Appendix 4: Bacterial Pathogen Growth and Inactivation

This appendix contains information on the growth and inactivation of bacterial pathogens.

Table #A-1 contains information on: the minimum water activity (a_W), acidity (pH), and temperature; the maximum, pH, water phase salt, and temperature; and oxygen requirements that will sustain growth for the bacterial pathogens that are of greatest concern in seafood processing. Data shown are the minimum or maximum values, the extreme limits reported among the references cited. These values may not apply to your processing conditions.

Table #A-2 contains information on maximum, cumulative time/internal temperature combinations for exposure of fish and fishery products that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in seafood processing. These maximum, cumulative exposure times are derived from published scientific information. Because the nature of bacterial growth is logarithmic, linear interpolation using the time/temperature guidance is not appropriate.

In summary, the table indicates that:

- If the product is held at internal temperatures above 70˚F (21˚C) during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures above 50˚F (10˚C), but not above 70˚F (21˚C), exposure time should ordinarily be limited to six hours (twelve hours if *Staphylococcus aureus* is the only pathogen of concern);

- If the product is held at internal temperatures both above and below 70˚F (21.1˚C), exposure times above 50˚F (10˚C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70˚F (21.1˚C).

It is not possible to furnish recommendations for each pathogen, process, type of seafood, 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 ("Pathogen Modeling Program" [PMP]) and the United Kingdom ("Food MicroModel" [FMM]). These programs can provide growth curves for selected pathogens. 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, generation time). FDA does not endorse or require the use of such modelling programs, but recognizes that the predictive growth information they provide may be of assistance to some processors. However, you are cautioned that significant deviations between actual microbiological data in specific products and the predictions do occur, including those for the lag phase of growth. Therefore, you should validate the time-temperature limits derived from such predictive models.

Table #A-3 contains information on the destruction of *Listeria monocytogenes*. Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference internal product temperature of 158˚F (70˚C) (i.e. z = 13.5˚F [7.5˚C]). For example, one minute at 145˚F (63˚C) is 0.117 times as lethal as one 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.* The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of *L. monocytogenes* (6D) is, in part, dependent upon the food in which it 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

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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 innoculum in the food.

Table #A-4 contains information on the destruction of *Clostridium botulinum* type B (the most heat resistant form of nonproteolytic *Clostridium botulinum*). Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference product internal temperature of 194˚F (90˚C) (i.e. 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];). 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. However, they may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential protective effect of lysozyme. 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 innoculum in the food.

Table #A-1

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*
Bacillus cereus	.92	4.3	9.3	10	39.2˚F 4˚C	131˚F**** 55˚C	aerobe
Campylobacter jejuni	.987	4.9	9.5	1.5	86˚F 30˚C	113˚F 45˚C	micro- aerophilic*
Clostridium botulinum, type A, and proteolytic B and F	.935	4.6	9	10	50˚F 10˚C	118.4˚F 48˚C	anaerobe**
Clostridium botulinum, type E, and nonproteolytic B and F	.97	5	9	5	37.9˚F 3.3˚C	113˚F 45˚C	anaerobe**
Clostridium perfringens	.93	5	9	7	50˚F 10˚C	125.6˚F 52˚C	anaerobe**
pathogenic strains of *Escherichia coli*	.95	4	9	6.5	43.7˚F 6.5˚C	120.9˚F 49.4˚C	facultative anaerobe***
Listeria monocytogenes	.92	4.4	9.4	10	31.3˚F -0.4˚C	113˚F 45˚C	facultative anaerobe***
Salmonella spp.	.94	3.7	9.5	8	41.4˚F 5.2˚C	115.2˚F 46.2˚C	facultative anaerobe***
Shigella spp.	.96	4.8	9.3	5.2	43˚F 6.1˚C	116.8˚F 47.1˚C	facultative anaerobe***
Staphylococcus aureus – growth	.83	4	10	20	44.6˚F 7˚C	122˚F 50˚C	facultative anaerobe***
Staphylococcus aureus – toxin	.85	4	9.8	10	50˚F 10˚C	118˚F 48˚C	
Vibrio cholerae	.97	5	10	6	50˚F 10˚C	109.4˚F 43˚C	facultative anaerobe***
Vibrio parahaemolyticus	.94	4.8	11	10	41˚F 5˚C	113.5˚F 45.3˚C	facultative anaerobe***
Vibrio vulnificus	.96	5	10	5	46.4˚F 8˚C	109.4˚F 43˚C	facultative anaerobe***
Yersinia enterocolitica	.945	4.2	10	7	29.7˚F -1.3˚C	107.6˚F 42˚C	facultative anaerobe***

* requires limited levels of oxygen ** requires the absence of oxygen *** grows either with or without oxygen **** growth significantly delayed (>24 hr.) at 131˚F (55˚C)

Table #A-2

Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods

Potentially Hazardous Condition	*Product Temperature*	*Maximum Cumulative Exposure Time*
Growth and toxin formation by ***Bacillus cereus***	39.2-43˚F (4-6˚C) 44-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	5 days 17 hours* 6 hours* 3 hours
Growth of ***Campylobacter jejuni***	86-93˚F (30-34˚C) Above 93˚F (above 34˚C)	48 hours 12 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type A, and proteolytic B and F	50-70˚F (10-21˚C) Above 70˚F (above 21˚C)	11 hours 2 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type E, and nonproteolytic 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 (above 21˚C)	7 days > 2 days 11 hours 6 hours
Growth of ***Clostridium perfringens***	50-54˚F (10-12˚C) 55-57˚F (13-14˚C) 58-70˚F (15-21˚C) Above 70˚F (above 21˚C)	21 days 1 day 6 hours* 2 hours*
Growth of pathogenic strains of ***Escherichia coli***	44.6-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 6 hours 3 hours
Growth of ***Listeria monocytogenes***	31.3-41˚F (-0.4-5˚C) 42-50˚F (6-10˚C) 51-70˚F (11-2˚C) Above 70˚F (above 21˚C)	7 days 2 days 12 hours* 3 hours*
Growth of ***Salmonella*** species	41.4-50˚F (5.2-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 6 hours 3 hours
Growth of ***Shigella*** species	43-50˚˚F (6.1-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days* 12 hours* 3 hours*
Growth and toxin formation by ***Staphylococcus aureus***	44.6-50˚F (7-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	14 days 12 hours* 3 hours
Growth of ***Vibrio cholerae***	50˚F (10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio parahaemolyticus***	41-50˚F (5-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio vulnificus***	46.4-50˚F (8-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	21 days 6 hours 2 hours
Growth of ***Yersinia enterocolitica***	29.7-50˚F (-1.3-10˚C) 51-70˚F (11-21˚C) Above 70˚F (above 21˚C)	1 days 6 hours 2.5 hours

* Additional data needed.

Table #A-3

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)

Table #A-4

Inactivation of nonproteolytic *Clostridinum 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].

*Note: these lethal rates and process times may not be sufficient for the destruction of nonproteolytic *C. botulinum* in dungeness crabmeat, because of the potential that substances that may be naturally present, such as lysozyme, may enable the pathogen to more easily recover from heat damage.

Notes: