooling methods; only half cooled food in stainless steel containers and only about a third used containers <3 inches in depth or stirred the food. This resulted in almost half of the food items not meeting the cooling parameters required in the Food Code. Just over half of the foods cooled from 140°F to 70°F within 2 h. The initial 2-h cool period is a critical element of this cooling process (U.S. FDA, "Annex 3," 2017) and necessary to minimize the time that food is kept in the temperature danger zone (U.S. FDA, "Danger Zone," 2017). Clostridium perfringens, the leading cause of bacterial foodborne intoxication outbreaks, can grow very rapidly between 109°F and 117°F. Therefore, it is important for food to cool rapidly during this first step to prevent bacterial amplification (CDC, 2018).

It is critical that establishments use a combination of cooling methods to help achieve cooling success, but it does appear that some cooling methods, such as cooling in containers <3 inches in depth, may be more effective than others. By reducing the volume of food in an individual container, the rate of cooling is dramatically increased (Schaffner *et al.*, 2015, U.S. FDA, "Annex 3," 2017).

The use of stainless steel containers and having formal, written cooling procedures were also variables of interest. Stainless steel allows for better heat transfer than plastic containers, which slow cooling (U of M extension, 2018). Written procedures indicate that employees are more likely to have been trained on the cooling process and could be an indicator of good, active managerial control. Further research is needed to fully assess the success of these methods. Clear guidance on what is considered shallow and what containers best facilitate heat transfer would be beneficial to operators and regulators.

Table 3. Comparison of Cooling Knowledge Assessment Scores for Managers Pre- and Postintervention

Mean (SD)		Mean difference ^a	95% CI	t-statistic (df)	p
Pre vs. post ^b 5.2 (1.18)	7.8 (1.14)	2.6	2.1–3.1	11.4 (31)	<0.0001
Pre vs. routine ^c 5.2 (1.18)	6.1 (1.74)	1.5	0.9–2.1	2.5 (58)	0.01
Post vs. routine ^c 7.8 (1.14)	6.1 (1.74)	1.6	0.8-2.4	4.2 (45)	< 0.001

Routine has an n=28, 1 establishment had closed, and in one establishment, the assessment was not completed.

^aFisher's exact test right-sided $Pr \ge F$.

^aMean difference calculated by taking postscore minus prescore, routine score minus prescore, and postscore minus routine score.

^bFor same respondents, a paired *t*-test was performed.

^cWhere respondents may have differed, an independent *t*-test was performed.

CI, confidence interval; SD, standard deviation.

Providing cooling education improved manager knowledge scores. The large increase in postassessment compared with preassessment scores may partly be due to a carryover effect (Bjorndal, 2018) since most managers took the pre- and postassessments within a day. However, the routine inspection scores were also significantly higher than preassessment scores, suggesting that a long-term increase in knowledge may have occurred. Postassessment scores were significantly higher than scores at the routine inspection, which could indicate that knowledge gained decreases over time, highlighting the need for periodic refresher training. Additional research on manager training and how it relates to long-term changes in practice is necessary.

Increased manager knowledge did not decrease the number of cooling violations on future inspections. Study restaurants, compared with all MDH restaurants, had a higher percentage of cooling violations on their next routine inspection. Although this difference was not significant, it is still concerning.

It is likely that many cooling violations are being undocumented on routine inspections because inspectors are only in the restaurant for a small portion of operating hours; inspectors may have looked more closely at cooling practices onsite in the study restaurants, allowing them to find more violations. Additionally, most study restaurants were independent restaurants with managers working at the restaurant for 5 years or less. Research has shown that independent restaurants have more food safety issues than chain restaurants due to inadequate training of staff and no formal policies (Brown *et al.*, 2014) and that inexperienced managers have less food safety knowledge and training to ensure good practices (Brown *et al.*, 2014). High employee turnover and physical facility or equipment constraints are other factors that may affect the inability to maintain practice changes.

This study had several limitations, we used a convenience sample of restaurants with English-speaking managers; therefore, the restaurants included in this study may not represent all restaurants that cool food within Minnesota. Due to our small sample size, there was a lack of power, making it difficult to determine factors of significance. Additionally, self-reported data were collected through manager interviews and may be affected by social desirability bias. Percentages of restaurants with food safety errors should be viewed as minimum estimates. Last, our conclusions regarding manager knowledge at the routine inspection have limitations since managers who took the pre- and postassessments may have not been the same, and the length of time routine inspections were conducted after the intervention varied, potentially affecting knowledge retention.

Conclusions

This study identified significant food safety gaps in cooling. Restaurant managers were often unaware of the requirements pertaining to proper cooling and did not utilize cooling methods to cool food as outlined in the Food Code, resulting in improperly cooled food. Our results suggest that education on cooling can increase manager knowledge; however, this did not translate into fewer cooling violations in the next routine inspection.

The lack of translation of knowledge into sustained, improved food safety practices remains a major challenge for

the environmental health profession; overcoming this challenge should be a focus for behavioral scientists and others interested in improving practices in restaurants in the long term. Restaurants are dynamic environments and it can be difficult for food workers to closely monitor cooling of food. Training food workers and regulatory staff on cooling methods that best facilitate rapid cooling, such as portioning food into shallow containers with a depth of <3 inches, can help address the issue of improper cooling.

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Supplementary Material

Supplementary Figure S1 Supplementary Figure S2 Supplementary Figure S3 Supplementary Figure S4

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Research Paper

Validation of a Simple Two-Point Method To Assess Restaurant Compliance with Food Code Cooling Rates

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ABSTRACT

Outbreaks from improperly cooled foods continue to occur despite clearly described Food Code cooling guidelines. It is difficult for regulators to enforce these guidelines because they are typically in an establishment for less than the 6 h needed to document proper cooling. Prior research proposed using a novel method to estimate cooling rates based on two time-temperature points, but this method has not yet been validated. Time-temperature profiles of 29 different foods were collected in 25 different restaurants during cooling. Cooling curves were divided into two categories: typical (21 foods) and atypical (eight foods) prior to further analysis. Analysis of the typical cooling curves used simple linear regression to calculate cooling rates. The atypical cooling profiles were studied using Monte Carlo simulations of the cooling rate. Almost all linearized typical cooling curves had high (>0.90) R² values. Six foods with typical cooling profiles that did not pass Food Code cooling times were correctly identified by the two-point model as having slow cooling rates. Three foods that did not pass Food Code cooling times were identified by the two-point model as having marginal cooling rates. Ten of 12 foods identified by the two-point model as having acceptable cooling rates met Food Code cooling times. Most (six of eight) foods that were considered to have atypical cooling curves failed to meet the Food Code cooling times. The two-point model was also able to determine whether these foods would fail based on Food Code guidelines depending upon the simulation criteria used. Our data show that food depth has a strong influence on cooling rate. Containers with a food depth ≥7.6 cm (3 in.) were more likely to have cooling rates slower than the U.S. Food and Drug Administration Model Food Code cooling rate. This analysis shows that the two-point method can be a useful screening tool to identify potential cooling rate problems during a routine restaurant inspection visit.

HIGHLIGHTS

- Containers with food depth \geq 7.6 cm were likely to have slow cooling rates.
- Most (21 of 29) foods had linearized cooling rates with high (>0.90) R^2 values.
- Most (15 of 17) slow cooling foods were identified by the two-point method.
- All (12 of 12) fast cooling foods were identified by the two-point method.
- The two-point method can be used to identify potential cooling rate problems.

Key words: Cooling; Inspection; Model; Refrigeration; Simulation

Bacterial intoxications from *Clostridium perfringens*, *Bacillus cereus*, and *Staphylococcus aureus* cause approximately 10% of foodborne outbreaks in the United States (11), and improper cooling is a leading contributing factor in many of these outbreaks (14). If foods are held out of temperature control (above 5 or below 57°C) for too long, bacteria such as *C. perfringens* and *B. cereus* can proliferate to high levels, resulting in illness (13). *C. perfringens* is typically associated with improper cooling of large cuts of meat, because the spores of the organism can survive the cooking process (31). *C. perfringens* cells can multiply between 15 and 55°C, with an optimal temperature of 45°C (6). Spores germinate in response to cooking, and cells

subsequently multiply rapidly during cooling, doubling as often as every 20 min (i.e., 1 log CFU increase every hour) or even faster (27). C. perfringens is estimated to cause 1 million illnesses in the United States each year (15), surpassed only by Salmonella and norovirus (25). C. perfringens caused a confirmed 15,208 illnesses, associated with 289 outbreaks between 1998 and 2010 in the United States (15). B. cereus can also survive the cooking process and is typically associated with improper cooling of cooked rice (8). B. cereus was linked to 56 confirmed outbreaks causing 881 illnesses between 1998 and 2008 in the United States (3). Proper cooling time and temperature control for cooked foods can be crucial in preventing foodborne disease outbreaks by these organisms.

The U.S. Food and Drug Administration (FDA) Model Food Code has recommendations that specify time and

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temperature parameters for cooling of cooked food. These guidelines state that time-temperature control for safety (TCS) foods must be cooled from 57.2 to 21.1°C (135 to 70°F) within 2 h and from 57.2 to 5°C (135 to 41°F) within 6 h (30). Many states have adopted these specific recommendations for their own state food codes, as Minnesota did in January 2019. Prior to adopting the FDA Model Food Code parameters, Minnesota was using similar but older parameters (23), which required that potentially hazardous foods (i.e., TCS foods) be cooled from 60 to 21.1°C (140 to 70°F) within the first 2 h, and from 57.2 to 5°C (70 to 41°F) within the next 4 h. The FDA Model Food Code also outlines methods that can help cool foods quickly, such as the use of shallow pans or the use of containers that facilitate heat transfer (30). These recommendations provide minimal details on which methods are optimal or on what constitutes "shallow" or what container best facilitates heat transfer.

Even with clearly described food code guidelines, outbreaks from improperly cooled foods continue to occur (5, 28). It is often difficult for operators to monitor time and temperatures during cooling due to a lack of suitable tools and the awareness of its importance. It is also often difficult for regulators to enforce these guidelines because they are typically in an establishment for a period less than the 6 h needed to document proper cooling. The FDA attempted to assess restaurant food cooling processes in their Retail Risk Factor Study, but they encountered difficulties because cooling was observed in only few retail establishments due to the limited amount of time collectors were present (29).

Because observation of cooling in retail establishments over the entire 6-h time period is impractical, Schaffner et al. (26) proposed using a novel method to estimate cooling rates based on two time-temperature points. These researchers noted that although temperature profiles during cooling are nonlinear, the logarithm of the driving force is linear with time, so cooling rates can be estimated from any two time points in the cooling process. Whereas Schaffner et al. (26) made some useful observations, because their study consisted solely of time-temperature point pairs (not full cooling curves) they could not validate that their two-point method was representative of full cooling curves. Our study seeks to further examine restaurant cooling by using complete cooling curves captured from restaurant food items to calculate cooling rates and then to use these rates to validate the two-point approach proposed by Schaffner et al. (26) as well as to identify additional risk factors predictive of poor cooling.

MATERIALS AND METHODS

Two-point method description. Foods temperatures change in a nonlinear fashion as they cool, dropping more rapidly at the start because of the greater difference between the food temperature and that of the environment. This temperature difference is known as the driving force (26). Whereas temperatures change nonlinearly with time, the logarithm of the driving force changes linearly with time. The estimated cooling rate (27) can be assumed to be $[\text{Log}(T_1 - T_{\text{df}}) - \text{Log}(T_2 - T_{\text{df}})]/t$, where T_1 and T_2 are any two temperatures measured during cooling, T_{df} is the driving force temperature (i.e., the temperature

of the cooling environment), and t is the time between the two temperature measurements. Schaffner et al. (26) found that the FDA Food Code recommended guidelines for food cooling results in a cooling rate of 0.23, where a rate faster than 0.23 cooled faster than the Food Code recommended rate, and vice versa (26). This rate is log linear for a driving force of 2.8°C (37°F). Note that this rate is the same whether calculated using °C or °F, if the units for time (i.e., hours) remain the same.

Data collection. Time-temperature profiles of 29 different foods were collected in 25 different restaurants during cooling, and time and temperature data from the center of the food (i.e., the cold spot) were recorded every 5 min (17). Cooling curves were divided into two categories, typical and atypical, prior to further analysis. Curves were considered atypical when they had many dips and peaks, usually due to either stirring or a change of cooling method. Most cooling curves (21 curves of 29 total) had approximately log-linear driving force changes with time and were considered typical, whereas atypical cooling curves (8 of 29) had non-log-linear driving force changes with time, due to temperature spikes or dips from stirring or other factors.

Typical cooling curves analysis. Our analysis of the typical cooling curves (21 of 29 foods) used five points selected from each food's cooling profile. The selections corresponded to (i) the time immediately following a food temperature below 60°C (140°F), (ii) the time immediately following a food temperature below 21.1°C (70°F), and (iii) the time immediately following a food temperature below 5°C (41°F), as well as the times corresponding to interpolation between these temperatures (40.6 and 13.1°C [105 and 55.5°F]). The driving force temperature for each cooling curve was taken from the auditors' records (17) made at the time of their visit. The logarithm of the driving force ($\log[T-T_{\rm df}]$) for each of the five points was plotted versus time, and simple linear regression in Excel (Microsoft Corporation, Redmond, WA) was used to calculate cooling rates.

Atypical cooling curves analysis. The atypical cooling profiles (8 of 29 foods) were studied using simulations of the cooling rate created with @Risk software (Palisade Corporation, Ithaca, NY). First, temperature and time data from each cooling profile were divided into two groups: <60 and >21.1°C (<140 and >70°F) and <21.1 and >5°C (<70 and >40°F). Next, @Risk selected one random time-temperature pair value from each group and used the two points to estimate the cooling rate. A total of 10,000 cooling rates were estimated for each food with an unusual cooling curve. Histograms and summary statistics (mean, median, mode, upper and lower 90%, and fraction of rates faster and slower than the previously measured cooling rate based on FDA Food Code recommendations) were calculated for each set of 10,000 iterations.

RESULTS

Typical cooling curves results. Table 1 shows the 21 foods with typical cooling curves and includes important characteristics of the cooling process, including cooling rate, whole container type, container depth, ventilation, and cooling method. The entries in Table 1 are sorted according to the estimated cooling rate calculated using the method from Schaffner et al. (26). All linearized rates created showed strong fit as indicated by high (>0.87) R^2 values. Approximately half (11 of 21) of the foods in Table 1 failed

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TABLE 1. Estimated cooling rates created for foods with "typical" cooling profiles, sorted from slowest to fastest cooling

Food	Cooling rate (1/h)	Speed ^a	R^2	Container	Cooling method	Ventilated?	Excess product depth >7.6 cm (3 in.)	Pass ^b
Vegetable beef soup	-0.102	Slow	0.921	Metal	Walk-in cooler	Yes	Yes	No
Vegetable beef barley soup	-0.117	Slow	0.876	Plastic	Walk-in freezer/walk-in cooler		Yes	No
Veggie burger soup	-0.122	Slow	0.999	Plastic	Walk-in cooler	Yes	Yes	No
Mashed potatoes	-0.137	Slow	0.999	Metal	Walk-in cooler	Yes	Yes	No
Bacon potato soup	-0.147	Slow	0.984	Plastic	Ice wand/walk-in	Yes	Yes	No
Chinese beef and broccoli soup	-0.176	Slow	0.964	Metal	Ice wand/walk-in	Yes	Yes	No
Rice	-0.243	Borderline	0.999	Metal	Walk-in cooler	Yes	Yes	No
Turkey (deboned)	-0.246	Borderline	0.915	Metal	Walk-in cooler	Yes	No	No
Rice	-0.252	Borderline	0.998	Plastic	Walk-in cooler	Yes	Yes	No
Alfredo sauce	-0.309	Fast	0.992	Metal	Walk-in cooler	Yes	No	Yes
Noodles	-0.312	Fast	0.969	Metal	Walk-in cooler	No	No	No^c
Meat broth	-0.322	Fast	0.999	Metal	Reach in cooler	Yes	Yes	Yes
Mashed potatoes	-0.337	Fast	0.998	Metal	Walk-in cooler	Yes	No	Yes
Chicken wings	-0.383	Fast	0.941	Metal	Walk-in cooler	No	No	Yes
Steak and potato soup	-0.394	Fast	0.999	Plastic	Ice wand/walk-in	Yes	Yes	Yes
Rice pilaf	-0.489	Fast	0.997	Metal	Walk-in cooler	Yes	No	Yes
Toscana soup	-0.522	Fast	0.971	Plastic	Ice bath/wand/walk-in	Yes	Yes	Yes
French onion soup	-0.537	Fast	0.983	Metal	Walk-in cooler	Yes	No	No^d
Rice	-0.643	Fast	0.974	Metal	Walk-in cooler	Yes	No	Yes
Par-cooked chicken	-1.050	Fast	0.984	Metal	Walk-in cooler	Yes	No	Yes
Chicken wild rice soup	-2.178	Fast	0.923	Metal	Walk-in cooler/ice over top	Yes	No	Yes

^a The speed column identifies foods that cooled slower than the linearized cooling rate of 0.23 proposed by Schaffner et al. (26), foods that are borderline, or foods that cooled faster than the linearized cooling rate of 0.23.

to meet the cooling rates required by the 1998 MN State Food Code (or FDA 2001 Model Food Code). This is indicated in the last column of Table 1 entitled Pass, with an entry of "no." About one-third (6 of 21) of the foods had cooling rates that were less than the linearized Food Code rate (0.23) proposed by Schaffner et al. (26). These six foods are shown in the top six rows of Table 1 and are identified by "slow" in the Speed column. Five of the six foods are soups, and the sixth is mashed potatoes. Not surprisingly, none of these foods met the 1998 MN/FDA 2001 Food Code cooling conditions. The next three rows of Table 1 are identified as "borderline"; they represent foods that had cooling rates just slightly faster than 0.23 but had cooling profiles that did not meet the Food Code requirements. Two of these samples are rice, and the third is deboned turkey. The rice samples missed the upper frame of the cooling profile slightly (\sim 10 min) but easily passed the lower frame (well under 4 h). The deboned turkey exceeded the upper frame by almost 1 h but passed the lower frame by more than 1 h. Most (8 of 9) of the foods in the "slow" or "borderline" rows of Table 1 had product depth greater than or equal to 7.6 cm (3 in.). The three other foods with product depth at or exceeding 7.6 cm (3 in.) were meat broth, steak and potato soup, and Toscana soup, and these foods had a fast cooling rate (>0.23) and met the Food Code cooling parameters. Both soups had assisted cooling, however, using an ice bath and/or ice wand. Most

(18 of 21) of the foods observed in the study were properly ventilated to allow cooling. Three foods were not properly ventilated: vegetable beef barley soup was partially ventilated but had a product depth \geq 7.6 cm (3 in.), cooled slower than 0.23, and did not meet the Food Code cooling parameters; noodles cooled faster than 0.23 but did not meet the Food Code cooling parameters; and chicken wings cooled faster than 0.23 and did meet the Food Code cooling parameters.

Atypical cooling curves results. Table 2 shows the mean cooling rates of foods with atypical cooling curves calculated from 10,000 Monte Carlo simulations and includes other important characteristics of the cooling process: container type, container depth, ventilation, and cooling method. Most (6 of 8) of the foods that were considered to have "atypical" cooling curves, as defined above in "Materials and Methods," failed to meet the Food Code cooling times, as indicated by "no" in the rightmost column of Table 2. Almost all (7 of 8) of these foods used a refrigeration method involving an ice bath and ice wand or both. One-quarter (2 of 8) of the foods with atypical cooling curves had average simulated cooling rates less than 0.23 ("slow" rows of Table 2), but neither met Food Code cooling parameters. Two of the three foods that had average simulated cooling rates of greater than 0.23, but less than 0.28 ("borderline" rows of Table 2), did not meet the Food

b Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

^c Food missed the guideline by only 5 min.

^d Food had somewhat atypical profile due to formation of a surface fat layer during cooling.

TABLE 2. Cooling rate estimates for eight foods with atypical cooling profiles

Food	Cooling rate $(1/h)^a$	Speed ^b	Container	Refrigeration method	Ventilated?	Excess product depth >7.6 cm (3 in.)	Pass ^c
Garlic cream sauce	-0.045	Slow	Metal	Ice bath	Yes	Yes	No
Red sauce	-0.112	Slow	Plastic	Ice bath/walk-in cooler	No	Yes	No
Gumbo soup	-0.249	Borderline	Plastic	Ice bath/walk-in cooler	Yes	Yes	No
Chicken wild rice soup	-0.261	Borderline	Metal	Walk-in cooler	Yes	No	No
Chicken wild rice soup	-0.267	Borderline	Plastic	Ice bath/ice wand/walk-in	Yes	Yes	Yes
Alfredo sauce	-0.285	Fast	Plastic	Ice bath/walk-in cooler	Yes	Yes	No
Red pepper bisque	-0.298	Fast	Plastic	Ice wand/walk-in cooler	Yes	Yes	No
Refried beans	-1.101	Fast	Metal	Ice bath/walk-in cooler	Yes	No	Yes

^a Rates are the mean of 10,000 Monte Carlo simulations where single points were picked from upper and lower parts of the cooling curve and used to estimate cooling rate.

Code cooling parameters. Only one food (red sauce) was not properly ventilated. Two foods (chicken wild rice soup and refried beans) had a product depth <7.6 cm (3 in.). The soup had a borderline simulated average cooling rate (0.26) but did not meet the Food Code cooling parameter, whereas the beans had an acceptable simulated average cooling rate and did meet the Food Code cooling rates.

Table 3 shows the summary statistics from the results of the Monte Carlo simulations used to create cooling rates from foods that had nontypical cooling curves. The table is sorted by the percentage of time that the simulated rate (based on two randomly selected times from the upper and lower portions of the cooling curve) was faster or slower than the rate of 0.23. Note that the only two products that met the Food Code cooling rates also had simulation estimated cooling rates that cooled faster than 0.23 for the greatest percentage of simulations. Other summary statistics were less useful in predicting agreement with Food Code cooling parameters. The mean, median, mode, and 5th and

95th percentiles for the refried beans simulations all show a faster cooling rate than for all the other foods, and the refried beans data set met the Food Code cooling recommendation. Most of these summary statistics were not able to distinguish the chicken wild rice soup data set, which also met the Food Code cooling recommendation. In three or four cases, the mean, mode, or 5th percentile for foods that did not meet the Food Code cooling recommendations showed a faster rate than for chicken wild rice soup, and in one case the mode showed a faster rate. The 95th percentile of simulated cooling rates for one chicken wild rice soup data set and the refried beans data set were greater than all the other food data sets.

COOLING RATE METHOD VALIDATION

Table 3 indicates that the data sets from foods that showed an atypical cooling profile can result in a very wide range of simulated rates, which shows the difficulties in applying a two-point extrapolation to estimate cooling rates for atypical cooling profiles. The nuances of these difficulties can be further elucidated by examining the

TABLE 3. Summary statistics of 10,000 Monte Carlo simulations done on foods with atypical cooling profiles

			Cooling ra					
	Summary statistics			Upper and lov	ver percentiles	Simulation predicted cooling rate relative to $0.23 (1/h)^a$		
Food	Mean	Median	Mode	5th	95th	% slower	% faster	$Pass^b$
Garlic cream sauce	-0.045	-0.120	0.000	-0.166	0.088	99	1	No
Red sauce	-0.112	-0.096	-0.125	-0.205	-0.066	94	6	No
Gumbo soup	-0.249	-0.224	-0.348	-0.417	-0.161	52	48	No
Chicken wild rice soup	-0.267	-0.246	-0.270	-0.481	-0.146	43	57	No
Red pepper bisque	-0.298	-0.272	-0.426	-0.514	-0.166	28	72	No
Alfredo sauce	-0.285	-0.250	-0.226	-0.464	-0.184	24	76	No
Chicken wild rice soup	-0.261	-0.251	-0.186	-0.325	-0.192	18	82	Yes
Refried beans	-1.101	-0.932	-1.522	-2.375	-0.574	0	100	Yes

^a Fractions slower than and faster than the target represent the percentage of rates created that were slower or faster than the recommended cooling rate of 0.23.

^b The speed column identifies foods that cooled slower than the linearized cooling rate of 0.23 proposed by Schaffner et al. (26), foods that are borderline, or foods that cooled faster than the linearized cooling rate of 0.23.

^c Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

^b Pass indicates whether the food met the 2017 MN State Food Code (or FDA 2001 Model Food Code) cooling rates of ≤2 h between 60.0 and 21.1°C (140 and 70°F), and ≤4 h between 21.0 and 5°C (70 and 41°F).

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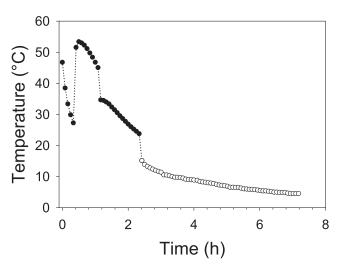


FIGURE 1. Atypical cooling profile for Alfredo sauce. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).

actual cooling profiles, which are shown in Figures 1 and 2 as representative of foods with "unusual" cooling profiles.

In Figure 1, which illustrates the atypical cooling profile for Alfredo sauce, the solid symbols show times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F), and the open symbols show times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F). When the product was removed from the stove, it was placed in an ice water bath, which produced the immediate sharp temperature drop over the first 20 min. At this point, the product was stirred; this raised the temperature being monitored by the probe, producing the sharp spike in temperature back above 50°C. The product remained in the ice bath for approximately 2 h until it was moved to a walk-in cooler set at 2.8°C (37°F). It is not known what produced the temperature shift at approximately 1 h, but it could have been additional stirring of the product that was not recorded. This particular product was stored in a plastic container, and although it was ventilated, the product depth in the container exceeded 7.6 cm (3 in.).

In Figure 2, which illustrates the atypical cooling profile for chicken wild rice soup, the solid symbols show times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F), and the open symbols show times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F). This product was in a plastic container with a product depth exceeding 7.6 cm (3 in.). Temperature monitoring began when the product was placed into an ice bath. The product was allowed to cool for approximately 15 min before it was stirred, which raised the temperature being measured by the thermocouple. The product temperature dropped slowly for the remainder of the hour until an ice wand was used to stir the product. The product was removed from the ice bath and transferred to a walk-in cooler set at 36°F (2.2°C). At approximately 1.5 h, the

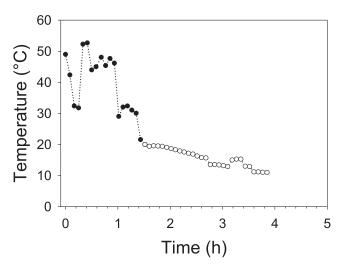


FIGURE 2. Atypical cooling profile for chicken wild rice soup. Solid circles, times and temperatures associated with product temperatures between 60.0 and 21.1°C (140 and 70°F). Open circles, times and temperatures associated with product temperatures between 21.0 and 4.4°C (70 and 41°F).

product was stirred again with a new ice wand, causing another temperature drop, after which the product remained in the walk-in cooler, where it was stirred again at approximately 3 h 15 min, causing another small temperature rise.

Figure 3 shows the distribution of simulated cooling rates from the Alfredo sauce simulation. The x axis shows the cooling rate with a vertical black line at -0.23, the cooling rate that is equivalent to the FDA Model Food Code. The y axis of the top panel represents iterations of the simulation that predict a cooling rate; the height of the gray bar represents the number of iterations for a given rate. Cooling rates to the right of the black line represent rates slower than permitted, whereas cooling rates to the left represent rates faster than permitted. There are a small number of iterations with relatively fast cooling rates, which are not visible in the top panel of Figure 3. These are visible once the y axis is transformed to a log scale, which is shown in the bottom panel of Figure 3. This figure shows that most of the simulations predicted cooling rates that were faster than what is required by code. These results indicate that an inspector using a two-point method on a cooling profile, represented by the Alfredo sauce, would, most of the time, conclude that the product was being cooled at a rate permitted by the code.

Figure 4 shows the distribution of simulated cooling rates from the chicken wild rice soup simulation. The axes and layout are all identical to those from Figure 3. Figure 4 shows a similar pattern to Figure 3, although there is less variability in cooling rates, while the overall distribution is less highly peaked. More of the chicken wild rice soup simulations result in cooling rates that are slower than that required by the code (versus Alfredo sauce), but most of the simulations also predict faster cooling rates than required. As with Figure 3, Figure 4 also shows that if an inspector used the two-point method on a cooling profile represented by the chicken wild rice soup, the inspector would generally

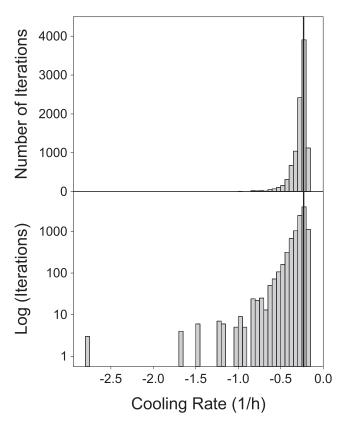


FIGURE 3. Distribution of simulated cooling rates from the Alfredo sauce simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, -0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line are slower than permitted, whereas cooling rates to the left are faster than permitted.

conclude that product was being cooled at a rate permitted by the code.

DISCUSSION

Improperly cooled foods are a major source of foodborne illness. However, it is very difficult to monitor cooling rates of restaurant foods because they occur over \sim 6 h (14), whereas inspectors are typically only present in an establishment for 1 to 2 h. The FDA assessed restaurant food cooling processes in their Retail Risk Factor Study but encountered difficulties because cooling was observed in few retail establishments due to the limited amount of time collectors were able to spend in establishments (29). Schaffner et al. (26) proposed use of a pair of points from the cooling curve to identify fast and slow cooling foods through a mathematical model and correlation of those model estimates with best and worst practices observed in restaurants. Schaffner et al. (26) could not validate their modeling approach because they did not have full cooling profiles. Our current study sought to validate the two-point approach, using full cooling curves as well as observations regarding retail establishment practices.

The data in this study showed that approximately onethird of foods that had "typical" cooling curves had rates that were unacceptable based on Food Code guidelines, which is concerning because improper cooling of foods can

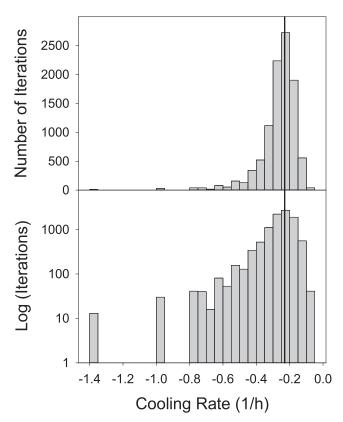


FIGURE 4. Distribution of simulated cooling rates from the chicken wild rice soup simulation. Top panel, distributions of iterations; bottom panel, log (iterations). Vertical black line, -0.23 (1/h), is equivalent to the FDA Model Food Code cooling rate. Cooling rates to the right of the black line are slower than permitted, whereas cooling rates to the left are faster than permitted.

cause foodborne illness. In the remaining cases, the cooling rates created for foods with "typical" cooling curves were in agreement with the 1998 MN Food Code guidelines, which state that foods should be cooled to 21.1° C (70° F) in ≤ 2 h and then to 5°C (41°F) in an additional ≤4 h. Many of these observations showed an estimated cooling rate that was only slightly slower than the Food Code guideline, which suggests that many restaurants may need to make only small changes to their cooling practices to comply with the Food Code guideline. There were few instances of false positives, in which the cooling rate was faster than the recommended rate but failed based on the guidelines recommended by the Food Code. In one instance, the food (noodles) was only 5 min over the 4-h limit to cool from 70 to 41°F (21.1 to 4.4°C), which caused the failure, and in another instance, the food (French onion soup) had a very rapid initial cooling period, cooling from 139 to 70°F (59.4 to 21.1°C) in 1 h 25 min, followed by a very slow period of cooling of 70 to 41°F (21.1 to 5°C) in 4 h 40 min. This soup contained a large amount of butter, which formed a fat layer on top during the cooling process and may have aided in insulating the food and preventing quick cooling. It is concerning to see that the cooling rates can be skewed this heavily by rapid initial cooling stages; however, it seems to be an unusual case, because most foods that have an initial

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rapid cooling phase do not tend to have such a slow secondary cooling phase.

The data show that foods with "unusual" cooling profiles are generally similar to foods that have "typical" cooling profiles, for which the two-point model was, in general, adequately able to determine whether the food would fail based on Food Code guidelines. The mean, median, and mode of the simulations were generally in agreement for all foods, with the mode being much faster or slower than the mean and median in some cases. The results that have the strongest relation to whether or not the food passed the Food Code guidelines is the percentage of simulations that created models faster or slower than the recommended rate: the two foods that passed according to the Food Code guidelines also had the lowest percentage of simulated rates that were slower than the recommended rate. This analysis shows that creating cooling rates using two points from the entire cooling profile should generally create representative cooling rates. The upper and lower percentiles do, however, show that caution needs to be taken in situations where the temperature profile of the food rapidly changes, such as if the food is stirred or rapidly cooled.

The data from Schaffner et al. (26) showed that following the Food Code guidelines (storing foods at shallow depths, ventilating foods, and monitoring cooling) facilitated faster estimated cooling rates. Our data support that the container depth showed a strong correlation to the cooling rate, finding that containers that were ≥ 7.6 cm (3) in.) were more likely to have cooling rates slower than the equivalent FDA Model Food Code cooling rate. Our results show little trend in the effect of the container type (metal or plastic) and cooling method. The effect that the ventilation of the foods has is inconclusive because a very limited number of foods were unventilated during cooling. The effects that observed environmental factors (e.g., refrigerator temperature, use of ice wand or baths) have on the cooling rates are also in agreement with Schaffner et al. (26), and we also recommend that managers monitor these environmental factors as easy ways to improve cooling rates. Some experimental data have also confirmed these observations in the cooling of brown rice (2). These researchers tested various combinations of container depth, cooling method, and container ventilation to determine the effect on cooling rate of brown rice based on the parameters set in the FDA Model Food Code. Their results showed that container depth and ventilation significantly impacted the time that it took for the container to cool from 57 to 5°C (135 to 40°F), consistent with the results from our study. Although some of the conditions they observed did not meet FDA Model Food Code cooling requirements, no significant increases in B. cereus concentration were noted (2).

Some other environmental factors that should be considered include the outside ambient temperature, which has been shown to make the cooling of foods more difficult due to the strain put on refrigeration units (12). Research has shown that repeated opening and closing of refrigeration units, coupled with increased ambient temperature, could lead to increased occurrences of cold-holding violations and, potentially, breakdowns of refrigeration units (12).

Without consistent monitoring (4, 16), there could be a rise in cooling equipment temperature, which could lead to inadequate cooling rates. These studies (as well as another currently in review) also showed that the results of food cooling monitoring were often not recorded anywhere, and that only about 60% of restaurants had verified that their cooling processes adequately cooled the foods in the proper amount of time (4, 16, 17). The methods used in our research may potentially prove to be a simple way to verify that cooling has been completed in an appropriate amount of time, without the need for constant temperature monitoring.

C. perfringens is the pathogen that is most closely associated with foodborne illnesses related to the cooling of foods (1, 21). C. perfringens spores can survive the cooking process, and during inadequate cooling, the spores can begin to germinate and grow to levels that could cause illness (18). C. perfringens is typically associated with the improper cooling of large cuts of meat; however, predictive models have been created for the growth of C. perfringens in many different substrates, such as rice, refried beans, and soups (7, 9, 22, 27). Models have shown that C. perfringens can grow at low temperatures; however, growth rates decrease and lag times increase, meaning the outgrowth of spores would take significantly longer at lower temperatures (10). Because C. perfringens cells need to grow to very high concentrations, foods held at temperatures <70°F (21.1°C) would most likely be much less of a health risk than foods held above this temperature for long periods of time; this shows the importance of proper temperature control, especially at the initial cooling stages. Illness due to B. cereus is also associated with the improper cooling of foods, because spores can survive the cooling process and, subsequently, germinate once the food has cooled (19). B. cereus can grow in a wide range of foods but is typically associated with the improper storage of cooked rice and pastas (20, 24). Predictions from growth models for C. perfringens and B. cereus could be made for the cooling profiles of the foods in this study to further characterize risk from these pathogens during cooling.

This research has confirmed the previous research from Schaffner et al. (26) that showed that simple linear regression models could be created using two temperature points taken from the cooling profile of restaurant foods. Our research elaborated on these models by using similar methods with additional data points, finding very similar results. Caution should be taken for foods that have been recently stirred or placed into a different cooling container, because sudden changes in temperature can cause cooling profiles to not give accurate results, as seen with the "atypical" curves. Our results were also in agreement with findings that simple methods such as reducing container depth size and adequately ventilating foods can easily help properly cool foods after cooking. The methods laid out in this paper and previous works may allow for a simple way for inspectors and operators to verify that cooling methods are adequate to conform to FDA Model Food Code guidelines without the need for lengthy periods of monitoring.

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GUEST COMMENTARY



Tools and Techniques to Promote Proper Food Cooling in Restaurants

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Abstract slow cooling of hot foods is a common pathogen proliferation factor contributing to restaurant-related outbreaks. The Food and Drug Administration (FDA) model Food Code provides guidelines on the time and temperatures needed for proper cooling and recommends several methods to facilitate rapid food cooling. Restaurants continue to struggle with proper cooling even given these guidelines (Hedeen & Smith, 2020). Research summarized in this guest commentary indicates that portioning foods into containers with a depth of <3 in. and ventilating the containers during the cooling process promote rapid cooling. Restaurant operators and health department inspectors could use these cooling methods to maximize cooling efforts. Additionally, a simple method (using a mathematical equation) could help restaurant operators and inspectors to estimate the cooling rates of foods. This simple method uses only two food temperatures taken at any two points in the cooling process (using the equation [Log(T, - T_{HF}) - Log $(T_1 - T_{HF})$]/ δt) to estimate whether the food is expected to meet FDA cooling guidelines. This method allows operators and inspectors to identify foods unlikely to meet FDA guidelines and take corrective actions on those foods without having to monitor food temperatures for the entire cooling process, which typically takes 6 hr. More research is underway to further refine aspects of this method.

Introduction

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen proliferation factors contributing to restaurant-related outbreaks (Gould et al., 2013). Of the 251 outbreaks that occurred during 2014–2016, 10% had improper cooling as a

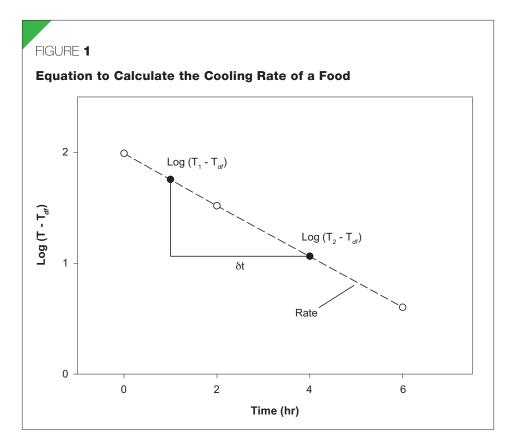
contributing factor to the outbreak (Lipcsei et al., 2019). Hot foods should be cooled rapidly to minimize pathogen proliferation and subsequent foodborne illness risk.

The Food and Drug Administration (FDA) model *Food Code* (Section 3-501.14) provides guidelines for retail and foodservice establishments to cool foods classified as needing time and temperature control for safety. These

guidelines state that foods must be cooled from 135 °F (57 °C) to 70 °F (21 °C) within 2 hr, and from 135 °F (57 °C) to 41 °F (5 °C) within a total of 6 hr or less (U.S. Department of Health and Human Services, 2017). To help reduce foodborne illness risk, the Food Code also recommends several methods to promote rapid food cooling. These methods include separating food into smaller portions; stirring food in a container placed in an ice water bath; adding ice as an ingredient; and placing food in shallow pans, in containers that promote heat transfer, and in rapid cooling equipment. Even with these guidelines, restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020). And as a model code for regulating retail and food service establishments, the Food Code does not specify how to apply cooling methods in varying situations or whether some methods are better than others.

The Food Code recommends that retail food establishments verify that their cooling practices are effective as well as monitor and record food temperatures during the cooling process, but research suggests that many establishments do not always engage in these practices (Brown et al., 2012; Hedeen & Smith, 2020). A study by FDA (2018) found that cooling practices did not meet FDA guidelines at least once in 72% of 273 full-service restaurants where cooling was observed.

Cooling is difficult for operators and inspectors to assess because of the time required to adequately monitor the cooling process. Restaurant operators work in a dynamic and busy environment, and fre-



quent monitoring of temperatures is not always feasible. Multiple factors influence an operator's ability to monitor food temperatures to ensure proper cooling. These factors can include insufficient staffing, the time of day foods are cooled (e.g., early or late shifts), and how busy a restaurant is throughout the day (Green & Selman, 2005). Inspectors are typically in an establishment for fewer than the 6 hr needed to document proper cooling. Other options for assessing proper cooling include discussions with the restaurant manager, review of temperature logs to determine cooling start time, and subsequent comparison with food time and temperatures taken during the inspection. Use of thermocouples and data loggers for later retrieval or returning later in person to continue the inspection and check temperatures are other options, although inspectors cannot always conduct multiple visits to an establishment during a day. Focusing on specific cooling methods, rather than the full cooling process, might be another way to identify cooling issues during routine inspections.

Identification of practices that best promote proper food cooling can support operators and inspectors in their efforts to cool

food properly. Research conducted by the Centers for Disease Control and Prevention's Environmental Health Specialists Network (EHS-Net), Rutgers University, and the Minnesota Department of Health has identified two common themes described next regarding cooling methods that ensure proper cooling (Hedeen & Smith, 2020; Igo et al., 2021; Schaffner et al., 2015).

Shallow Depth and Ventilation

Schaffner et al. (2015) examined 596 food items being cooled in refrigerators in 410 restaurants. They measured the temperature of these foods at two time points, approximately 80 min apart, and used modeling to determine the cooling rates and compliance with *Food Code* guidelines. Foods not actively monitored by food workers were more than twice as likely to cool more slowly than recommended in the *Food Code*. Foods stored at a container depth >3 in. were twice as likely to cool more slowly than specified in the *Food Code*. Moreover, unventilated foods were almost twice as likely to cool more slowly than specified in the *Food Code*.

Hedeen and Smith (2020) used data loggers to collect time and temperature data points at 5-min intervals for 34 cooling food items. They plotted the data points to form a cooling curve for each food item. They then assessed the cooling curves of the foods and found that those cooled in containers with a depth <3 in. were more likely to meet the first cooling parameter (i.e., 140 °F to 70 °F within 2 hr) than those cooled in containers with a depth ≥ 3 in. (p = .035). As almost all the food items in this study were ventilated, the relationship between ventilation and cooling rates was not evaluated. Using these same cooling curves, Igo et al. (2021) also found that food depth has a strong influence on cooling and verified that containers with a food depth ≥ 3 in. were more likely to have cooling rates slower than the cooling rate specified in the Food Code.

Using containers with a depth of <3 in. and ventilating foods during refrigerated cooling (as recommended in Section 3-501.15 of the *Food Code*) are simple ways for operators to maximize cooling efforts. They also serve as indicators for inspectors to assess cooling at restaurants. The extra space needed to use shallow pans and ventilation is a potential drawback; to address this drawback, restaurants could small-batch recipes or use speed racks in walk-in coolers.

Two-Point Temperature Monitoring

Schaffner et al. (2015) identified a simple two-point method to measure cooling rates in restaurants and identify cooling issues. This method was developed using on-site observations of cooling food times and temperatures. Operators and inspectors can use this method to quickly determine if the cooling method used is expected to cool foods properly before the entire 6-hr period has elapsed.

The equation to calculate the cooling rate of a food is $[Log(T_1 - T_{df}) - Log(T_2 - T_{df})]/\delta t$, where T_1 and T_2 are any two temperatures measured during the cooling process, T_{df} is the driving force temperature (i.e., the temperature of the cooling environment), and δt is the time between the two temperature measurements (Figure 1). When the temperature and time values from the *Food Code* guidelines for food cooling results are plugged into this equation, and a driving force of 37 °F is assumed, this produces the best fit (i.e., highest R^2 value). The slope of this best-fit line equates to a cooling rate of 0.23 when time

is measured in hours (or 0.0039 when time is measured in minutes). Thus, a food with a cooling rate faster or equal to 0.23 would meet *Food Code* recommendations, but a rate slower than 0.23 would not (Igo et al., 2021; Schaffner et al., 2015). Under some circumstances, the driving force will not be constant, which can influence the cooling rate estimate.

Igo et al. (2021) used cooling curves for 29 different foods that were collected in 25 different restaurants to verify the two-point rate calculation method. Cooling curves were divided into two categories: typical and atypical. Curves were considered atypical when they had many dips and peaks, which are typically caused by stirring the food or changing the cooling method. Most cooling curves (21 out of 29) were considered typical (i.e., log linear rate changes with time). Atypical cooling curves (8 of 29) had non-log linear rate changes with time resulting from stirring or other factors.

Almost all typical cooling curves identified had highly predictable cooling rates (Igo et al., 2021). Among 9 foods with typical cooling curves that did not meet the cooling times recommended in the Food Code, the two-point model identified 6 as having slow cooling rates and 3 as having marginal cooling rates; among 12 foods identified by the two-point model as having acceptable cooling rates, 10 met the cooling times recommended in the Food Code. Among 8 foods that were considered to have atypical cooling curves, 6 failed to meet the cooling times recommended in the Food Code. These findings indicate that for most foods that are cooling at a steady rate (e.g., not stirred, not moved to a different environment), taking only two temperature measurements at any point in the cooling process should reliably indicate whether the food is going to meet the cooling guidelines in the *Food Code*.

During routine inspections, this two-point method could help inspectors identify cooling issues. Specifically, when inspectors see a food item cooling, they could note an initial time and temperature of the food. Then they could take a second temperature reading, preferably at the end of their inspection to allow for the greatest elapsed time between the two temperature readings. The simple equation described previously would enable inspectors to estimate the cooling rate. They could use the calculated rate to determine whether the cooling rate of the food is predicted to follow the recommendations in the Food Code. Inspectors could use this tool to educate restaurant operators. If the equation predicts that a food will not cool within the guidelines of the Food Code, the inspector could discuss alternative cooling methods with operators and develop a plan for properly cooling the food. Operators could also use this method to help verify whether their cooling process is effective or to evaluate the effect of changes in their process.

Additional research is needed to potentially determine ideal times during the cooling process when inspectors should take the two temperature readings (i.e., between 135 °F and 70 °F and then again after the food is below 70 °F). Differences in time between the two temperature measurements also might affect the outcome (e.g., are measurements 60 min apart better than measurements 15 min apart?).

Foodborne disease outbreaks resulting from improper cooling continue to occur

(Lipcsei et al., 2019). Proper cooling is sometimes difficult for restaurants to accomplish and for inspectors to verify. Although the Food Code provides valuable information on suggested cooling methods, beyond specifying to monitor temperatures, it does not provide guidance on determining how cooling is to take place. Logging continuous time and temperature data is an ideal way to determine if foods are cooled correctly, but this process is not always practical for operators or inspectors. Portioning foods into containers with a depth <3 in. and ventilating them during the cooling process are best practices that can promote rapid cooling and that restaurants can easily apply. As described in this study, calculating cooling rates to determine if foods meet FDA Food Code recommendations is one way that operators and inspectors can determine if a cooling method can be expected to work without having to monitor a food for the entire 6-hr cooling process. More research is underway to further refine aspects of this method.

Disclaimer: The findings and conclusions in this guest commentary are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry.

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Did You Know?

NEHA is a partner association of the Retail Food Safety Regulatory Association Collaborative, a group of agencies and associations working to reduce the incidence of foodborne illness at the retail level. The Collaborative has posted a variety of resources including a toolkit to help jurisdictions adopt the latest editions of the Food and Drug Administration Food Code, an assessment of the impact of active managerial control incentive programs, an interactive map of Food Code adoption by state, and more. Check it out at www.retailfoodsafetycollaborative.org.

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Operational Antecedents Associated with *Clostridium* perfringens Outbreaks in Retail Food Establishments, United States, 2015–2018

Beth C. Wittry, 1,i Meghan M. Holst, 1 Janet Anderberg, 2 and Nicole Hedeen 3

Abstract

Clostridium perfringens is a common foodborne pathogen, frequently associated with improper cooking, and cooling or reheating of animal products. The U.S. Food and Drug Administration Food Code outlines proper food preparation practices to prevent foodborne outbreaks; however, retail food establishments continue to have C. perfringens outbreaks. We qualitatively analyzed responses to two open-ended questions from the National Environmental Assessment Reporting System (NEARS) to understand patterns of unique circumstances in the retail food establishment that precede a C. perfringens outbreak. We identified three environmental antecedents, with three subcategories, to create nine operational antecedents to help explain why a C. perfringens outbreak occurred. Those antecedents included factors related to (1) people (a lack of adherence to food safety procedures, a lack of food safety culture, and no active managerial control), (2) processes (increased demand, a process change during food preparation, and new operations), and (3) equipment (not enough equipment, malfunctioning cold-holding equipment, and holding equipment not used as intended). We recommend that food establishments support food safety training and certification programs and adhere to a food safety management plan to reduce errors made by people and processes. Retail food establishments should conduct routine maintenance on equipment and use only properly working equipment for temperature control. They also should train workers on the purpose, use, and functionality of the equipment.

Keywords: foodborne outbreak, *Clostridium perfringens*, retail food, environmental health

Introduction

CLOSTRIDIUM PERFRINGENS, the third-most common foodborne pathogen, causes around 1 million foodborne illnesses each year in the United States (Scallan *et al.*, 2011). *C. perfringens* is a bacterium found on raw animal products and produces spores that form a coating to help it survive cooking. When food is kept at unsafe temperatures during cooking, cooling, and holding processes, *C. perfringens* can proliferate (Smith-Simpson and Schaffner, 2005). Proper reheating can kill *C. perfringens* that survived the original cooking process or multiplied during improper cooling (Taormina and Dorsa, 2004).

Data obtained from investigations of *C. perfringens* outbreaks provide important insights into the prevention of *C. perfringens* illness; these data can identify food preparation practices and circumstances that lead to illness. For example, the Centers for Disease Control and Prevention's (CDC) outbreak investigation data indicate that *C. perfringens* outbreaks are commonly associated with foods prepared in large quantities (CDC, 2018).

The U.S. Food and Drug Administration (FDA) Food Code contains food safety guidelines intended to reduce foodborne illness risk from pathogens, such as *C. perfringens*, in retail food establishments. The Food Code lists specific time and temperature ranges for proper cooking, holding, cooling, and

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reheating (FDA, 2017b). Despite these guidelines and our increased understanding of the foods and practices associated with *C. perfringens* outbreaks, illnesses and outbreaks continue to occur (Hedeen and Smith, 2020).

Understanding environmental antecedents, the root causes, to *C. perfringens* outbreaks can help us prevent future outbreaks. Environmental antecedents are factors in the environment that ultimately lead to pathogen contamination, proliferation, or survival to cause an outbreak (CDC, 2015).

We examined data from the National Environmental Assessment Reporting System (NEARS), a voluntary reporting system that some state and local environmental health regulatory programs use to report data to the CDC from their investigations of retail food establishment outbreaks (CDC, 2019). NEARS data from *C. perfringens* outbreak investigations describe the environment in which the outbreaks occurred and can identify outbreak antecedents (Lipcsei *et al.*, 2019). This study analyzed these data to better understand environmental antecedents of *C. perfringens* outbreaks. These data were used to identify operational antecedents of outbreaks, or the actions or factors that occur during food operations that explain the survival or proliferation of pathogens in food.

Methods

The NCEH/ATSDR Human Subjects Contact has reviewed this data collection system and determined that it is not research and does not require CDC Institutional Review Board (IRB) review. Ten state and local health departments reported 41 confirmed or suspected *C. perfringens* outbreaks that occurred from 2015 to 2018 to NEARS. We excluded seven outbreaks that were missing 75% or more NEARS data. The final data set consisted of 34 single-setting retail food establishment outbreaks that occurred in Connecticut, Georgia, Iowa, Minnesota, New York, Rhode Island, South Carolina, Tennessee, Washington, and Wisconsin.

During their investigations, environmental health staff interview outbreak establishment managers about establishment characteristics (e.g., food safety policies and practices that might have contributed to the outbreak). They also observe worker food preparation, especially of items suspected to be associated with the outbreak. Afterward, investigators report selected information and observations from their investigations to CDC through the NEARS web-based reporting system (Brown *et al.*, 2017; Lipcsei *et al.*, 2019).

Our analysis focused on qualitative data collected from two open-ended questions investigators answered about the outbreak establishments' food operations after they completed their establishment observations:

- (1) Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?
- (2) During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?

The first question was designed to identify differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. If the investigation implicated a food item associated with the outbreak, investigators also answered the second question. These questions were asked because research suggests that unusual circumstances frequently precede outbreaks (World Health Organization, 2008). Understanding these circumstances can enhance our understanding of outbreak antecedents.

Analysis

We first calculated descriptive statistics on several outbreak and establishment characteristics collected through manager interviews and establishment observations to describe our sample (Table 1). We then conducted a qualitative analysis of the data from the two open-ended questions about differences in establishment operations at the time of *C. perfringens* exposure. We used the grounded theory

Table 1. Outbreak and Establishment Characteristics of *Clostridium perfringens* Outbreaks, United States, 2015–2018 (*N*=34)

Characteristic	n (%)
Agent $(N=34)^a$	
Suspected	20 (58.8)
Confirmed	14 (41.2)
Primary contributing factor ^{b,c} $(n=32)$	
Contamination (ii 32)	2 (6.2)
Proliferation	29 (90.6)
Survival	1 (3.2)
When the primary contributing factor occurred	(n=32)
Before food vehicle entering establishment	1 (3.2)
While food vehicle was at the establishment	26 (81.2)
After food vehicle left the establishment	5 (15.6)
Establishment type ^d $(N=34)$	
Complex	34 (100.0)
Cook–Serve	0 (0.0)
Preparation-Serve	0 (0.0)
Facility type ^c $(N=34)$	
Caterer	4 (11.8)
Mobile food unit	2 (5.9)
Restaurant	28 (82.3)
Ownership type ^d $(N=25)$	
Independent	21 (84.0)
Chain	4 (16.0)
Meals per day ^d $(N=24)$	
≤100	11 (45.8)
>100	13 (54.2)
Menu type ^c $(N=34)$	
American	11 (32.3)
Latin	14 (41.2)
Other	9 (26.5)
Critical violations on last inspection ^e $(N=34)$	
0–1	19 (55.9)
2–9	15 (44.1)

^aObtained from investigators' epidemiology and laboratory counterparts.

^bContributing factors are food preparation practices that lead to pathogens contaminating, proliferating, and surviving in food.

Environmental health investigator determination.

^dData obtained from the investigator's interview with the establishment manager.

^eCritical violations are those more likely to contribute to the contamination of food or the proliferation or survival of the pathogens if not corrected. These are determined on a routine inspection and unrelated to the foodborne outbreak.

approach, in which we identified patterns and groupings in the qualitative data using inductive reasoning (i.e., from the "ground up") (Corbin and Strauss, 1990). The food system environmental antecedent conceptual model was used to categorize the data; researchers have theorized that five main variables of environmental antecedents influence food safety in establishments (Selman and Guzewich, 2014):

- (1) People (characteristics and attitudes of people working in the establishments)
- (2) Processes (characteristics of the processes used to prepare food and food preparation complexity)
- (3) Economics (costs and profit margins)
- (4) Equipment (the physical layout and equipment of establishments)
- (5) Food (the inherent qualities of food prepared in establishments)

Two independent coders reviewed the raw text responses to the two open-ended questions with other NEARS variables to obtain a comprehensive view of the outbreak; they identified environmental antecedent themes based on the above model. They then again reviewed the raw text responses and further grouped the environmental antecedents into subcategories for each theme, or operational antecedents, applying theoretical comparison coding. For each review of the data, the coders independently identified their antecedents and then compared them. If the coders differed in their groupings, they each reviewed the data again, repeating this process until they reached a consensus. The final framework consisted of three environmental antecedents and nine operational antecedents (Fig. 1).

Results

Outbreak and establishment characteristics

In 41.2% of the outbreaks, the pathogen was confirmed in one or more clinical or environmental samples (Table 1). The primary outbreak contributing factor was pathogen proliferation (90.6%) and occurred while the food was at the establishment (i.e., during food preparation) (81.2%). Most of the outbreak establishments were restaurants (82.3%) and independently owned (84.0%). The majority served more than 100 meals per day on average (54.2%) and had a menu type classified as Latin cuisine (41.2%).

Among the outbreak establishments, 44.1% had two or more critical violations (i.e., violations more likely to contribute to pathogen contamination, proliferation, or survival) on their last routine inspection. All establishments engaged in complex food processes (i.e., food preparation requiring a kill step and holding beyond same-day service or a kill step and some combination of holding, cooling, reheating, and freezing). These processes present a higher risk for bacterial contamination, proliferation, and survival.

For 13 outbreaks (38.2%), investigators answered the question about differences or unusual circumstances in establishment operations during the time customers were exposed to *C. perfringens*. For 32 outbreaks (94.1%), investigators answered the question about differences from ordinary operating procedures at the time customers were exposed, as described by managers or workers. A qualitative analysis of these responses (see Table 2 for text excerpts) yielded the identification of three categories of antecedents:

people, processes, and equipment. Further analysis of these antecedents led to nine operational antecedents. Although the antecedents of food and economics were considered, analysis found they were not applicable to this data set.

Antecedents related to people

People antecedents were identified in 27 outbreaks (79.4%). All three operational antecedents in this category were related to workers' failure to follow food safety practices to prevent pathogen survival and proliferation.

- (1) In 15 outbreaks (55.6%), workers did not follow established food safety procedures designed to control bacterial survival and proliferation. In some of these outbreaks, investigators noted that the establishments had formal food safety procedures, but workers were not following them. For example, during one investigation, some pieces of meat required three attempts at reheating to achieve the proper internal temperature even though the establishment's process was to reheat only once.
- (2) A lack of food safety culture (i.e., the values, shared assumptions, and behaviors of workers) anteceded eight outbreaks (29.6%); examples included a documented pattern of poor inspections, long-standing critical violations, and a history of outbreaks. This antecedent is characterized by multiple, consistent poor food safety practices. For example, one investigator noted that the establishment was "in the exact same (poor) condition as during a previous norovirus outbreak investigation." Many establishments had multiple temperature issues; one investigator said, "there is a history of repeated temperature violations, including reheating, cold holding, hot holding and room temperature storage noted on 3 consecutive visits in the last 8 months."
- (3) A lack of managerial control, or food safety supervision, to ensure adherence to food safety policies or processes was mentioned for four outbreaks (14.8%). In one outbreak, the manager was on leave at the time of the outbreak and many workers did not show up to work, leaving the establishment short-staffed and vulnerable to food safety errors. In two outbreaks, untrained persons were responsible for food safety at a catered event; they did not ensure that food temperatures were monitored and controlled.

Antecedents related to processes

At least one process antecedent was identified in 14 outbreaks; a total of 18 process antecedents (52.9%) were associated with these outbreaks. All three categories in this antecedent theme were characterized by insufficient processes to control foodborne pathogens.

(1) In 11 of the outbreaks with process issues (61.1%), preparation of the implicated food item differed from the establishment's normal procedure. For example, in one establishment, time constraints caused by the late arrival of a food item led to suspension of standard preparation processes. Other observations included workers using ineffective cooling procedures (e.g., inappropriate food depth, cooling at room temperature), and failing to verify temperatures during cooling.

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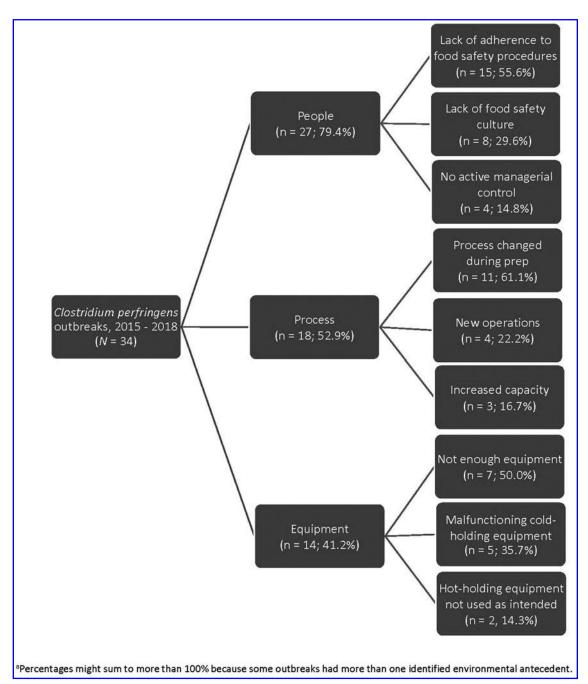


FIG. 1. Operational antecedents in *Clostridium perfringens* outbreaks, National Environmental Assessment Reporting System, 2015–2018 (*N*=34).

- (2) A new circumstance, such as a new establishment, food preparation process, or event type, was mentioned for four outbreaks (22.2%). For example, an establishment prepared a large roast for a holiday buffet, but the staff were not familiar with the proper procedure of cooking and holding this item. One establishment (which did not have a permit to operate) stored food in "a car from 6:00 a.m. to 6:00 p.m.," and neglected to ensure that time or temperature parameters were met.
- (3) Increased capacity led to three outbreaks (16.7%). Because of increased demand, these establishments

exceeded their typical operational volume and were unable to manage food safety risks. For example, one establishment experienced an extremely busy night, during which they prepared large quantities of food for a large number of people in a short time.

Another establishment catered three events on the same night. The investigator noted that "this is an unusually large amount of food for the establishment, a higher volume of food being prepared in the establishment at one time." These establishments were not equipped to handle the increased volume and had difficulty properly cooling the food.

TABLE 2. TEXT EXCERPTS FROM TWO OPEN-ENDED QUESTIONS **Operational** Theme antecedent Selected text excerpts People Lack of While cold and hot holding temperatures are monitored and recorded, cooling, cooking and adherence to reheating temperatures are not being monitored or recorded. During the environmental food safety assessment, it was observed that some larger pieces of the carnitas required three attempts at reheating in the fryer to reach an internal temperature of 165°F. The normal procedures establishment process is to only to fry once, then place in team table, without verifying internal temperature of pork before hot holding. Chicken was partially cooked then stored at room temperatures, then improperly cooled, stored at room temperature again, stir-fried to order. Lack of food Improper cooling and hot holding of beans. Hot holding has been an ongoing problem at this safety culture facility. Cold holding problems regularly observed. Here is a history of repeated temperature violations – including reheating, cold holding, hot holding, and room temperature storage noted on three consecutive visits within the last 8 months. Establishment is in the exact same poor condition as during a previous noro outbreak investigation. Noncontinuous cooking done improperly, RTS of foods, improper cooling of foods, unclean equipment and utensils used. Many foods found improperly cooled, undercooked, crosscontaminated. No active Kitchen manager was on vacation, many workers did not show up for shift. Operating without managerial hot water, cold hold units not maintaining proper temperature. control The caterer had no other reports of issues from food served to other customers from the same pork that day. Also, the food was for a graduation party and most likely left out for an extended period of time. Process Process changed Managers said they were cooling with ice, but multiple large containers of food found out of during temp. In walk-in cooler-hadn't cooled properly and were covered. Items discarded. preparation Unusually large batch of pork was cooled improperly in large containers, in a walk-in cooler that was undersized, slow reheat. No temps recorded at any point in process. New operations This is the first time that the facility prepared the large steamship round roast for the easter Warm food stored in a car from 6:00 a.m. to 6:00 p.m. Cooking/cooling in an unpermitted kitchen-caterer. The firm does not normally cater events. The cooking process for this event did not involve a cool step for food prepared for the event. Cook serve only. Caterer had three large events to provide food for on the same evening, this is unusually large Increased amount of food for him—higher volume of food being prepared in the establishment at one capacity time—unusually large batch of pork was cooled improperly in large containers, in a walk in cooler that was undersized, slow reheat. No temps recorded at any point in process. Very large quantities of food prepared for large number of people over a short time Food was placed in cardboard boxes and transported without appropriate temperature control. Not enough Hot holding units were not functioning properly or adequately for food capacity. equipment The food establishment has insufficient cold storage space for the amount of food preparation they do for events. Most foods are prepared the day before and many hot foods are kept in a small reach in cooler. Malfunctioning Walk-in was being repaired due to temperature issues on the meal date in question which may cold-holding have contributed to time/temperature abuse of food items. equipment Deep pan cooling, covered cooling, cooling in broken refrigerator. (1) Rice improperly cooled in deep pans stored in a broken refrigerator at 65°F. (2) Goat was cooled in deep pan and broken refrigerator then cold held in 65°F refrigerator. Reheated for service. Slow cooling at room temperature and in a broken refrigerator of both rice and chicken. (1) After thawing, chicken is partially cooked, then cooled in malfunctioning refrigeratorreheated to order. No temperatures taken. (2) Rice held in steamer overnight—unattended and improperly cooled in bags in a malfunctioning refrigerator then microwaved to order. Hot-holding Phfs stored in turned off oven, sometimes overnight. Continued history of hot holding, cold holding, and reheating of phfs. (1) Beans stored in the turned off oven. Room temperature equipment not used as storage followed by inadequate reheating. (2) Cooked carne asada held on the grill inadequate hot holding. (3) Ground beef held in the oven (turned off) at unsafe intended temperatures. Room temperature storage followed by inadequate reheating. (4) Rice hot held at 118°F. Extra rice held in the turned off oven followed by inadequate reheating. Roasts were stored in nonmechanical holding units for transport. Followed by inadequate reheating and hot holding of roasts at food service location. The establishment did not properly hot hold the hamburgers. Hamburgers were held in

cambros that did not plug in and were meant for transport only.

Were there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?

During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and/or workers?

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Antecedents related to equipment

Equipment antecedents were identified in 14 outbreaks (41.2%). Retail food equipment includes cold-holding (e.g., refrigerators, freezers) and hot-holding equipment (e.g., bainmarie or hot-holding cabinets), and food storage and insulated transportation containers. The three categories in this antecedent theme were related to failure of equipment intended to prevent bacterial growth in food.

- (1) In seven outbreaks (50.0%), the establishment did not have enough equipment or used inappropriate alternatives to approved equipment for food storage or holding. For example, in one outbreak, food was transported in cardboard boxes, which lacked appropriate temperature control, instead of in insulated or temperature-controlled units. In addition, in five outbreaks, investigators reported that the cold- or hotholding equipment used was not large enough for the establishment's operational demand.
- (2) Malfunctioning cold-holding equipment that did not keep food cold enough to minimize pathogen proliferation anteceded five outbreaks (35.7%). Several investigators reported that establishments were using inoperable or malfunctioning refrigerators for cooling and storing hot foods. One investigator stated that the establishment's "walk-in was being repaired due to temperature issues on the meal date in question."
- (3) Hot-holding equipment was not used as intended in two outbreaks (14.3%). Thus, foods were not held at temperatures hot enough to control pathogen proliferation. For example, one establishment held hot foods in an oven without power; another used containers designed for food transportation, rather than for maintaining appropriate temperatures, to hold hot foods.

Discussion

This qualitative analysis identified three environmental antecedents of *C. perfringens* outbreaks—people, processes, and equipment—which break down further into nine operational antecedents. These antecedents led to inadequate temperature control of food, which led to *C. perfringens* survival and proliferation in food and subsequent outbreaks among those who ate the food. Our findings suggest that establishments and regulators should consider focusing outbreak prevention efforts on workers, food preparation processes, and equipment used to prepare, store, and serve food.

People

Overall, most outbreaks had a people operational antecedent characterized by workers' lack of adherence to food safety procedures. In some outbreaks, workers did not follow established food safety procedures. This oversight could be attributed to several factors, including a lack of food safety culture, a lack of knowledge about proper procedures, and feelings of "burn-out" (Powell *et al.*, 2011; Sahin, 2012).

Some research indicates that establishments with higher frequencies of regulatory inspections are less likely to be associated with foodborne outbreaks (Kufel *et al.*, 2011). Regulatory programs might consider providing additional

support to establishments with a pattern of poor inspections, long-standing critical violations, or a history of outbreaks. FDA data indicate that cooling violations are among the most common problems noted by inspectors in restaurants that engage in complex food preparation practices (FDA National Retail Food Team, 2018). Regulatory programs might consider developing a better understanding of complex food preparation to identify risks and target worker training.

Establishment workers with food safety training or certification have greater food safety knowledge than those without (Hedberg *et al.*, 2006; Sumner *et al.*, 2011; Brown *et al.*, 2014, 2016; Hoover *et al.*, 2020). Inspectors could educate managers about the public health reasoning behind food safety errors to empower managers to train other workers. By providing a train-the-trainer approach, establishments might be more likely to follow sustainable food safety practices to prevent risk factors and avoid errors.

Certification and training alone are likely not sufficient to control all foodborne risks. Active managerial control and a strong food safety management system, such as a hazard analysis critical control point (HACCP) plan, are strategic approaches to reduce food safety errors (FDA, 2017a). Corrective actions, including monitoring and recording of food temperatures, or the critical limits of critical control points, and the verification of the HACCP plan, are essential steps to ensure safe food. Regulatory programs and the restaurant industry should consider supporting food safety training and certification programs and active managerial control, cultivation of a food safety culture, and the use and verification of a robust food safety management system.

Process

Standard food preparation processes were not followed at many outbreak establishments; instead, a different process that contributed to food temperature abuse and pathogen proliferation was used. Often, these differences resulted from unusual circumstances, such as preparation of larger food amounts than usual and increased customer volume. Ensuring that workers follow their establishment's procedures, rather than revising processes (e.g., taking shortcuts) regardless of unusual circumstances, is key to outbreak prevention.

Studies show that proper cooling is critical to avoiding *C. perfringens* proliferation and that cooling errors are a common cause of *C. perfringens* outbreaks (Kalinowski *et al.*, 2003; Smith-Simpson and Schaffner, 2005; Hedeen and Smith, 2020). Research suggests that many establishments do not follow proper cooling procedures (e.g., no recording or verification of cooling processes) (Brown *et al.*, 2012; Hedeen and Smith, 2020). Establishments can help prevent *C. perfringens* proliferation by monitoring temperatures during cooling and taking corrective actions when temperatures are not met.

The use of HACCP principles to develop a risk control plan can help establishments identify process failures to avoid pathogen proliferation (FDA, 2017a). If process parameters (i.e., time and temperature) are too difficult to use, managers could consider using physical parameters, such as cooling pan depth, to ensure proper cooling. For example, one jurisdiction assesses whether foods are cooled using procedures likely to ensure rapid cooling (uncovered in

shallow [≤2 inches] containers), rather than assessing time and temperature. This alternative method can help ensure proper cooling and increase verification efficiency for inspectors and operators (Oravetz, 2019).

Equipment

Equipment operational antecedents included a lack of or improper equipment for food storage and holding. Ensuring that an establishment has proper equipment for these processes requires an understanding of the establishment's operational capacity, which is based on the volume of complex preparation food items and the capacity and functionality of existing equipment. Other equipment issues included malfunctioning cold-holding equipment and improper use of hotholding equipment.

Hedeen and Smith (2020) recently found that improper cooling procedures and inadequate equipment are prevalent in the retail food industry. Research has also found that equipment problems are the most common barrier to holding food properly in restaurants (Green and Selman, 2005), restaurants with sufficient refrigeration capacity were more likely to have properly cold-held food (Liggans *et al.*, 2019), and restaurants with multiple refrigerators had a lower likelihood of bacterial outbreaks (Kramer, 2019).

Equipment issues also could be related to the antecedent theme of economics. Financial challenges might limit establishments' ability to buy new equipment or maintain existing equipment. The role that economics plays in outbreaks is difficult for outbreak investigators to evaluate. They might not understand establishments' financial situations and are likely unable to collect economic data (e.g., profit margins). Further research is needed to understand and identify economic antecedents to outbreaks.

To help prevent equipment antecedents to *C. perfringens* outbreaks, establishments can conduct routine maintenance of equipment used for temperature control and worker training on proper equipment use and maintenance. Regulators can also assess equipment during routine inspections to ensure it meets the establishment's capacity and operational requirements and to verify that workers know how to properly use and maintain the equipment.

Limitations

The generalizability of this study's findings is limited because the sample is only a subset of all *C. perfringens* outbreaks—outbreaks investigated by state and local agencies that report to NEARS. The qualitative data we analyzed consisted of observations and perspectives of the investigator, which might be influenced by their unique experiences. Therefore, the investigative approach and outbreak explanation might vary between investigators and reporting sites. The results are qualitative and should not be generalized to a larger population in any statistical sense. However, these results can be useful for guiding future work in food safety.

Conclusion

Data on outbreak operational antecedents can inform food safety interventions to prevent future foodborne outbreaks. We recommend that retail food establishments and regulators educate workers about why food safety tasks are performed. This will help instill a culture of food safety and support use of sustainable and robust food safety management systems.

We also recommend incorporating principles of HACCP, a prevention tool used to prevent foodborne outbreaks and correct process failures, to verify food safety processes at establishments. Finally, regulators and establishments can train workers to use equipment properly and to determine when corrective actions are required to avoid equipment failures that contribute to pathogen proliferation and survival. More research will help to further understand the underlying antecedents of *C. perfringens* outbreaks and prevent them.

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Disclosure Statement

No competing financial interests exist.

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December 14, 2022

Nicole Hedeen Senior Epidemiologist Minnesota Department of Health

Dear Ms. Hedeen:

On behalf of the National Restaurant Association, this letter is to express our support of the proposed revision to Section 3-501.14(B) of the Food and Drug Administration's Model Food Code. Specifically, we support the concept of allowing for "shallow layering" of foods being actively cooled. We acknowledge that this will be presented as an Issue to the 2023 Conference for Food Protection.

The data you have shared show a correlation between this method of cooling and control of *Bacillus cereus* and *Clostridium perfringens* – both spore-forming bacteria that can cause public health concern when cooling foods. Additionally, the data suggest that this method is safe and allows for easier management of actively cooling foods within a restaurant setting.

The National Restaurant is the largest foodservice trade association in the world. We represent and advocate on behalf of more than 500,000 restaurant businesses. Our mission is to serve our industry and impact its success. We strengthen operations, mitigate risk, and develop talent; advance and protect business vitality through national, state, and local advocacy; and drive knowledge and collaboration.

Thank you for sharing the data you have collected and thank you for your efforts to promote and protect public health and food safety.

Sincerely,

Patrick L Guzzle

Patrick L Guzzle
Vice President, Food Science
National Restaurant Association



July 29, 2022

Taco Time would like to endorse the shallow pan cooling (2") cooling method – instead of manually tracking the 6 hour cooling curve.

- Taco Time NW have been successfully using this procedure at our 75 restaurants.
- We have used this procedure with black beans (whole), pinto bean (blended/smooth) and chicken.
- We have found this procedure to be simple and easy for our staff to follow, and easy for the PICs to visually evaluate.
- This procedure is less labor intensive for our staff to track.
- The labeling of pans allows our staff to know which product to use first and rotate newly added pans with hot food to the upper shelves of the cooling racks with appropriate spacing.

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