System Number: 1346

Submitted by: Nick Koreen

Date Opened: 12-23-2024

Additional Submitter: N/A

| **2025-III-30** | Amend Food Code to include an alternative to the time and temperature provisions of 3-501.14A |
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**Issue you would like the Conference to Consider:**

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 or combine those methods to ensure rapid cooling is achieved. We recommend that operators have the option to utilize a 2-inch cooling method that is known to consistently facilitate rapid cooling without obtaining the needed time and temperature data points to establish a rate of cooling.

**Public Health Significance:**

Time and temperature control for safety (TCS) foods need to be cooled rapidly to minimize pathogen growth and prevent outbreaks. The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures to establish if foods are cooling at an acceptable rate. Unfortunately, cooling is often difficult for inspectors to observe, as it is challenging to obtain enough time and temperature data points to establish if it should be marked as in or out. The result is that cooling is marked as not observed during most routine health inspections.

Improper cooling of TCS food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling TCS 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)

Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators and an easy to interpret standard for regulators. Cooling TCS foods uncovered and filled to 2 inches or less poses little risk of pathogen growth (Koreen et. al, 2024). Washington State codified this cooling alternative many years ago and has reported no foodborne illness contributed to this method. They have also reported that most operators have enthusiastically modified their cooling practices to this prescribed method. For those retail operators that would like to continue to pursue other methods for cooling TCS foods within the minimum time and temperature parameters that option still exists for them.

**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); and P

(2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. P

(B) Filled no more than 2 inches deep and placed in equipment maintaining an ambient temperature of 5°C (41°F). P

(~~B~~ C) 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

(~~C~~ D) Except as specified under (D) 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 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. P

(~~D~~ E) 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

| **Submitted Attachments** | **Attachments included in PDF** |
|---|---|
| Cooling Uncovered Foods … | See attachments for Issue 2025-III-29 |
| References | See attachments for Issue 2025-III-29 |

System Number: 1386

Submitted by: Cody Sprague

Date Opened: 12-23-2024

Additional Submitter: N/A

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|---|---|
| **2025-III-31** | Amend the Food Code – Add Reheating Methods for Hot Holding |

**Issue you would like the Conference to Consider:**

Add 3-403.12 Reheating Methods. The current version of the food code does not allow inspectors to effectively mark reheating violations without waiting for reheating to pass the critical limit to verify non-compliance. If reheating is performed in equipment unable to reheat to 165°F within two hours there would be an opportunity to remedy the reheating method to reach the time and temperature parameters.

**Public Health Significance:**

Reheating poses a particular risk of foodborne illness proliferation for a number of specific pathogens: Bacillus cereus, Staphylococcus aureus, and Clostridium perfringens. As food is moving gradually through the temperature danger zone (41°F - 135°F), these pathogens can multiply and produce toxins that can cause severe foodborne illness. This gradual increase in temperature is especially relevant when considering reheating procedures that may go unmonitored or are performed using a method that is more gradual than operators' might realize. Reheating can be particularly challenging to evaluate when inspections are shorter than two hours, when operators are unaware of reheating requirements, or when food is placed into a steam table to be reheated and reheating is not monitored. As stated in the marking instructions for Item 19, a final reheating temperature must be observed in order to mark Item 19 out of compliance. If a final reheating temperature is not obtained during the inspection, it is not possible to cite a reheating violation - even if the method of reheating is not sufficient.

More realistic requirements for marking reheating or reheating methods are important to manage the risk of the aforementioned pathogens given the rate at which they can become pathogenic and the importance of warm temperatures on their proliferation as demonstrated by R. J. Gilbert et al., Satomi Tsutsuura et al., and Jihong Li et al. (1)(2) (3).

The exact rate of toxin production depends largely on factors such as food media, pH, salinity, and water activity. However, bacterial growth and toxin production can occur relatively quickly during a reheating process that doesn't rapidly reheat food to 165°F and may be allowed to linger between 98.6°F and 135°F. Being able to mark an item based on evidence and a discussion about reheating with the operator would go a long way towards recording and better educating operators about the importance of rapid and effective reheating.

**The Conference Recommends:**

sending a letter to the FDA asking the agency for the following:

Add a section 3-403.12 to the Food Code to address reheating methods in teh same manner that cooling foods are provided in Section 3-501.15. Sample language could be:

<u>3-403.12 Reheating Methods.</u>

<u>(A) Reheating shall be accomplished in accordance with the time and temperature criteria specified under § 3-403.11 by using one or more of the following methods based on the type of FOOD being reheated:</u>

<u>(1) Reheating the food in pans over a stove; Pf</u>

<u>(2) Using rapid reheating equipment; Pf</u>

<u>(3) Using containers that facilitate heat transfer; Pf or</u>

<u>(4) Other effective methods. Pf</u>

<u>(B) When placed in reheating or hot holding EQUIPMENT, FOOD containers in which FOOD is being reheated shall be:</u>

<u>(1) Arranged in capable EQUIPMENT to provide rapid heat transfer through the container walls.</u>

| **Submitted Attachments** | **Attachments included in PDF** |
|---|---|
| Reheating methods Issue | N/A |

Issue Number: 1344

Submitted by: Nick Koreen

Date Opened: 12-23-2024

Additional Submitter: N/A

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| **2025-III-29** | Amend Food Code to clearly define shallow pan cooling within 3-501.15A |

**Issue you would like the Conference to Consider:**

The 2022 Food Code outlines cooling methods that may be effective in rapidly cooling time and temperature control for safety (TCS) foods. However, those concepts do not include notable thresholds or critical limits to better understand how to apply those concepts into effective retail cooling methods. The result is that instructive words within 3-501.15A such as “shallow”, “smaller”, and “thinner” have been inconsistently applied by retail food operators and regulators often resulting in elongated cooling times.

We recommend that the language within 3-501.15(A) be altered to provide a clear understanding of how to perform shallow pan cooling safely and consistently.

**Public Health Significance:**

Improper cooling of TCS food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling TCS 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 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)

When cooling TCS foods within a shallow pan food fill depth is a variable of significance as it relates to the rate of cooling (Koreen et. al, 2024). Surveyed State Retail Program Managers and food safety fact sheets recommend food depths ranging from 2 to 4 inches. Whereas cooling TCS foods uncovered at a depth of 2 inches or less poses little risk of pathogen growth the same safety claims cannot be made for foods filled to 3 inches or more (Koreen et. al, 2024). Foods filled beyond 3 inches have been shown to not consistently reduce the rate of cooling below the acceptable minimum time and temperature parameters of the Food Code (Hedeen & Smith, 2020).

Our proposed action of establishing shallow pan cooling as filling food to a depth of 2 inches or less provides a clear and safe standard for operators and an easy to interpret standard for regulators. For retail operators that would like to cool TCS foods with a different combination of cooling methods outlined within the Food Code those options still exist for them.

**The Conference Recommends:**

that a letter be sent to FDA asking the agency to amend Section ***3-501.15*** to read:

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

~~(1) Placing the food in shallow pans; Pf~~

(1) ~~Separating the food into smaller or thinner portions~~ Fill the container with food to a depth of 2 inches or less; Pf

(2) Using rapid cooling equipment; Pf

(3) Stirring the food in a container placed in an ice water bath; Pf

(4) Using containers that facilitate heat transfer; Pf

(5) Adding ice as an ingredient; Pf or

(6) Other effective methods. Pf

| **Submitted Attachments** | **Attachments included in PDF** |
|---|---|
| Cooling Uncovered Foods … | Cooling Uncovered Foods … |
| References | References |

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Research Paper

# Cooling Uncovered Foods at a Depth of ~5.1 cm (2 in.) or Less Poses Little Risk of Pathogen Growth

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A R T I C L E  I N F O

*Keywords:*
*Bacillus cereus*
*Clostridium perfringens*
FDA Model Food Code
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A B S T R A C T

The U.S. Food and Drug Administration has guidelines for cooling cooked foods in retail operations. Data on foodborne illness risk factors in restaurants indicate that cooling is often out of compliance with these guidelines. We sought to identify factors under the control of the operator that had a significant effect on the cooling rates of cooked foods. Minneapolis Minnesota Health Inspectors were trained in standardized operating procedures for cooling data collection. Data loggers set to appropriate time intervals and calibrated to ±0.5 °C (~1°F) were used in data collection. Analysis was performed using the R statistical computing language version 4.2.2. Preexisting pathogen models were used to predict Log CFU increases of *Clostridium perfringens* or *Bacillus cereus*. Data from 224 recipes were recorded by inspectors between October 2018 and October 2019. Food depth had a highly significant effect ($p = 8.90E-08$) on cooling rate. The use of an ice bath or ice wand was also significant ($p < 0.005$). There was a significant correlation between container material (metal or plastic) and food depth because foods with a greater depth are often being cooled in plastic containers. Foods at a depth greater than 5.1 cm (2 in.) that cooled faster than 0.23 log(°C)/h were often wholly or partially cooled in blast chillers or freezers, cooled using an ice bath or ice wand (or both), or were composed of protein pieces (e.g., chicken wings) that facilitated more rapid cooling due to air gaps in the food. Foods in shallow containers at a food depth of less than or equal to ~5.1 cm (2 in.) that cooled more slowly than 0.23 log(°C)/h were being cooled at temperatures greater than 5 °C (41°F) or were partially or wholly covered. These foods also showed little evidence of pathogen growth from predictive models. Our analysis shows that cooling foods in shallow containers at a food depth of less than or equal to ~5.1 cm (2 in.) poses little risk of significant pathogen growth.

Foodborne diseases remain a significant public health concern in the United States and result in an estimated 9 million illnesses, 56,000 hospitalizations, and 1,300 deaths annually (Scallan et al., 2011). The Centers for Disease Control and Prevention (CDC) estimates foodborne illness outbreaks involving *Clostridium perfringens* account for 10% of all foodborne illness (Scallan et al., 2011). The 2017 annual report from the CDC identified 41 outbreaks (6% of total outbreaks) where *C. perfringens* was confirmed or suspected (Centers for Disease Control and Prevention (CDC) (2019)), with similar data reported in the 2015 and 2016 reports (Centers for Disease Control and Prevention (CDC) (2017), Centers for Disease Control and Prevention (CDC) (2018)).

Spore-forming bacteria pose a risk when cooked time/temperature control for safety (TCS) foods spend extended time in the temperature danger zone between 57° and 5 °C. Spores from spore-forming bacteria can survive the cooking process and those spores germinate vegetative cells as their temperatures remain in the pathogens' growth range making extended cooling timeframes problematic (Setlow & Johnson, 2019). This risk is especially elevated in the retail food setting where process control points are not commonly monitored (Brown et al., 2012).

The U.S. Food and Drug Administration (FDA) has established guidelines for cooling cooked foods in the retail food service sector. The 2022 FDA Food Code states that cooked TCS foods cool from 135 to 70°F (57°–21 °C) within two hours and subsequently to 41°F (5 °C) within a total of six hours (US Food and Drug Administration, 2023a). The 2022 FDA Food Code provides a list of acceptable methods for restaurant operators to utilize when cooling foods. These

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methods include: "(1) placing food in shallow pans; (2) separating food into smaller or thinner portions; (3) using rapid cooling techniques; (4) stirring food in a container placed in an ice bath; (5) using containers that facilitate heat transfer; (6) adding ice as an ingredient; (7) other effective methods." Regardless of the cooling methods utilized above, the code states when food containers are placed into cold-holding equipment, they should be arranged to provide maximum heat transfer through container walls and be loosely covered or uncovered to facilitate heat transfer from the surface of the food (US Food and Drug Administration, 2023a). The FDA recommends that operators monitor time and temperature during the cooling process to verify that their TCS foods cool according to the minimum requirements outlined in the FDA Food Code annex (US Food and Drug Administration, 2023a). While FDA has provided guidelines for operators or inspectors (cool from 135 to 70°F within 2 h and subsequently to 41°F within a total of 6 h) limited information exists about which cooling methods will reliably result in meeting the FDA Food Code time/temperature requirements.

FDA data on foodborne illness risk factors in restaurants indicated that cooling was marked out of compliance almost 70% of time and was identified as the third most common out-of-compliance factor in 2017–2018 (US Food and Drug Administration, 2023b). Retail food inspections cover many different aspects of food safety evaluating both risk factors and good retail practices over the course of a single inspection. Cooling of cooked TCS foods takes place over many hours making its evaluation during an inspection very challenging (Schaffner et al., 2015).

There is a lack of peer-reviewed research on cooling methods in the retail food industry. Few studies have attempted to measure the success of cooling methods or further define each cooling method's limitations (Olds et al., 2013). Findings from a 2009–2010 study from CDC's Environmental Health Specialist Network (EHS-Net) resulted in predictive modeling for cooling success given two data points and the single variable of ambient air temperature. These efforts relied upon the collection of two data points during a cooling technique instead of continuous data collection over the duration of the cooling process (Schaffner et al., 2015).

Our study builds on the EHS-Net study cooling study data by using continuous data collection during the cooling process along with measurements of methods highlighted by the 2017 FDA Food Code. The objective of this study was to add to limited published research on cooling methods in retail food operations. We specifically sought to identify factors under the control of the operator that had a significant effect on the cooling rates of cooked foods. Mathematical and practical implications as well as limitations of common retail food cooling practices are discussed with respect to the effectiveness of the cooling methods outlined in the 2022 FDA Food Code.

## Methods

### *Data collection*

Health Inspectors within the Minneapolis Health Department and a local university student were trained on a standardized operating procedure for data collection. Each data collector was trained in a classroom and then again in a restaurant to increase the consistency of the data collection. The standard operating procedure for data collection was evaluated by the Minnesota Department of Health Institutional Review Board, and they determined that no additional review was needed. Data collectors visited restaurants and asked the person in charge if they would be willing to participate in the study. Standardized consent and privacy forms were signed by the operator before data collection began. Data were collected by eight different data collectors and collection spanned a 12-month period starting October 2018 and ending October 2019.

Restaurants were identified for collection based on their risk level and an online menu review. Minnesota state statute considers a restaurant high risk if they have food processes that go through the temperature danger zone twice, and only high-risk facilities were considered. Menu reviews were completed to find likely menu ingredients that would require a cook and cool down step. Facilities such as universities, schools, food trucks, and food carts were avoided as these facilities were deemed likely not to perform batch cook then chill procedures. Restrictions to language or cuisine type were not considered as some data collectors possessed bilingual skills. Once a list of facilities that met the case definition was generated, the secondary selection was based on proximity to the Health Department office and existing relationships with managers to efficiently capture a larger data set with limited resources. Some facilities were referred to the data collectors from inspectors due to identified cooling issues during routine inspections. Some facilities changed their technique in between data collection periods and used their participation in the study to verify a change to their cooling method. Specific feedback and consultation were offered to the operator as an incentive to participate. The study's objective was to measure cooling methods and not success rate, so randomized facilities were not considered to be prudent.

A second visit was scheduled for a time that a bulk recipe(s) was to begin the cooling process. Operators set up their recently cooked food in a cooling method that they preferred, and then, the data collector inserted a data logger into the approximate geometric center of the food. The data collector measured: (1) food depth; (2) pan material (3) initial air temperature of the location in the cold holding unit where the food was to be placed; (4) the surface area of the food in the pan; (5) presence of 2 in. (5.1 cm) air gap around the pan, (6) if the food was covered or uncovered; (7) type of cold holding equipment; (8) correct use of ice wand or; (9) ice bath; (10) ice used an ingredient; (11) if the food was stirred during cooling. An ice wand is a tool used to quickly cool down hot foods. It is typically a plastic device that is filled with water and frozen prior to use.

Foods that were cooling with either an ice wand or ice bath were considered to have an ambient air temperature of 0 °C (32°F) based on the driving force analysis performed by Schaffner et al. (Schaffner et al., 2015). The types of cold holding equipment used consisted of walk-in coolers, walk-in freezers, blast chillers, or other refrigeration units (such as an upright or reach-in cooler). Ice bath use was considered "correct" if the ice bath was at least as deep as the food and contained sufficient ice such that the food container did not float. Ice wand use was considered "correct" if the wand was filled and completely frozen on initial use.

Intrinsic food characteristics were also recorded including: (1) if the food was solid or liquid; (2) the consistency of liquid foods (e.g., smooth or chunky). A liquid was considered smooth if it was consistent throughout with no solid chunks (e.g., stock, pureed soup, or sauce).

Data loggers (DS1922T, iButtonLink Technology, Whitewater, WI) were set to appropriate time intervals, calibrated to ±0.55 °C (1°F), and were accurate at temperature ranges 85 °C to −18 °C (185–0°F). Data loggers were secured in a plastic dongle tied to a piece of unscented, unwaxed single-use floss. The floss was secured to the outside of the food container with masking tape. Data logger adapters (SK-TCDEL-BD, iButtonLink Technology) allowed time and temperature data to be exported to Microsoft Excel. Data chart with graph and corresponding recommendations were reviewed with the operator in person or electronically.

### *Data preparation*

Data from 224 recipes were recorded by inspectors between October 16, 2018, and October 30, 2019. Five recipes had insufficient data recorded and were discarded from analysis, resulting in 219 recipes. The questionnaire results discussed in the previous section were stored in Microsoft Excel files, which contained ten (10) data fields. These data fields include real numbers for the depth of the food and the surface area, and the ambient air temperature; categorical variables for the type of container (i.e., metal or plastic), the substance (i.e., solid or liquid), the consistency of the food item (i.e., smooth, chunky, or solid), the coverage of the food item (i.e., covered, partially covered, or not covered), the airflow gap (i.e., at least a two-inch (5.1 cm) gap, not a two-inch gap, or not observed), whether the food item was mixed (i.e. observed, indicated, or not mixed); and binary variables for whether an ice bath and an ice wand were used.

### Data cleaning

For each recipe, temperature readings of the food were recorded each one to five minutes, depending on the recipe, and spanned 29.4–196.7°F (−1.4 to 91.5 °C). In many cases, temperature recording started well before the cooling process and continued recording well after the temperature leveled off. Food temperature data were truncated automatically to start at the beginning of the cooling process and end when either the temperature remained unchanged for three consecutive observations or the temperature began to fluctuate due to some external factor, such as stirring.

Multiple cases exist in the raw data where the recorded ambient temperature indicates the temperature was either warmer or well below the minimum temperature of the food. In one example, the recorded ambient temperature was −7°F (−21.7 °C) but the cooling curve levels off at 41°F (5 °C). In many other examples, the recorded ambient temperature is several degrees warmer than the food's coolest temperature. In cases with these obvious discrepancies between the ambient temperature and the minimum recorded temperature, the ambient temperature was adjusted to 0.5°F (0.28 °C) lower than the minimum temperature of the food as an estimate.

A few of the categorical variables were reclassified as binary variables during analysis. The variable indicating coverage of the food item was changed to binary such that covered and partially covered were identified as covered. "Not observed" for airflow gap indicates the inspector was told there was a two-inch (5.1 cm) gap, but the inspector did not personally witness it. Therefore, it was changed to binary such that two-inch gap not observed was identified as two-inch gap.

Log-temperature by time graphs of each of the 219 recipes' truncated data were manually analyzed. Forty-nine (49) graphs with irregular curves, such as those caused by an external influence and those with insufficient data points were discarded, which resulted in 170 recipes. Insufficient number of data points is defined here as meaning less than 20 consecutive temperature readings. During the manual examination, 11 graphs were found to have sufficient data points before and after some external influence and were split into two separate cooling curves. The result was 181 observations representing the cooling curves. The number of temperature readings per recipe after cleaning ranged from 22 to 741 observations, with a mean of 88 observations and a median of 68 observations.

### Data analysis

Analysis was performed using the R statistical computing language version 4.2.2 R Core Team (2022) and the specialized R libraries named Tidyverse version 1.3.1 Wickhem et al., 2019. To determine the cooling rate for each of the 181 cooling curves, we fit linear models using ordinary least-squares linear regression by regressing the logarithm of the difference between the food temperature and the environmental temperature on elapsed time. A summary of cooling rates, $p$ values, and adjusted $r^2$ values by sample ID is shown in Supplemental Table 1. The adjusted $r^2$ values range from 0.899 to >0.999, with a mean of 0.991 and a median of 0.997. More than 90% of the curves had an adjusted $r^2$ greater than 0.97. Supplemental Figure 1 shows three representative cooling curves depicting the approximately linear relationship between the logarithm of the temperature difference between the food and the cooling environment as a function of time. The slopes of the linear models were saved with the existing data fields for each recipe. The data were analyzed graphically as a quick method to detect any interesting relationships. The data related to food depth and the binary conditions covered, container type, ice bath, ice wand, and mixing, were graphed against the cooling rate.

Modeling techniques were employed to detect any influence by the various conditions, such as covered or mixed, on the cooling rate. Correlations of conditions were examined using a correlation matrix to detect collinearities. Multiple linear models were fit using ordinary least-squares linear regression using the cooling rate as the dependent variable, with the various noncollinear conditions as independent variables, and backward selection determined the final model. We also attempted to classify the cooling rate as either greater than or less than 0.23 log(°C)/h which has been found to be the slope that differentiates a cooling process that does or does not meet FDA requirements (Schaffner et al., 2015). We fit logistic regression models using the various data fields as independent variables and backward-step selection determined the final model.

### Pathogen growth modelling

Preexisting pathogen models were used to predict log CFU increases for *C. perfringens* using Perfringens Predictor (ComBase, 2024; Peck et al., 2007) assuming pH 7 and 0.5% NaCl, or for *B. cereus* growth in pasta (Juneja et al., 2019). Each model is based on experimental data generated using spores and thus includes any germination outgrowth and lag time. The model from Juneja et al. (2019) was developed using a cocktail of two emetic and two diarrheal strains. Log-linear cooling rates as described above and by Schaffner et al. (2015) were used as inputs to the two models and a range of cooling rates from the Food Code minimum allowed rate of 0.23 log(°C)/h to 0.1 log(°C)/h were investigated. We also identified two manuscripts on the growth of *C. perfringens* in nonmeat foods which we used to validate ComBase Perfringens Predictor. These articles investigated *C. perfringens* growth in pea soup (de Jong, Rombouts, & Beumer, 2004) and refried beans (Cevallos-Cevallos, Akins, Friedrich, Danyluk, & Simmonne, 2012). When we compared Perfringens Predictor predictions (assuming pH 7 and 0.5% NaCl), any predicted increases were equivalent to or exceeded observed *C. perfringens* growth from spores in pea soup or refried beans as reported by those authors.

## Results

### Correlation matrix

Table 1 shows a correlation matrix displaying the relationship between all the regression variables. The most significant correlation (−0.64) is between metal or plastic container and food depth. This is because foods with a greater depth are often being cooled in plastic containers. Additionally, metal or plastic container type is correlated with surface area (0.46) for a similar reason, since plastic containers tend to have smaller surface areas. Other notable correlations are the use of an ice wand (0.47) or an ice bath (0.37) with food depth, again because these tools are often used when foods are being cooled in deeper containers. Ice bath use is also correlated with situations where mixing is indicated (0.45), because often mixing facilitates cooling when ice baths are used. Whether food is solid or liquid was correlated with surface area (0.44) since in some cases, liquid foods are being cooled in plastic buckets which have a smaller surface area. Surface area is correlated with food depth (−0.39) because foods are generally being cooled in metal pans with shallow food depth

**Table 1**
Correlation matrix for variables investigated, where the strength of the correlation is indicated by the magnitude of the number. Higher correlations (>0.30 or < −0.30) are depicted in bold text

| | Cooling rate | Food depth | Surface area | Ice bath used | Ice wand used | Solid or liquid | Covered or not | Airflow gap | Metal or plastic | Mixing indicated |
|---|---|---|---|---|---|---|---|---|---|---|
| Cooling rate | | −0.25 | 0.18 | 0.15 | 0.09 | −0.03 | −0.20 | 0.17 | 0.25 | 0.12 |
| Food depth | −0.25 | | **−0.39** | **0.37** | **0.47** | −0.21 | 0.09 | −0.16 | **−0.64** | 0.14 |
| Surface area | 0.18 | **−0.39** | | −0.17 | −0.21 | **0.44** | −0.19 | 0.13 | **0.46** | −0.05 |
| Ice bath used | 0.15 | **0.37** | −0.17 | | **0.31** | 0.00 | −0.10 | 0.06 | −0.23 | **0.45** |
| Ice wand used | 0.09 | **0.47** | −0.21 | **0.31** | | −0.21 | −0.16 | −0.02 | **−0.36** | 0.07 |
| Solid or liquid | 0.03 | −0.21 | **0.44** | 0.00 | −0.21 | | 0.11 | −0.07 | 0.17 | −0.10 |
| Covered or not | −0.20 | 0.09 | −0.19 | −0.10 | −0.16 | 0.11 | | −0.12 | −0.22 | −0.21 |
| Air flow gap | 0.17 | −0.16 | 0.13 | −0.06 | −0.02 | −0.07 | −0.12 | | 0.20 | −0.04 |
| Metal or plastic | 0.25 | **−0.64** | **0.46** | −0.23 | **−0.36** | 0.17 | −0.22 | 0.20 | | 0.03 |
| Mixing indicated | 0.12 | 0.14 | −0.05 | **0.45** | 0.07 | −0.10 | −0.21 | −0.04 | 0.03 | |

and large surface area or plastic buckets where the reverse is true. Use of ice wands is correlated with the choice of metal or plastic container (−0.36) because once again ice wands may be used in situations where food is being cooled in plastic buckets. Finally, ice wand and ice bath use are correlated with one another (0.31) because often these two tools are used together to facilitate cooling. Note that for some binary variables (e.g., solid or liquid; metal or plastic), the sign of the correlation is arbitrary, so the magnitude of the correlation is more important than the sign.

*Graphical analysis of container type, rate, and food depth*

Figure 1 shows the relationship between cooling rate ($y$ axis) and food depth $x$ axis), and metal (triangle) or plastic (circle) containers that are covered (solid) or not (open). Faster cooling foods are toward the top of the figure while slower cooling foods are towards the bottom. Foods with depths of 5.1 cm (2 in.) or greater which are to the right of the vertical dotted line, also tended to cool too slowly, falling below the recommended Food Code cooling rate (0.23 log °C/h) indicated by the horizontal dotted line.

*Linear regression model*

Table 2 shows the results of a linear regression where the cooling slope is regressed on food depth, the use of an ice bath, and the use of an ice wand. The resulting model has a low adjusted $R^2$ value of ~0.155, which means that the model parameters (food depth and use of an ice bath or ice wand) can only explain some of the variability of the cooling rate. The model does have a highly significant $p$ value (4.139e−07), and food depth ($p$ = 8.90E−08) in particular has a highly significant effect on the cooling rate. Use of an ice bath or ice wand are also significant (each with $p < 0.005$). When the interaction of ice bath and ice wand was added to the model, this variable was not significant (data not shown).

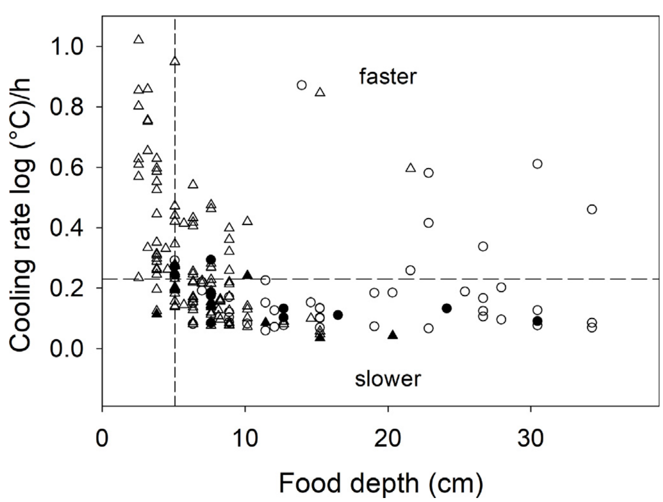


**Figure 1.** Relationship between cooling rate and food depth, indicating metal (triangle) or plastic (circle) containers that are covered (solid) or not (open). Food depth of 5.1 cm (2 in.) is indicated by the vertical dotted line. The recommended Food Code cooling rate of 0.23 log(°C)/h is indicated by the horizontal dotted line.

*Graphical analysis of ice wand and ice bath*

Figure 2 expands upon the results of the linear analysis and shows a plot of the relationship between food depth, and cooling rate where use of an ice wand or an ice bath are distinguished using separate symbols. Figure 2 shows the same data and axes as Figure 1, but now indicating use of ice wand (upside down triangle), ice bath (square) or both ice wand and ice bath (star) all with gray shading, where none of these techniques are used the data are represented by open circles. An ice wand or ice bath was rarely used to cool foods in shallow containers as shown by the predominance of open circles to the left of the vertical dotted line. Most of the foods being cooled with both an ice wand and an ice bath were cooling faster than the recommended cooling rate as shown by the stars in the upper right quadrant of the figure. There are also several instances where these foods are not cooling as fast as recommended. Many of the foods in deep containers (greater than 5.1 cm, ~2 in.) that are being cooled by an ice bath or an ice wand are cooling slower than the recommended cooling rate as shown by the squares and downward pointing triangles in the lower right-hand quadrant of the figure. There are a few instances of foods in shallow containers that are being cooled with an ice wand that are cooling faster than required as shown by the downward pointing triangles in the upper left quadrant. Both ice baths and ice wands were successful for some of the deeper containers, but not always. In these cases, ice bath or ice wand cooling may have been initiated but not monitored, leading to failure in the first two hours of cooling.

*Logistic regression model*

Table 3 shows the model parameters for a logistic regression model predicting whether a food will meet or exceed the FDA model code recommended cooling rate. Food depth is still highly significant ($p$ = 7.22E−06) as with the prior model. The combination of both the ice band bath with ice wand is highly significant ($p < 0.005$) in this model, while the use of ice bath or ice wand alone was not. When the interaction term was removed, each variable was significant on its own, however, the overall predictive ability of the model declined (data not shown). As shown in Figure 2, there are quite a few observations where ice bath and ice wand were used together that resulted in fast cooling in deep containers. This may be due to an operator either noticing slow cooling and attempting to remediate, or the awareness

**Table 2**
Linear regression model parameters and their statistical significance in predicting cooling rate in 0.23 log(°C)/h, where the adjusted $R^2$ is 0.155, and $p = 4.139e-07$

| Parameter | Estimate | Standard Error | *T* value | *P* value |
|---|---|---|---|---|
| Intercept | 0.339075 | 0.023454 | 14.457 | < 2.00E − 16 |
| Food depth (cm) | − 0.012384 | 0.002218 | − 5.583 | 8.86E − 08 |
| Ice bath use | 0.130664 | 0.042102 | 3.109 | 0.00219 |
| Ice wand use | 0.124046 | 0.041904 | 2.960 | 0.00350 |

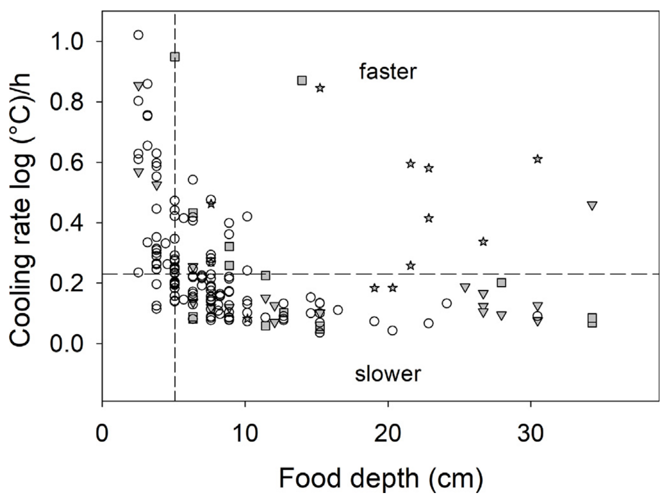


**Figure 2.** Relationship between cooling rate and food depth indicating the use of ice wand (upside down triangle), ice bath (square) or both ice wand and ice bath (star). Food depth of 5.1 cm (2 in.) is indicated by the vertical dotted line. The recommended Food Code cooling rate of 0.23 log(°C)/h is indicated by the horizontal dotted line.

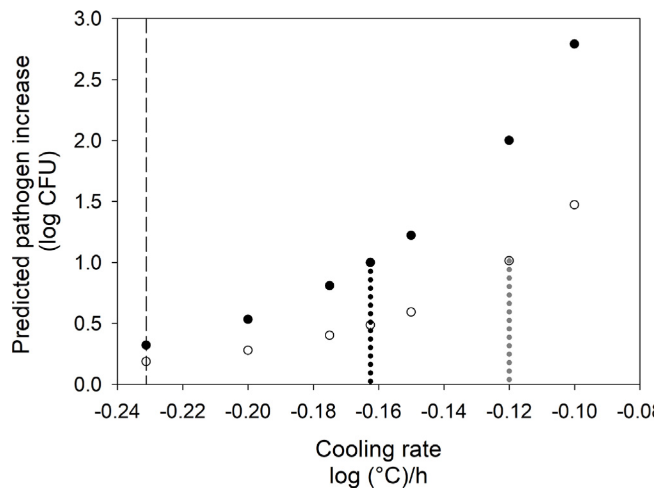


**Figure 3.** Relationship between cooling rate and the predicted increases in pathogen concentration for C. perfringens Perfringens Predictor, assuming pH 7 and 0.5% NaCl (closed circles) and B. cereus using Juneja et al. (2019) model (open circles). The vertical dashed line at − 0.23 log(°C)/h represents the cooling rate suggested in the model food code.

that cooling was going to take place in a deep container and needed extra intervention to ensure proper cooling.

*Pathogen growth modeling and cooling rate*

Figure 3 shows a plot of the relationship between cooling rate and the predicted increases in pathogen concentration for *C. perfringens* (closed circles) and *B. cereus* (open circles). The vertical dashed line at − 0.23 log(°C)/h represents the cooling rate suggested in the model food code. It is clear from the predictions that if a food is cooled at this rate, the predictive models would indicate less than a 0.5 log increase in either pathogen. There is approximately a one − log increase in the concentration of *C. perfringens* at a cooling rate of − 0.16 log(°C)/h which is indicated by the dotted vertical black line. There is approximately a one − log increase in the concentration of *B. cereus* at a cooling rate of − 0.12 log(°C)/h which is indicated by the dotted vertical gray line. A one − log increase in the concentration of *C. perfringens* is the guideline used by USDA FSIS for cooling deviations according to Appendix B (USDA Food Safety and Inspection Service, 2021). There is no equivalent standard for *B. cereus*, however, expert guidance has indicated that a one − log increase in a pathogen is typically the level a food microbiologist would judge to be sufficient to conclude that growth was occurring (National Advisory Committee on Microbiological Criteria for Foods, 2010). The data presented in this figure would indicate that even a food that is cooling slower than recommended in the model food code might still pose a negligible risk depending upon how slow the food was cooling.

*Foods cooling faster than 0.23 log(°C)/h*

Table 4 provides details on those 29 foods at a depth greater than 5.1 cm (2 in.) that cooled faster than a rate of 0.23 log(°C)/h. Twelve out of the 29 foods were cooled using a passive (e.g., no ice bath or ice wand use) technique. Seven of the 12 foods spent at least some of their cooling time being cooled in a freezer or a blast chiller which would accelerate the cooling rate. Two of the 12 foods only had a partial cooling curve and thus might have an estimated cooling rate that was not representative. Finally, three of the 12 foods were protein (specifically chicken dices, wings, or breasts) and thus had a more open matrix facilitating airflow from the cooling food. Seventeen of the 29 foods were cooled using an active (e.g., ice bath and/or ice wand) process. Five of the 17 foods were cooled using an ice bath, although in one

**Table 3**
Logistic regression model parameters and their statistical significance in predicting whether a cooling rate in log(°C)/h will meet or exceed the Model Food Code cooling rate of 0.23 log(°C)/h

| Parameter | Estimate | Standard Error | *Z* value | *P* value |
|---|---|---|---|---|
| Intercept | 1.4443 | 0.4260 | 3.391 | 0.000698 |
| Food depth (cm) | − 0.2672 | 0.1512 | − 4.487 | 7.22E − 06 |
| Ice bath use | 0.4570 | 0.7097 | 0.644 | 0.519606 |
| Ice wand use | 0.8543 | 0.6978 | 1.224 | 0.220849 |
| Ice bath and ice wand use | 4.0548 | 1.4175 | 2.861 | 0.004230 |

**Table 4**
Foods in pans at a depth greater than 5.1 cm (2 in.) that cooled faster than 0.23 log(°C)/h

| Active or Passive | Food | Cooling Rate log(°C)/h | Food Depth | | Comments |
|---|---|---|---|---|---|
| | | | (inches) | (cm) | |
| Passive | Venison soup | 0.270 | 3.0 | 7.6 | Cooled in blast chiller |
| | Cranberry Chutney | 0.361 | 3.5 | 8.9 | Cooled in blast chiller (partially) |
| | Black Beans | 0.420 | 4.0 | 10.2 | Cooled in blast chiller (partially) |
| | Black Beans | 0.398 | 3.5 | 8.9 | Cooled in blast chiller (partially) |
| | raw fries | 0.293 | 3.0 | 7.6 | Cooled in freezer |
| | Hot Sauce | 0.476 | 3.0 | 7.6 | Cooled in freezer (partially) |
| | Hot Sauce | 0.282 | 3.0 | 7.6 | Cooled in freezer (partially) |
| | Tomato Sauce | 0.418 | 2.5 | 6.4 | Partial cooling curve |
| | Spinach | 0.247 | 2.5 | 6.4 | Partial cooling curve |
| | Chicken Breasts | 0.414 | 2.3 | 5.8 | Protein pieces (breasts) |
| | Diced Chicken | 0.406 | 2.5 | 6.4 | Protein pieces (diced) |
| | Chicken Wings | 0.541 | 2.5 | 6.4 | Protein pieces (wings) |
| Active | Korma | 0.433 | 2.5 | 6.4 | Ice bath |
| | Korma | 0.258 | 3.5 | 8.9 | Ice bath |
| | Curry Chicken | 0.321 | 3.5 | 8.9 | Ice bath |
| | Au Jus | 0.871 | 5.5 | 14.0 | Ice bath |
| | Chicken Breasts | 0.241 | 4.0 | 10.2 | Ice bath, probe error, combined to double depth |
| | Jambalaya Sauce | 0.258 | 8.5 | 21.6 | Wand and Ice bath |
| | Ham and Potato Soup | 0.595 | 8.5 | 21.6 | Wand and Ice bath |
| | Gouda sauce | 0.610 | 12.0 | 30.5 | Wand and Ice bath |
| | Chowder | 0.337 | 10.5 | 26.7 | Wand and Ice bath |
| | Au Jus | 0.581 | 9.0 | 22.9 | Wand and Ice bath |
| | Aloo Tama soup | 0.463 | 3.0 | 7.6 | Wand and Ice bath |
| | Aloo Tama soup | 0.269 | 3.0 | 7.6 | Wand and Ice bath |
| | Alfredo | 0.415 | 9.0 | 22.9 | Wand and Ice bath |
| | Pork Stock | 0.255 | 2.5 | 6.4 | Wand and partially cooled in freezer |
| | Ramen broth | 0.846 | 6.0 | 15.2 | Wand, Ice bath, ice as ingredient |
| | Chicken Stock | 0.460 | 13.5 | 34.3 | Wands (2) |

case, the food was rearranged during cooling and the temperature probe may have been dislodged leading to inaccurate readings. Eight of the 17 foods were cooled using both an ice bath and an ice wand, leading to cooling faster than 0.23 log(°C)/h. The remaining four foods were cooled by a variety of means including an ice wand and using a freezer, ice wand, and ice bath plus ice as an ingredient, and use of multiple ice wands in one case in combination with an ice bath as well. All these methods result in cooling faster than 0.23 log(°C)/h.

### *Foods cooling slower than 0.23 log(°C)/h*

Table 5 summarizes those foods that had a depth of less than 2 in. (5.1 cm) but which cooled slower than 0.23 log(°C)/h. This table contains a total of 14 foods. Five of the foods met FDA cooling guidelines (57°–21 °C within 2 h and to 5 °C within a total of 6 h) although the estimated cooling rate was slower than 0.23 log(°C)/h. Nine foods had rates slower than 0.23 log(°C)/h and did not meet Food Code cooling requirements. Two of these foods were cooled either fully or partially in environments that exceeded 41°F (5 °C). Seven of these foods were either fully or partially covered or improperly stacked. One food (garden veggie soup) almost met Food Code cooling requirements, and ComBase modeling software predicted less than 1 log growth of *C. perfringens*.

## Discussion

### *Plastic vs metal*

Interesting relationships were discovered from the analysis of this data set. The relationship between container type and food depth was strong, which supports the use of metal food pans commonly found within restaurants. Many metal pans designed for the industry

**Table 5**
Foods in shallow containers at a depth of less than or equal to ~5.1 cm (2 in.) that cooled more slowly than 0.23 log(°C)/h

| Food code cooling met? | Food | Cooling Rate log(°C)/h | Food depth | | Comments |
|---|---|---|---|---|---|
| | | | (inches) | (cm) | |
| Yes | Squash Soup | 0.157 | 2 | 5.1 | Cooling temperature > 41°F (partially) |
| | Tomato Basil Soup | 0.141 | 2 | 5.1 | Cooling temperature > 41°F (partially) |
| | Tomato Soup | 0.193 | 2 | 5.1 | <2 h high-risk, <1 log *C. perfringens* predicted |
| | Tomato Soup | 0.204 | 2 | 5.1 | <2 h high-risk, <1 log *C. perfringens* predicted |
| | Tomato Soup | 0.194 | 2 | 5.1 | <2 h high-risk, <1 log *C. perfringens* predicted |
| No | Sausage Gravy | 0.139 | 2 | 5.1 | Cooling temperature > 41°F |
| | Chicken Dish Raw | 0.114 | 1.5 | 3.8 | Cooling temperature > 41°F (partially), covered, stacked |
| | Raw Fries | 0.201 | 2 | 5.1 | Covered |
| | Chicken Stock | 0.000 | 1 | 2.5 | Covered (partial, assumed) |
| | Chicken Curry | 0.198 | 2 | 5.1 | Covered (partial, assumed) |
| | Chorizo | 0.199 | 2 | 5.1 | Covered (partial, assumed) |
| | Kraut | 0.125 | 1.5 | 3.8 | Covered (partial, assumed), probe error |
| | Turkey Chili | 0.196 | 1.5 | 3.8 | Covered (partial) |
| | Garden veggie soup | 0.183 | 2 | 5.1 | Less than 7 h total, <1 log *C. perfringens* predicted |

are hotel pans that are manufactured in rectangular shapes with a large surface area in proportion to their depth (Katsigris & Thomas, 2009). This contrasts with plastic containers that are commonly designed for storage and are therefore more likely to have a bucket-like shape, with a smaller surface area in proportion to their depth. Published peer-reviewed data on the impact of food container material on cooling rates has been recently reviewed (Coorey et al., 2018), but data on the suitability of plastic buckets for cooling are limited. Extension publications commonly recommend against the practice of cooling in plastic buckets (Garden-Robinson et al., 2022). Our analysis supports the idea that restaurant managers should opt for metal pans over plastic buckets when selecting a container for cooling. We observed that most of the restaurant operators in this study utilized metal pans when attempting to cool food in shallow containers.

### *Food depth*

Both models presented above show that food depth has a highly statistically significant impact on the rate of cooling. The peer-reviewed literature has often called out three inches (7.6 cm) as an appropriate food depth for cooling (Hedeen & Smith, 2020; Igo et al., 2021; Schaffner et al., 2015). Surveyed State Retail Program Managers and food safety fact sheets recommend food depths from 2 to 4 in. (5.1–10.2 cm) when cooling (Koreen, 2022). An issue for consideration at the 2023 Conference for Food Protection to amend the FDA Model Food Code to allow cooling without time and temperature monitoring was recently submitted (Hedeen & Shelton, 2023). The issue submitters propose amending the Food Code to include an option to cool foods at a depth of 2 in. (5.1 cm) or less, uncovered, and refrigerated, without time and temperature monitoring. Washington State has allowed the cooling of foods in a shallow layer of two inches (5.1 cm) or less since 2005 (Washington State Department of Health Division of Environmental Health Food Safety Program, 2005). As summarized by Hedeen and Shelton (2023), since allowing this cooling practice outbreak in Washington State, the state has seen 42 outbreaks that could have been caused by cooling deficiencies. Deep pan cooling was listed as the primary contributing factor in 30 outbreaks. There were also 6 outbreaks where room temperature storage was listed as the primary contributing factor, 6 other outbreaks where hot-holding or cold-holding was listed as the primary contributing factor and the cooling method was not identified/evaluated. No outbreaks were linked to use of the 2-inch (5.1 cm) cooling practice.

### *Ice wands and baths*

Observations of the use of ice wands and ice baths were each statistically significant factors when predicting cooling rates, although not as significant as food depth. When using logistic regression to predict whether the food would meet or exceed the 0.23 log(°C)/h cooling rate, food depth was still the most significant variable, but ice bath and ice wand were only significant when considered together. This likely occurred because these foods were being cooled in very deep containers, and so extra measures like ice wands and baths were both used to facilitate cooling. This emphasizes the observation made previously that 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 (Schaffner et al., 2015).

### *Limitations and future research*

This study collected data from restaurants that were open and functioning normally which limited our ability to systematically study all variables associated with cooling rate, as one might in a laboratory. Some variables that we were unable to test might have a meaningful impact on the rate of cooling. Principles of heat transfer would indicate that airflow over the cooling food both for initial countertop cooling and during cooling in refrigeration units would be important. Airflow is known to impact how blast chillers work to quickly cool food (Hu & Sun, 2001). We saw evidence of procedures with initial cooling under ambient kitchen conditions to be more successful than in refrigeration units when the objective was to cool freshly prepared food temperatures down to 57 °C (135°F), which may be due to better airflow under ambient kitchen conditions vs. in refrigeration units. We also saw evidence that walk-in coolers tended to outperform reach-in coolers which also suggests that air flow may be an important variable. It is important to note that because of the length of time needed to collect cooling data, those collecting the data were not always able to stay present for the duration of data collection. This might have resulted in a restaurant operator accidentally or intentionally impacting data collection, although we did make every effort to remove unusual cooling curves resulting from such events from our data prior to analysis.

Our analysis shows that food depth ($p = 8.90E-08$) was highly significant in predicting the cooling rate. Our data also show that the use of an ice bath or ice wand was also predictive ($p < 0.005$) of cooling rate. There was a significant correlation between container material (metal or plastic) and food depth because foods with a greater depth are often being cooled in plastic containers. Foods in containers at a food depth greater than 5.1 cm that cooled faster than 0.23 log(°C)/h were often wholly or partially cooled in blast chillers or freezers, cooled using an ice bath or ice wand or both, or were composed of protein pieces (e.g., chicken wings) that facilitated more rapid cooling due to air gaps in the food. Foods in shallow containers at a food depth of less than or equal to ~5.1 cm that cooled more slowly than 0.23 log(°C)/h were being cooled at temperatures greater than 5 °C (41°F) or were partially or wholly covered. Those foods in shallow containers showed little risk from pathogen growth (i.e., <1 log CFU increase) according to predictive models. Our analysis shows that foods cooled in shallow containers at a food depth of less than or equal to ~5.1 cm (2 in.) pose little to no risk of significant pathogen growth.

## CRediT authorship contribution statement

**Nicklaus Koreen:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **W. Clifton Baldwin:** Writing – review & editing, Writing – original draft, Software, Methodology, Formal analysis, Data curation. **Donald W. Schaffner:** Writing – review & editing, Writing – original draft, Visualization, Project administration, Formal analysis, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary material

Supplementary material to this article can be found online at https://doi.org/10.1016/j.jfp.2024.100356.

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# New Food Code Update: Maintaining “Molluscan Shellfish” Identification

U.S. FOOD & DRUG ADMINISTRATION

In the 2022 Food Code, ¶¶ 3-203.12(B) and (C) were updated. Invoices are now acceptable for tracing "Molluscan shellfish" to its original source in addition to tags and labels. When invoices are used, they must contain required information for tracing "Molluscan Shellfish" to its original source (refer to the section called, What is required to be on the tag, label, or invoice for proper traceback for specific details). An invoice that does not include all of the required information is not acceptable.

## Why does the Food Code include the term 'invoice'?

Accurate "Molluscan shellfish" identification records must be maintained in a "Food establishment" so "Regulatory authorities" can move quickly during an outbreak to prevent further illnesses. These records must be kept for 90 days to allow time for shellfish-borne diseases to surface. Record keeping may be difficult to keep for “in-shell products” and “shucked shellfish”.

"In-shell product" may not have tags, instead product may have a label or required information on a master container. Keeping the entire master container may not be feasible and soiled labels may be difficult to read.

***Note:*** *If "Shucked shellfish" are sold in prepackaged consumer self service containers,the label information needs to be retained by the “Food establishment”. Date sold and equivalent required label information can be retained in a record keeping system, such as a log sheet, maintained for at least 90 days.*

## Flow Chart of FDA Food Code Terminology

**"Molluscan Shellfish"**

Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof. (Except when the scallop product consists only of the shucked adductor muscle.)




**"Shellstock"**

LIVE in the shell(s)

**"Shucked Shellfish"**

Both shells removed

**"In-Shell Product"**

Non-living, processed in the shell(s)

“Molluscan Shellfish” includes the following: "Shellstock", "Shucked Shellfish", "In-Shell Product".

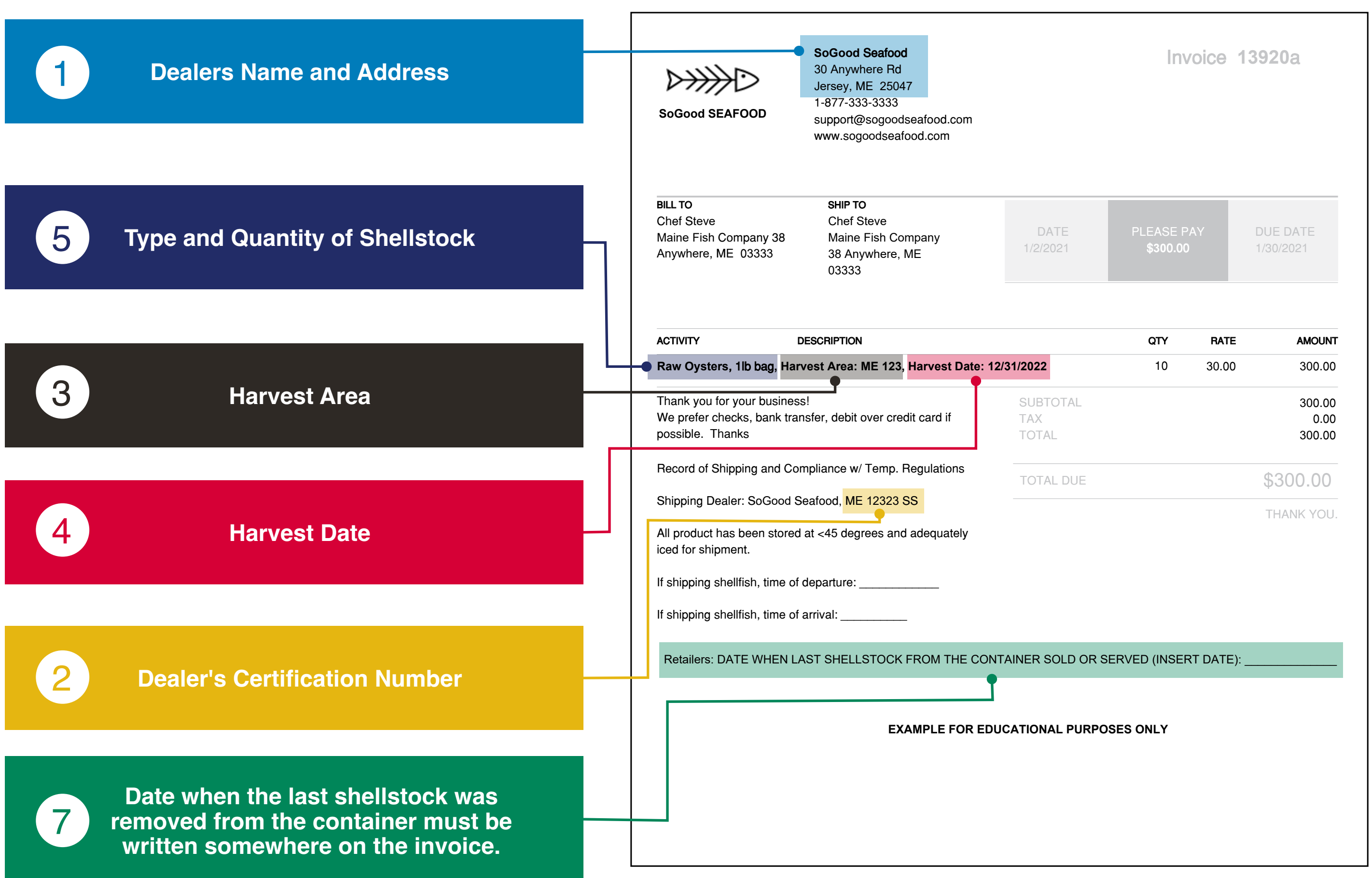
# What is required to be on the tag, label or invoice for proper traceback?

The identification requirements in the Food Code follow the National Shellfish Sanitation Program (NSSP) Guide for Control of Molluscan Shellfish.

The tag, label or invoice may vary slightly; however, "Molluscan shellfish" must contain the following for traceback:

1. the dealer's name and address,
2. the dealer certification number (ex. from dealer that depurates, packs, ships, or reships),
3. the most precise identification of the harvest location,
4. the harvest or shucking date,
5. the type and quantity,
6. the 'sell-by' or 'best if used by' date on "shucked shellfish" (if less than 1.89 L or one-half gallon) and "in-shell product".
7. the date when the last "Molluscan shellfish" from the container is sold or served shall be recorded on the tag, label, or invoice.

***Note:*** *""Molluscan Shellfish" must be received from businesses listed on the Interstate Certified Shellfish Shipper's List (ICSSL) and accompanied by tags or labels. When an invoice is maintained in the food establishment for traceback, it must have the required information listed in Items 1-6 above. It is key that the "Food establishment" records the date in Item 7 because that date starts the 90 day clock for maintaining the "molluscan shellfish" invoice.*




This illustration does not include Item 6 (from above) because it does not apply to “shellstock” which is used in this example.

# For more information:

- FDA Food Code is available at: http://www.fda.gov/FoodCode
- National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish (Model Ordinance): https://www.fda.gov/media/143238/download
- Conference for Food Protection (CFP) developed guide for: Retail Industry Best Practices and Regulatory Guidance Toolkit for Shellstock Investigations http://www.foodprotect.org/guides-documents/retail-industry-best-practices-and-regulatory-guidance-toolkit-for-shellstock-investigations/
- Interstate Certified Shellfish Shipper's List (ICSSL): https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

# Expired Infant Formula

While the FDA requires formula to have a use-by date, there is no federal law banning its sale after that date, making it a state-level issue.  Expired formula can lose nutritional value and may not meet the dietary needs of infants.

FDA advises not to use infant formula past use by date:

***"Use By" Date*** *- Don't use a package or container of infant formula after this date. The manufacturer guarantees the nutrient content and quality of the formula only up to the "use by" date. FDA rules require a "use by" date on every container of infant formula.*

**USDA**

*Federal regulations require a "Use-By" date on the product label of infant formula under inspection of the U.S. Food and Drug Administration. Using formula by this date ensures that it contains each nutrient in the quantity listed on the label. Formula must maintain an acceptable quality to pass through an ordinary bottle nipple.*

*The "Use-By" date is selected by the manufacturer, packer or distributor of the product based on product analysis throughout its shelf life, tests or other information. It is also based on the conditions of handling, storage, preparation, and use printed on the label. Do not buy or use baby formula after its "Use-By" date.*

# New Food Code Update: Maintaining "Molluscan Shellfish" Identification

FDA U.S. FOOD & DRUG ADMINISTRATION

In the 2022 Food Code, ¶¶ 3-203.12(B) and (C) were updated. Invoices are now acceptable for tracing "Molluscan shellfish" to its original source in addition to tags and labels. When invoices are used, they must contain required information for tracing "Molluscan Shellfish" to its original source (refer to the section called, What is required to be on the tag, label, or invoice for proper traceback for specific details). An invoice that does not include all of the required information is not acceptable.

## Why does the Food Code include the term 'invoice'?

Accurate "Molluscan shellfish" identification records must be maintained in a "Food establishment" so "Regulatory authorities" can move quickly during an outbreak to prevent further illnesses. These records must be kept for 90 days to allow time for shellfish-borne diseases to surface. Record keeping may be difficult to keep for "in-shell products" and "shucked shellfish".

"In-shell product" may not have tags, instead product may have a label or required information on a master container. Keeping the entire master container may not be feasible and soiled labels may be difficult to read.

***Note:*** *If "Shucked shellfish" are sold in prepackaged consumer self service containers,the label information needs to be retained by the "Food establishment". Date sold and equivalent required label information can be retained in a record keeping system, such as a log sheet, maintained for at least 90 days.*

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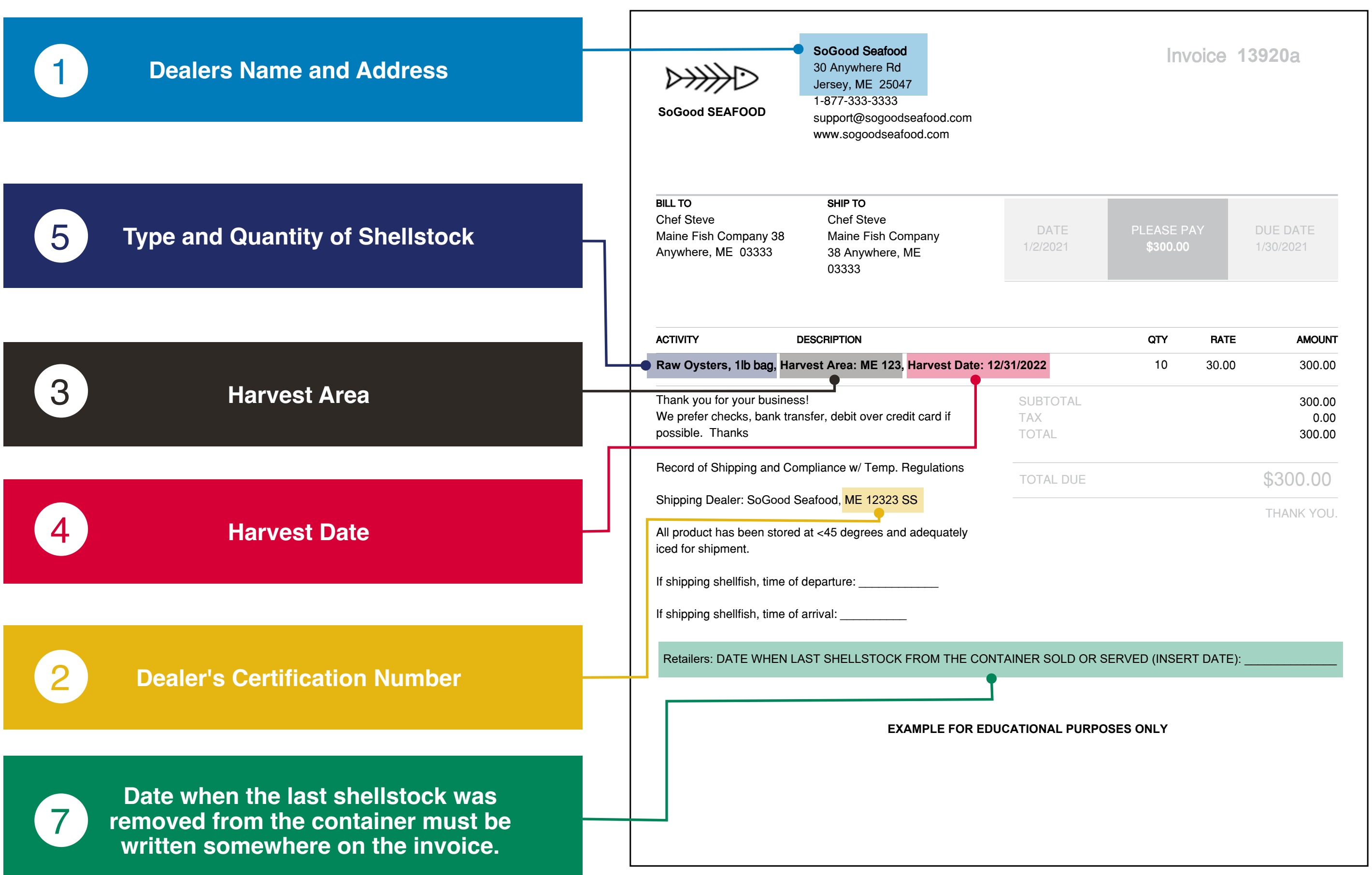
7. the date when the last "Molluscan shellfish" from the container is sold or served shall be recorded on the tag, label, or invoice.

***Note:*** *""Molluscan Shellfish" must be received from businesses listed on the Interstate Certified Shellfish Shipper's List (ICSSL) and accompanied by tags or labels. When an invoice is maintained in the food establishment for traceback, it must have the required information listed in Items 1-6 above. It is key that the "Food establishment" records the date in Item 7 because that date starts the 90 day clock for maintaining the "molluscan shellfish" invoice.*

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- Interstate Certified Shellfish Shipper's List (ICSSL): https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list

# Significant Changes Chapter 3

- **3-201.17 Game Animals**

  Game animals may now be offered for sale if they are under a voluntary inspection program administered by the ODA State Meat Inspection Program for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with OAR 603-029-4000 to 603-029-4075.

- **3-203.12 Shellstock, Maintaining Identification**

  Invoices are now acceptable for tracing molluscan shellfish to its original source. FDA has developed a handout entitled *New Food Code Update: Maintaining Molluscan Shellfish Identification* that provides additional information on molluscan shellfish terminology and the requirements for the invocies.

- **3-304.12 In-Use Utensils, Between-Use Storage.**

  Removing the option to store in use utensils in a container of water if the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7); and the water is maintained at a temperature of (41°F) or less. This previous allowance was Oregon specific and was not included in the FDA Model Food Code. ODA will be removing the option to store utensils in ice water because of the following:
  - In-use utensils can be stored in water that is maintained at 135F since this would control the multiplication for pathogenic bacteria. However, discussions at Conference for Food Protection have discouraged FDA from allowing in-use utensils in water at 41F due to concerns that bacteria would not be adequately controlled, the water could be overwhelmed with bacteria, and there is no kill step.

- **3-402.12(B) (1),(2) Records, Creation and Retention**

  The parasite destruction letter no longer requires the specific species of fish to be listed and does not need to be updated annually. This was an Oregon specific provision and is not included in the 2022 FDA Model Food Code.

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- **3-501.13(E) Thawing**

All reduced oxygen packaged fish labeled as “must be kept frozen” must be removed from packaging when thawing. 2022 FDA Model Food Code Annex 3: If a “Keep Frozen” label is not present on each individual ROP package unit, it may or may not be acceptable to store under refrigeration depending in part on whether there are barriers such as pH or water activity to growth of C botulinum in addition to refrigeration.

As an added safeguard to prevent the possibility of C. botulinum formation, the Food Code requires that any frozen ROP fish that does not have barriers to growth of C. botulinum in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41°F or less for a prolonged time period and/ or selling it as a refrigerated product.

- **3-501.14(B) Cooling**

  Provides operators with the option to utilize a 2-inch cooling method that is known to consistently facilitate rapid cooling without obtaining the needed me and temperature data points to establish a rate of cooling. The additional cooling option allows food to be cooled uncovered and protected from contamination in a shallow layer of two inches or less in equipment that maintains an ambient air temperature of 5ºC (41ºF) or less. **2025 Proposal (III-029-30)** outlines the public health reasoning and science associated with the additional cooling allowance.

- **3-502.12(D) Reduced Oxygen Packaging Without a Variance**

  Does not require a variance for reduced oxygen packaging (ROP) of cooked food held for up to 30 days if held at or below 1°C (34°F), or up to 7 days at or below 5ºC (41ºF).

- **3-502.12(F) Reduced Oxygen Packaging Without a Variance**

  A Hazard Analysis of Critical Control Points (HACCP) plan is no longer required if the food is labeled with production time and date, held at or below 5ºC (41ºF), and removed from its package within 48 hours.