HOT HOLDING
NACMCF – September 2001

FDA is seeking advice as to whether the recommendation for the hot holding temperature in the Food Code should be changed from 140°F to a lower temperature, and if so, should there be associated monitoring and record keeping requirements.

- Is there an increased risk to food safety if the temperature is lowered from 140°F?
- If a "margin of safety" needs to be associated with a lower temperature, what should it be?
- What minimum time/temperature parameters for hot holding would ensure food safety?
- Should there be monitoring and /or record keeping requirements associated with hot holding at temperatures less than 140°F?

A. Background

Since 1962, the Food and Drug Administration (FDA), in its recommended model codes for foodservice and retail food stores, has stated that 140°F is the critical limit for hot holding potentially hazardous foods. That requirement is now being challenged as too conservative and not supported by science.

In their Issues that were submitted to the Conference for Food Protection (CFP) at the 1998 meeting, the National Restaurant Association and the Food Marketing Institute (FMI) recommended that the hot holding temperature in the Food Code be lowered to 130°F. They stated that although improper hot holding has been associated with foodborne illnesses, the following factors need to be considered:

- According to the Surveillance for Foodborne-Disease Outbreaks, United States, 1988-1992 (Ref. 8), a large percentage of reported outbreaks involving the referenced pathogens at the beginning of this issue were attributed to improper hot holding. Closer review of Morbidity Mortality Weekly Reports for these reported outbreaks revealed that outbreaks were attributed to improper hot holding at room temperature (70^{o}F $\underline{+}$ 5^{o}F), not at temperatures of 130^{o}F or higher.

- The USDA recognizes the health risk associated with the referenced pathogens and has established minimum upper temperature for hot holding at 130^{o}F (Ref. 11). [Note added: The 130°F is established as part of a mandatory HACCP plan]

- The state of South Carolina has had the 130^{o}F hot holding temperature since 1983.

FMI listed the following references to support its position:

1. FDA (Food and Drug Administration), 1999 Food Code. U.S. Public Health Service, U.S. Dept. of Health and Human Services. Pub. No. PB99-115925.

2. Halpin-Dohnalek, M.I. and Marth, E.H. 1989. *Stahpylococcus aureus*: Production of extracellular compounds and behavior in foods. – A review. J. Food Protect. 52(4):267-282.

3. Hauschild, A.H.W. 1989. *Clostridium botulinum*. In Foodborne Bacterial Pathogens. Doyle, M.P. ed. Marcel Dekker, New York, NY.

4. Johnson, K.M., Nelson, C.L., and Busta, F.F. 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of *Bacillus cereus* in a broth medium and in rice. J. Food Sci. 48:286-287.

5. Juneja, V.K, Snyder, O.P., Cygnarowicz-Provost, M. 1994. Influence of Cooling Rate on Outgrowth of *Clostridium perfringens* Spores in Cooked Ground Beef. J. Food Protection. 57:1063-1-67.

6. Labb, R. 1989. *Clostridium perfringens*. In Foodborne Bacterial Pathogens. Doyle, M.P. ed., Marcel Dekker, Inc., New York, NY.

7. Palop, a., Pilar, M. and Condon. S. 1999. Sporulation Temperature and Heat Resistance of *Bacillus* Spores: A Review. J. Food Safety. 19:57-72.

8. Surveillance for Foodborne-Disease Outbreaks, United States, 1988-1992, Center for Disease Control, Morbid. Mortality Weekly Report. #45(SS-5);1-55, October 25, 1996.

9. Tatini, S.R. 1973. Influence of food environments on growth of *Staphylococcus aureus* and production of various enterotoxins. J. Milk Food Technol. 36:474.

10. Van Netten, P., van de Moosdijk, A., van Hoensel, P., Mossel, D.A.A., and Perales, I. 1990. Psychrotrophic strains of *Bacillus cereus* producing enterotoxin. J. Appl. Microbiol. 69:73-79.

11. USDA (U.S. Dept. of Agriculture) FSIS (Food Safety and Inspection Services). Jan 1999. Appendix A, Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products; USDA FSIS Jan 1999. Appendix B, Compliance guidelines for Cooling Heat-Treat Meat and Poultry Products (Stabilization). Federal Register, Jan 6, 1999. Vol64/No. 3/732-749.

12. Willardsen, R.R., Busta, F.F. Allen, C.E., and Smith, L.B. 1977. Growth and survival of *Clostridium perfringens* during constantly rising temperatures. J. Food Sci. 43:4670.

13. Wong, H.C., Chen, Y.L., and Chen, C.L.F. 1988. Growth, germination and toxigenic activity of *Bacillus cereus* in milk products. J. Food Protect. 51:(9):707.

At the 1998 CFP meeting, Issue 98-03-01 recommended changing the safe hot holding temperature from 140ºF to 130ºF without mandatory monitoring or record keeping. The Council accepted the Issue, as amended. However, at the final session, the voting state delegates failed to accept the Council's recommendation. It is anticipated that the issue will once again come before the CFP at its April 2002 meeting.

B. ISSUES:

ISSUE 1: What is the target organism of concern to be used for establishing the hot holding guidance in the Food Code?
Establishing a target organism for hot holding guidance should be based on food survey and epidemiological data.

A. Food Surveillance

Two spore-forming bacteria, *Clostridium perfringens* and *Bacillus cereus*, have traditionally been associated with foods linked to foodborne illness caused by inadequate hot holding. The prevalence of both organisms in raw and processed foods has been established and is partially summarized in Tables 1 and 2.

Table 1. Prevalence and levels of *Bacillus cereus* in selected foods.

Food Products	% Positive	Range Log CFU/g or/ml	Bibliography
Raw rice	100	Detected	5
Boiled rice	93	1-3	5
Fried rice	86	1-3	5
Egyptian rice dishes	40	1-4	8
Raw milk	9	1-2	1
Pasteurized milk	35	1-3	1

Cheddar cheese	14	1-2	1
Ice cream	48	1-2	1
Spices	40	2-3	13
Spices, flavorings	37	1-5	2
Seasoning mixes	55	2-3	13

Table 2. Prevalence and levels of *Clostridium perfringens* in selected foods.

Food	% Positive	Range Log CFU/g	Bibliography
Spaghetti sauce mixes	53	3-4	20
Sauce and gravy mixes	13	3-5	20
Soup mixes	4	3-5	20
Cheese and cheese sauce	17	3-6	20
Processed meat and meat dishes	20	1-2	11
Beef	29	1-2	26
Pork	66	1-2	26
Lamb	85	1-2	26
Frozen foods	3	1-2	27
Raw fruits and vegetables	4	1-2	27
Spices	5	1-2	27
Meat, poultry and fish	6	1-3	27
Ground beef	50	1-2	14
Chicken feet	69	1-4	15

The numerous reports demonstrating the presence of spores in cooked products indicate that *B. cereus* and *C. perfringens* represent a persistent risk for foodborne illness from foods that are held hot.

B. Human Epidemiology

The estimated total cases of illness in the United States caused by *Clostridium perfringens* or *Bacillus cereus* were reported by Meade et al (17) to be 250,000 and 27,000, respectively.

Data from New York State and Washington State further classify cases of foodborne illness by contributing factors as well as by the bacterial agent (22). These data are summarized in Tables 3, 4 and 5.

Table 3. Contributing environmental factors for foodborne illness cases in New York state, 1980-1999.

Contributing factor	Percentage of total factors cited (%)
Contaminated ingredients	14
Infected person	10
Consumption of raw or lightly heated food (animal origin)	10
Unapproved source	9
Inadequate refrigeration	9
Inadequate cooking	7
Inadequate hot holding	**7**

Table 4. Contributing environmental factors for foodborne illness outbreaks in Washington State, 1990-1999.

Contributing Factor	Percentage of total factors cited (%)
Inadequate hand washing	31
Inadequate hot-holding	**24**
Inadequate refrigeration	20

Slow cooling	20
Cross contamination	18
Bare hand Contact	13
Ill or infected Person	13

Table 5. Foodborne illness cases caused by inadequate hot holding by bacterial agent in New York State, 1980-1999.

Bacterial agent	Total cases reported	Number of cases reporting environmental factors	Cases due to inadequate hot-holding	% Due to inadequate hot holding
Clostridium perfringens	130	97	47	48
Salmonella	349	238	41	17
Bacillus cereus	60	44	23	52
Staphylococcus aureus	75	51	13	25

Inadequate hot holding was attributed to 7% and 24% of the investigated outbreaks for New York and Washington states, respectively (Tables 3 and 4). The numbers of associated cases (suspected or confirmed) indicate that inadequate hot holding was the 7th and 2nd leading contributing factor for foodborne illness in these states.

C. perfringens has been implicated in cases of illness when food was not held at adequate temperatures (21). The New York state data confirm *C. perfringens* and *B. cereus* as organisms of concern for hot held food (Table 4). Inadequate hot holding was associated with approximately 50% of cases attributed to both *C. perfringens* and *B. cereus* (Table 4).

Although spore-forming pathogens contributed significantly to cases of foodborne illness when hot holding was inadequate, *Salmonella* and *S. aureus* were also shown to be causative agents. This suggests that post-cooking contamination and subsequent survival by vegetative infectious and toxigenic agents can occur. However the heat stability of *Staphylococcus* enterotoxin makes it impossible to determine if staphylococcal contamination occurs more commonly pre- or post-cooking.

ISSUE 2: Given the time limits in the practical application of hot holding in the retail and foodservice industries, what is the highest temperature of concern for outgrowth of spores?

The maximum temperature for the outgrowth of *Bacillus cereus* and *Clostridium perfringens* spores and growth parameters have been reported in the literature and are summarized in Tables 6 and 7.

Table 6. Effect of temperature on *Clostridium perfringens* growth parameters.

Temp °F	Temp °C	Food or substrate	Lag time (h)*	Generation time (min)*	pH	Bibliog.
109.4	43	Cooked meat broth	0	56	-	6
110	43.3	Chicken broth	1.08	20	6.4	7
110	43.3	Cooked meat medium	0.73	15	6.8	7
113	45	TG broth	0	20	-	17
113	45	Cooked chicken thigh	0	12	-	7
113	45	Autoclaved ground beef	1.5	7	6.1	21
113	45	Raw ground beef	1.4	9	6.0	31
113	45	Cooked meat broth	0-2	25	-	6
115	46.1	Chicken broth	2.28	32	6.4	7
115	46.1	Cooked meat medium	1.43	21	6.8	7
119.8	48.8	Cooked roast beef	ND	51	-	4
120	48.9	Brick chili	3	11	-	3
120	48.9	Cooked meat medium	4	27	6.8	7

120.6	49.2	Autoclaved ground beef	ND	11	6.1	21
122	50	TG broth	0	23	7.2	17
122	50	Cooked roast beef	ND	84	-	4
122	50	Raw chicken breast	0	40	5.7	10
122	50	Raw chicken Leg	1	28	6.6	10
123.8	51	Autoclaved ground beef	ND	30	6.1	21
124	51.1	Cooked roast beef	ND	218	-	4
126.1	52.4	Cooked meat medium	3	36	7.0	25

* Generation times and lag phase duration reported in literature or estimated

Table 7. Effect of temperature parameters on *Bacillus cereus* growth.

Temp °F	Temp °C	Food or substrate	Lag time (h)*	Generation time (min)*	pH	Bibliog.
104	40	Skim milk	ND	30	6.6	18
104	40	TSB	ND	25	7	12
107.6	42	BHI	0	-	7.4	9
109.4	43	Rice	ND	41	-	19
110	43.3	Chicken broth	2.90	42	6.4	10
110	43.3	Cooked meat medium	2.10	29	6.8	10
113	45	TSB	ND	76	7.0	12
113	45	Rice + 10% beef extract	ND	55	7.0	12
114.8	46	BHI	ND	120	7.4	9
115	46.1	Chicken broth	4.50	29	6.4	10
115	46.1	Cooked meat medium	3.53	29	6.8	10
120	49.9	Chicken broth	NG	-	6.4	10
120	48.9	Cooked meat medium	NG	-	6.8	10
122	50	TSB	NG	-	7.0	12
122	50	BHI	NG	-	7.4	9
131	55	Rice + 10% beef extract	NG	-	7.0	12
131	55	TSB	NG	-	7.0	12
131	55	TSA	48	-	-	24

* Generation times and lag phase duration reported in literature or estimated from graphs

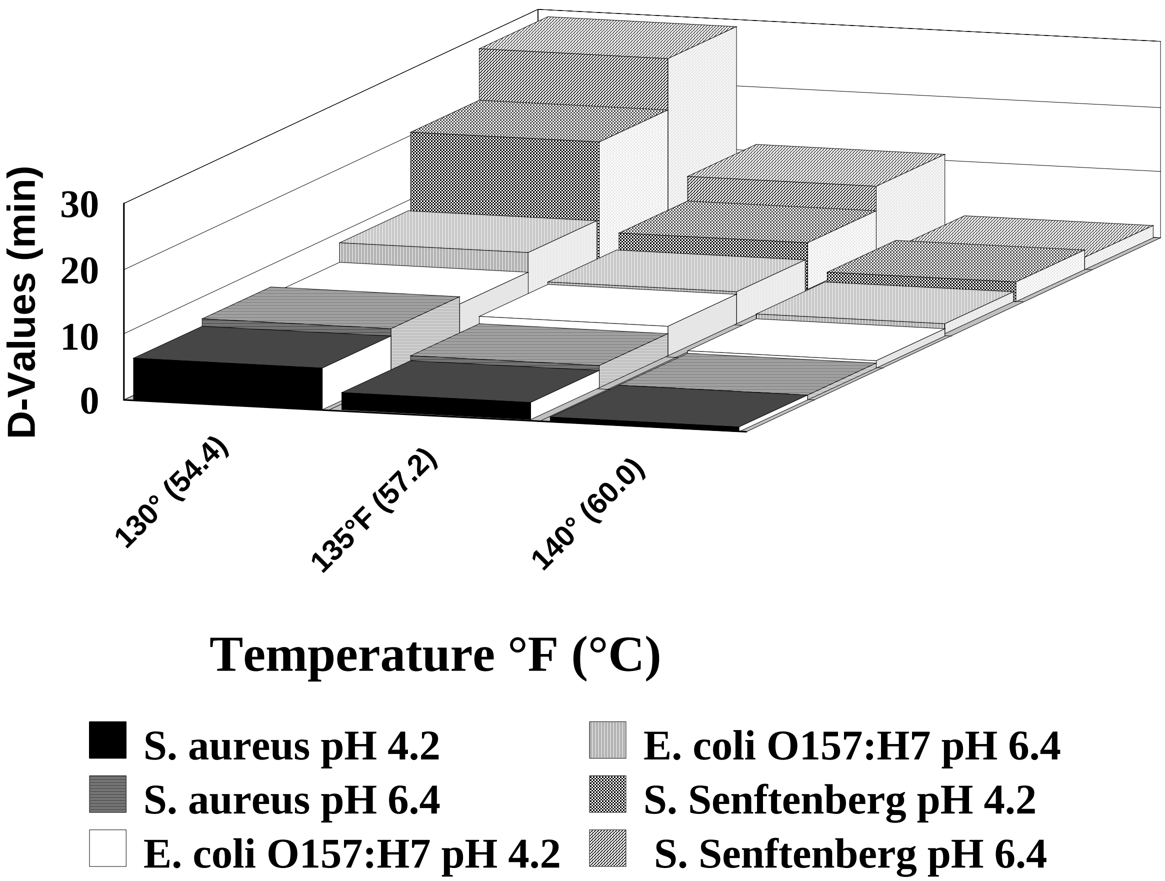
C. perfringens was reported to grow at 126.1°F (52.3°C) (Table 6), however the lag phase duration reported was several hours (25). The study also reported strict anaerobic conditions had to be maintained for growth to occur (25). The literature shows that the lag phase duration and generation times at incubation temperatures below 120°F (48.9°C) were generally shorter than those at 125°F (51.7°C). However, the temperature at which outgrowth of *C. perfringens* may become likely in hot held food cannot be determined unless a conservative estimate of storage times are made.

There are no studies to show the range of average hot holding times used in the retail food industry; however 4 to 8 hours is considered the time range customarily used for food that is hot held for sale by grocery store deli operations (30). For the food service industry, a few foods may be held for up to 12 hours, such as a *soup du jour*, or roasts held after cooking in a low temperature-high humidity oven, such as an Alto Shaam®. However, food quality concerns usually limit the hot holding time for the vast majority of foods to 4 to 8 hours. Prolonged high temperatures cause loss of food quality by causing loss of texture, taste and nutrient content in vegetables and seafood, and causing meat to become tough and lose flavor. Thus, saleability of the food is greatly reduced.

One study reported growth of *Bacillus cereus* at 131°F (55°C) (Table 7), demonstrating growth was reported of 4% of *Bacillus cereus* strains on TSA agar after 48 hours of incubation at 131°F (55°C) (24). The second highest growth temperature reported was 115°F (46.1°C) with a lag phase of 4 hours. None of the other studies listed in Table 7 sampled at time periods longer than 24 hours, therefore growth at a later time could not be reported. This study also differed from others by assaying for growth on an agar rather than in broth or a food matrix. The time needed for growth reported in this study far exceeds any practical time limits for retail hot held foods. Other than this report of growth under prolonged conditions, the literature suggests that if the temperature is high enough to prevent *C. perfringens* growth, growth of *B. cereus* should be prevented.

Although vegetative cells of pathogenic bacteria will not survive the recommended Food Code time/temperature combinations for cooking, there is epidemiological evidence that contamination periodically may be introduced to cooked food from the hands of infected workers, customers or from unclean equipment (Table 4). Recent FDA data (unpublished) illustrates the increase in survival of 3 vegetative cell pathogens when the hot holding temperature is decreased from 140° to 130°F (Figure 2).

Figure 2. D-values for 3 vegetative cell pathogens in chicken broth (pH 6.4) and tomato soup condensate (pH 4.2) between 130-140°F (54.4-60°C)



The thermal death times (D-values) of each organism increased approximately 3-fold as the temperature were lowered from 140 to135°F (60.0 to 57.2°C) (Figure 2), which equated to a 6 to 10 fold increase in survival. Thus, the rate at which vegetative pathogens can survive in hot held food was deemed to be a function of the holding time and temperature. Of these microorganisms, *S. aureus*, specifically its enterotoxin is the most problematic because of its thermal stability. Keeping the food at a sufficiently high hot holding temperature is an additional control against the survival and growth of post-cooking bacterial contamination.

ISSUE 3: What role does evaporative cooling play in determining the critical limit?

During hot holding, food that is held at a constant temperature loses heat to the surrounding environment at the surface interface. This phenomenon is most critical when food is particulate and the establishment does not stir the food frequently. In this case the food at the interface surface may be held at a temperature significantly lower than the interior. Frequent stirring or placing covers on the food would create more homogenous temperatures throughout the food. Covering the food also raises the humidity in the atmosphere immediately above the food. Another factor to consider is that the food is intended to be sold or served, and therefore the surface will be disrupted each time a portion is dispensed. However, the foodservice industry's practices on stirring or covering hot held food has not been evaluated.

FDA visited several full service restaurants in suburban Maryland to evaluate the differences in temperature between the interior of food and the surface. Surface temperatures were checked using an IR (Raytek) device. Triplicate readings were made for each food then averaged. A thermocouple was used to estimate the interior of the food at 4 locations within the pan at various depths. These numbers were also averaged. Both measuring devices were calibrated and accurate to within 1° C according to the Food Code paragraph 4-204.112 E. The data are summarized in Table 8.

Table 8. Temperature profiles (surface and interior) of hot held foods from four full service Maryland restaurants.

Product	Surface °F (std)	Interior °F (std)	Difference °F
Liquids:			
Gravy	150(3)	159(3)	9
Bean soup	170(4)	181(11)	11
Potato soup	168(7)	173(12)	5
Crab soup	176(5)	182(5)	6
White gravy	143(2)	158(2)	15
Clam chowder	130 (5)	140(6)	10
Solid or Semi-Solid			
Refried beans	105(7)	161(3)	56
Refried bean dip	105(6)	145(8)	40
Charro beans	136(7)	171(3)	35
Baked beans	131(4)	183(7)	52
Green beans	159(2)	187(4)	28
Mashed potatoes	127(5)	143(11)	16
Rice	137(3)	163(3)	16
Wild rice	146(14)	172(4)	26
Stuffing	138(5)	173(11)	35
Potatoes	140(8)	170(11)	30
Taco meat	111(12)	170(19)	59
Chicken	128(7)	147(15)	19
Beef	100(5)	130(4)	30
Turkey	113(5)	139(10)	26
Pork	98(4)	135(5)	37
Beef barbeque	102(6)	171(5)	69

The average interior and surface temperatures of the food listed in Table 8 was 163°F (72.8°C) and 132°F (55.5°C), respectively. The average difference between the surface and interior was 31°F. Although Table 8 comprises a very small data set, it underscores the wide range of temperature differentials between the surface and interior of food in a hot holding environment. In general, liquid foods (Table 8) such as soups and gravy had smaller temperature differentials than solid or semi-solid products. It has not been determined if the spores that are present at the surface micro-environment (and therefore subject to the effects of evaporative cooling) are consistent with the dispersion of spores in the remainder of the food.

Although the IR measuring device gave readings significantly lower than the interior temperature, the standard deviations between readings are approximately 20% greater than those of the thermocouple. This greater variability is most likely attributed to steam escaping the food confounding the IR reading. The use of IR measuring devices requires inspectors ensure that the distance and angle between the food and the device does not affect the temperature readings. Currently FDA regional food specialists monitor temperatures with thermocouples. State and local inspectors predominately use bimetal stem thermometers to measure temperatures. If evaporative cooling phenomenon is present at only the top few millimeters of the surface of the food, the use of bimetal stem thermometers will not record these temperatures especially if the food is less than 2 inches deep. Despite the advantages of IR in measuring the coldest spots in containers of hot held food, the cost of the devices may prohibit increased usage by state and local agencies. Annex 4 (Section 8) of the Food Code (29) lists the type of measuring devices acceptable for use in inspections and the limitations of each. Despite the problems with instrumentation in the field, each food item should have its temperature measured at its coldest spot regardless of its depth, width or length.

Another factor to consider is the pan sizes that are commonly used in the industry that might affect surface evaporative cooling. Hotel pans (12x20x2½) are commonly used for buffets whereas ½, 1/3 or ¼ hotel pans or *bain marie* inserts (1-2 quarts) may be used more commonly in the back of the house.

ISSUE 4: What should the Food Code recommend as the critical limit for the hot holding temperature?

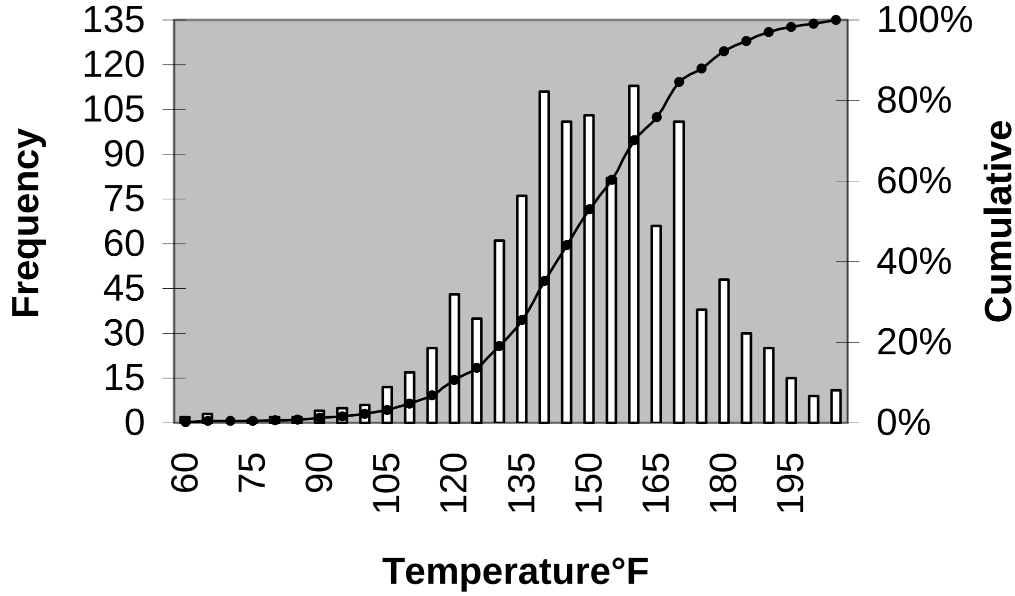
The Food Code section 3-501.16 recommends that potentially hazardous food be maintained at 140°F (60°C) or above. The Food Code does not stipulate any time restrictions for food held at constant temperature. The exceptions to this recommendation are summarized in Table 9.

Table 9. Exceptions to hot holding requirements of 140°F (60°C).

Food Code Citation	Foods	Temperature parameters
3-501.19	All	No temperature requirement is necessary **if** time alone is used as the control and the food is consumed or discarded within 4 hours after removal from temperature control. Either the food or containers must be marked to indicate time.
3-401.11(B)	Beef roasts, corned beef roasts, pork roasts, cured pork roasts	<u>Cooking</u>: If roasts are cooked observing the oven type and oven temperature parameters, and all parts of the roast achieve one of the following time/temperature parameters: 130°F for 121 min. 132°F for 77 min. 134°F for 47 min. 136°F for 32 min. 138°F for 19 min. 140°F for 12 min. 142°F for 8 min. 144°F for 5 min or 145 for 3 min., THEN <u>Hot Holding</u>: the roast may be hot held at 130°F.
3-403.11(E)	Beef roasts	<u>Reheating</u>: Remaining unsliced portions of roasts that are cooked according to paragraph 3-401.11(B) may be reheated to a time/temperatures combination listed in paragraph 3-401.11(B) <u>Hot Holding</u>: THEN hot hold at 130°F

In order to assess the adequacy of current guidelines, it is important to evaluate current compliance practices. To do this, FDA conducted a survey of US retail establishments. The FDA Retail Food Program Database of Foodborne Risk Factors (28) provides actual temperatures that food is being held at different establishment types across the country.

Figure 1. Range and frequency distribution of hot holding temperatures in foods across food service and retail establishments in the U.S. (n=1147)



The data are based on equal numbers of 6 different types of establishments (see Table 10). The data were obtained by FDA regional food specialists. Of the foods tested, 74% were at or above the critical limit recommended by the Food Code (140°F or 60°C)). Of the food items not in compliance, 26% were below 140°F (60°C), 14% were below 130°F (54.4°C) and 7% were below 120°F (48.9°C) (Figure 1). There are no data to predict changes occurring in commercial practices if the critical limit for hot holding were changed. For example, it is unknown if the distribution shown in Figure 1 would simply shift to the left yielding a higher proportion of establishments below 140°F (60°C). Alternatively, it is unknown if the proportion of establishments below the new critical limit would increase. Although Figure 1 gives some insight into hot holding practices across the country, the overall percentages of food held at 140°F (60°C) or above for all establishment types may be misleading because of differences in hot holding practices between establishment types. An estimate of percentages of hot holding temperatures at different establishment types is included in Table 10.

Table 10. The percentage[A] of hot holding temperatures between establishment types.

Establishment Type	≥140°F [B] (60°C)	< 140°F [B] (60°C)	< 130°F [B] (54.4°C)	< 120°F [B] (48.9)
Deli	53%	47%	29%	15%
Full service restaurant	74%	26%	14%	8%
Elementary schools	74%	26%	13%	7%
Hospitals	82%	18%	9%	3%
Fast food	83%	17%	7%	6%
Nursing homes	89%	11%	6%	2%

[A] Although the data provides differences in hot holding practices between institution types, the percentages reported are for comparison only and do not constitute statistical significance between establishment types

[B] Percentage of temperature measurements of foods that have hot holding requirements in the Food Code

The data show that institutions that serve immunocompromised or elderly populations more closely adhere to guidelines than do institutions that serve the general public. One exception to this is fast food establishments, which demonstrated one of the highest in compliance percentages of food held at 140°F (60°C) or above (83%). The minimal number of items needing hot holding, the type of foods served, and the method of service may explain the differences in percentages compared to the deli and full service restaurant categories.

Food Code section 3-401.11 recommends several time/temperature scenarios for cooking raw animal food safely (27). A summary of recommended time/temperature cooking scenarios is listed in Table 11.

Table 11. Food Code time and temperature recommendations for cooking products.

Code Citation	Food	Temp °C (°F)	Time
3-401.11(A)(1)(a)	Raw shell eggs that are prepared for a consumer's order and served immediately	63 (145)	15 sec
3-401.11(A)(1)(b)	Fish, meat, pork including game animals commercially raised for food under subparagraph 3-201.17(A)(1) and game animals under a voluntary inspection program as specified under 3-201.17(A)(2)	63 (145)	15 sec
3-401.11(A)(2)	Ratites, injected meats, comminuted fish, comminuted meat, comminuted game animals commercially raised for food under subparagraph 3-201.17(A)(1) and comminuted game animals under a voluntary inspection program as specified under 3-201.17(A)(2), and raw eggs that are not prepared for a consumer's order and served immediately	63 (145) 66 (150) 68 (155) 70 (158)	3 min 1 min 15 sec <1 sec
3-401.11(A)(3)	Poultry and wild game animals as specified under subparagraphs 3-201.17(A)(3)(4), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites	74 (165)	15 sec
3-401.11(B)(2)	All parts of whole beef roasts, pork roasts and cured pork roasts which are cooked according to oven temperatures based on roast weight given in subparagraph 3-401(B)(1)	54 (130) 56 (132) 57 (134) 58 (136) 59 (138) 60 (140) 61 (142) 62 (144) 63 (145)	*121 min 77 min 47 min 32 min 19 min 12 min 8 min 5 min 3 min
3-401.11(C)(3)	Raw or undercooked whole muscle intact beef steak that is labeled and not served to a highly susceptible population	63 (145 - on the surface)	**

* Holding time may include post oven heat rise
** Steak is cooked on both top and bottom to 63°C (145°F) and a cooked color change is achieved on all external surfaces

As chronicled by the literature summarized in Tables 1 and 2, strict adherence to Food Code guidelines for cooking will not eradicate spores of pathogenic organisms such as *Clostridium perfringens* or *Bacillus cereus* from product. Long time/low temperature combinations can actually heat shock spores and increase their growth potential.

The ability of *C. perfringens* and *B. cereus* to grow between 115-130°F (46.1-54.4°C) has been studied and reported in the literature. Other than one study discussed earlier (24), there are no reports of growth above 130°F (54.4°C). The likelihood of outgrowth of either organism at or above 125°F (51.7°C) during time parameters conducive to the sale of hot held food is minimal. Furthermore, the hot holding of food at 131°F for 48 hours, that one study suggested allowed growth of *B. cereus* (24), is highly unlikely due to the loss of food quality.

The difference between surface and interior temperatures of food adds a degree of uncertainty as to how well food temperature is maintained. The time duration that the food spends in hot holding before sale is a significant factor influencing both safety and quality. Retail stores and food service establishments prepare food prior to core times of business, such as lunch or dinner, and hot hold it for convenience and fast service. However, except for usual and customary practices, no frequency distribution is available to determine a worst-case scenario for the duration food is kept before establishments sell, serve, or discard remaining product. Establishing a time parameter in which a high percentage of food has been sold, served, or discarded would allow assessment of growth data, and facilitate determination of critical limits.

The science for outgrowth of *C. perfringens* and *B. cereus* suggest that if food is held at its coldest point at 130 (54.4°C) the food should remain safe during the time held for sale. However, conditions during hot holding cannot discount the possibility of large temperature differentials existing in food for extended periods. If a documented plan for temperature recording were in place, either by itself or part of a HACCP plan, variances could be implemented to take advantage of time and temperature parameters. Table 12 lists time and temperature parameters that would ensure the safety of hot held food based on a performance standard of no more than Log_{10} 1 growth of *C. perfringens*.

Table 12. Possible time and temperature combinations for variances to current hot holding recommendations.

Temperature °F (°C)	Time (hr)*
125 (51.7)	2
130 (54.4)	4
135 (57.2)	8
140 (60.0)	Indefinitely**

* Time reflects the possibility of no more than Log_{10} 1 growth of *C. perfringens* in food.
** No monitoring plan needed.

ISSUE 5: What impact does lowering the recommended hot holding temperature have on the public health of consumers in the United States?

It is not possible at this time to predict the full impact of lowering the recommended hot holding temperature would have on the number of foodborne illness cases in the United States. In order to assess this impact, an understanding of the range of illnesses generated by inadequate hot holding each year must be made.

CDC estimates (17) suggest that around 250,000 foodborne illness cases can be attributed to either *C. perfringens* or *B. cereus* each year in the United States. Data from New York State (22) (Table 5) suggests that roughly half of foodborne illness cases attributed to either organism were linked to inadequate hot holding. Although little certainty can be placed on CDC estimates and state epidemiological data, the data does suggest that tens of thousands of cases of foodborne illness cases potentially are caused by inadequate hot holding each year.

The impacts of changing hot holding temperature guidelines on food service establishments across the United States are also not possible to predict at this time. A higher proportion of foods could begin to be held at lower temperatures, which would shift the histogram in Figure 1 to the left. However, the impact of changing Food Code guidelines could be minimal on the hot holding practices of establishments across the country, producing no significant changes to the percentage of food that is held at dangerously low temperatures. Although it cannot be determined if the effect of lowering hot holding requirements would significantly increase the number of foodborne illnesses or not, there are no plausible scenarios that indicate that foodborne illness would decline if hot holding guidelines were lowered.

C. FDA's Current Thinking:

1. The target microorganisms for hot holding guidance in priority order are *Clostridium perfringens*, *Bacillus cereus* and *Staphylococcus aureus*.
2. The highest growth temperature, for time durations practical for food preparation and sale, is 125°F (51.7°C)
3. Evaporative cooling is significant and must be addressed appropriately.
4. The Food Code's critical limit for hot holding should stay at 140°F with no restrictions, but lower temperatures may be used based on a performance standard of no more than Log_{10} 1 growth of *C. perfringens* in food with time restrictions and/or documentation of temperature at the coldest point in the food.

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