Amend Food Code 3-501.14 to include an option to cool TCS foods at a depth of 2inches or less, uncovered, and refrigerated, without time and temperature monitoring

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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

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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.

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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,

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

5. **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.

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