

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting [your question](mailto:yourquestion@fda.gov) at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

Appendix 3: Bacterial Pathogen Growth and Inactivation

This appendix contains information on the growth and inactivation of bacterial pathogens. The tables in this appendix derive from our guidance entitled "Fish and Fishery Products Hazards and Controls Guidance." In these tables, and our discussion of these tables, we use the technical terms "D-value" and "z-value," which we briefly describe immediately below. For additional information about what these terms mean and how you can use the information in these tables to determine appropriate processing conditions for your product, you should consult standard food processing books and technical information.

- D-value: The relationship between the duration of a thermal treatment and the percentage of microorganisms surviving the treatment is generally logarithmic, and the results of such studies are usually presented in a plot that represents the log of the percent of surviving vegetative cells or spores versus time at a given temperature. The time required to destroy 90 percent of the vegetative cells or spores at a given temperature is called the decimal reduction time, usually referred to as the "D-value" (Larousse and Brown, 1997). The D-value usually varies inversely with temperature.
- z-value: In general, the slope of a plot of the log of the D-value versus temperature is approximately linear. A "z-value" is derived from the reciprocal of the slope of the best straight line and is equal to the increase in the number of degrees (from a given starting temperature) that results in a 90 percent reduction in the D-value (Larousse and Brown, 1997). The D-value and z-value for the vegetative cells or spores of a microbial strain at a specified temperature characterize its thermal resistance at that temperature. Therefore, D-values and z-values provide a means to compare the thermal resistance of different microorganisms, or different strains of the same microorganism, at one or more temperatures.

Table 3-A contains information on the minimum water activity (a_w), minimum and maximum pH, and minimum and maximum temperatures that limit growth for the bacterial pathogens that are of greatest concern in food processing. Table 3-A also provides data on the maximum water

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Appendix 3 that we issued for public comment in August 2016.

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phase salt that limits growth and the oxygen requirements for the pathogens listed. The data shown in Table 3-A are the extreme limits reported among the references cited. These values may not apply to your food or processing conditions.

Table 3-B contains information on maximum cumulative exposure time at internal product temperature ranges for exposure of foods that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in food processing. These maximum, cumulative exposure times are derived from published scientific information.

Table 3-C is a Quick Reference Guide based on Table 3-B.

Because the nature of bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix affects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth-restrictive agents). You should consider such attributes when using the information in Tables 3-A, 3-B, and 3-C.

Table 3-D contains information on the destruction of *Listeria monocytogenes* (*L. monocytogenes*). Lethal rate, as used in Table 3-D, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (using a $z = 13.5^\circ\text{F}$ (7.5°C)). For example, 1 minute at 145°F (63°C) is 0.117 times as lethal as 1 minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a “6D” process for *L. monocytogenes* (i.e., a process that will accomplish a 6 logarithm (factor of 1,000,000) reduction in the number of *L. monocytogenes*).

The length of time at a particular internal product temperature needed to accomplish a 6D reduction in the number of *L. monocytogenes* depends, in part, upon the food that is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if you anticipate relatively high initial levels in the food you are processing.

Table 3-E contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat-resistant form of non-proteolytic *C. botulinum*). (The non-proteolytic strains of *C. botulinum* can grow at refrigeration temperatures and may be a hazard requiring a preventive control in some foods intended to be held refrigerated for extended periods of time.) Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (for temperatures less than 194°F (90°C), $z = 12.6^\circ\text{F}$ (7.0°C); for temperatures above 194°F (90°C), $z = 18^\circ\text{F}$ (10°C)). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum*. The values in the table are generally conservative. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies.

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Table 3-A Limiting Conditions for Pathogen Growth

Pathogen	Min. a _w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
<i>Bacillus cereus</i>	0.92	4.3	9.3	10	39.2°F 4°C	131°F ¹ 55°C	facultative anaerobe ⁴
<i>Campylobacter jejuni</i>	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile ²
<i>Clostridium botulinum</i> , type A, and proteolytic types B and F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe ³
<i>Clostridium botulinum</i> , type E, and non-proteolytic types B and F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe ³
<i>Clostridium perfringens</i>	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe ³
Pathogenic strains of <i>Escherichia coli</i>	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe ⁴
<i>Listeria monocytogenes</i>	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe ⁴
<i>Salmonella</i> spp.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe ⁴
<i>Shigella</i> spp.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe ⁴
<i>Staphylococcus aureus</i> growth	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe ⁴

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Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
<i>Staphylococcus aureus</i> toxin formation	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe ⁴
<i>Vibrio cholerae</i>	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe ⁴
<i>Vibrio parahaemolyticus</i>	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe ⁴
<i>Vibrio vulnificus</i>	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe ⁴
<i>Yersinia enterocolitica</i>	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe ⁴

¹Has significantly delayed growth (>24 hours) at 131°F (55°C).

²Requires limited levels of oxygen.

³Requires the absence of oxygen.

⁴Grows either with or without oxygen.

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Table 3-B. Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products

Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth and toxin formation by <i>Bacillus cereus</i>	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
Growth of <i>Campylobacter jejuni</i>	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
Germination, growth, and toxin formation by <i>Clostridium botulinum</i> type A, and proteolytic types B and F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
Germination, growth, and toxin formation by <i>Clostridium botulinum</i> type E, and non-proteolytic types B and F	37.9-41°F (3.3-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
Growth of <i>Clostridium perfringens</i>	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours ¹ 2 hours
Growth of pathogenic strains of <i>Escherichia coli</i>	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth of <i>Listeria monocytogenes</i>	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
Growth of <i>Salmonella</i> species	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth of <i>Shigella</i> species	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth and toxin formation by <i>Staphylococcus aureus</i>	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours ¹ 3 hours

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Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth of <i>Vibrio cholerae</i>	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour ²
Growth of <i>Vibrio parahaemolyticus</i>	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour ²
Growth of <i>Vibrio vulnificus</i>	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour ²
Growth of <i>Yersinia enterocolitica</i>	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

¹ Additional data needed.

² Applies to cooked, ready-to-eat foods only.

Table 3-C is a Quick Reference Guide derived from Table 3-B:

Table 3-C Quick Reference Guide for Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products (for Internal Temperatures above 50°F (10°C) but below 135°F (57.2°C))

If the food is a ...	And the food is held at an internal temperature ...	Then you should limit the exposure time to ...	Or, if <i>Staphylococcus aureus</i> (<i>S. aureus</i>) is the only pathogen of concern, then you should limit the exposure time to ...	As long as ...
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	2 hours	3 hours	N/A
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	4 hours	N/A	No more than 2 of those hours are between 70°F (21.1°C) and 135°F (57.2°C)
Raw, RTE ingredient or food product	At any time above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A

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If the food is a ...	And the food is held at an internal temperature ...	Then you should limit the exposure time to ...	Or, if <i>Staphylococcus aureus</i> (<i>S. aureus</i>) is the only pathogen of concern, then you should limit the exposure time to ...	As long as ...
Raw, RTE ingredient or food product	At internal temperatures (or at ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A
Cooked, RTE ingredient or food product	At any time above 80°F (26.7°C)	1 hour	3 hours	N/A
Cooked, RTE ingredient or food product	At any time above 80°F (26.7°C)	4 hours	N/A	No more than 1 of those hours is above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time above 70°F (21.1°C) but never above 80°F (26.7°C)	2 hours	3 hours	N/A
Cooked, RTE ingredient or food product	Never held above 80°F (26.7°C)	4 hours	N/A	No more than 2 of those hours are above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A
Cooked, RTE ingredient or food product	At internal temperatures (or ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), which is the recommended maximum storage temperature for refrigerated food products, and 50°F (10°C). That is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most food processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table 3-B for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures.

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It is not possible to furnish recommendations for each pathogenic bacterium, process, type of food product, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture' (the Pathogen Modeling Program (PMP)) and by an international consortium of the Institute of Food Research (UK), the USDA Agricultural Research Service (USDA-ARS) and the University of Tasmania Food Safety Centre (CombBase database and Predictor). These programs can provide growth curves for selected pathogens. To use these models, you indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, and generation time). FDA does not endorse or require the use of such modeling programs, but recognizes that the predictive growth information they provide may be helpful to some processors. However, you should be aware that significant deviations between actual microbiological data in specific products and the predictions may occur, including those for the lag phase of growth. Therefore, you should validate the time and temperature limits derived from such predictive models if growth of pathogens during processing requires a preventive control.

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Table 3-D Inactivation of *Listeria monocytogenes*

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate	Time for 6D Process (minutes)
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02

Note: z = 13.5°F (7.5°C).

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Table 3-E Inactivation of Non-Proteolytic *Clostridium botulinum* Type B

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate*	Time for 6D Process (minutes)
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: For temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C).

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Contains Non-binding Recommendations
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