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General Interest

Utilization of Mathematical Models To Manage Risk of Holding Cold Food without Temperature Control

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ABSTRACT

This document describes the development of a tool to manage the risk of the transportation of cold food without temperature control. The tool uses predictions from ComBase predictor and builds on the 2009 U.S. Food and Drug Administration Model Food Code and supporting scientific data in the Food Code annex. I selected *Salmonella* spp. and *Listeria monocytogenes* as the organisms for risk management. *Salmonella* spp. were selected because they are associated with a wide variety of foods and grow rapidly at temperatures >17°C. *L. monocytogenes* was selected because it is frequently present in the food processing environment, it was used in the original analysis contained in the Food Code Annex, and it grows relatively rapidly at temperatures <17°C. The suitability of a variety of growth models under changing temperature conditions is largely supported by the published literature. The ComBase predictions under static temperature conditions were validated using 148 ComBase database observations for *Salmonella* spp. and *L. monocytogenes* in real foods. The times and temperature changes encompassed by ComBase Predictor models for *Salmonella* spp. and *L. monocytogenes* are consistent with published data on consumer food transport to the home from the grocery store and on representative foods from a wholesale cash and carry food service supplier collected as part of this project. The resulting model-based tool will be a useful aid to risk managers and customers of wholesale cash and carry food service suppliers, as well as to anyone interested in assessing and managing the risks posed by holding cold foods out of temperature control in supermarkets, delis, restaurants, cafeterias, and homes.

BACKGROUND

In August 2009, WABC-TV New York aired two stories describing the potential risks posed by transportation of perishable foods from a wholesale cash and carry food service supplier in the tri-state area. As part of their ongoing commitment to food safety, Jetro/Restaurant Depot contacted Rutgers University to develop a science-based means to assess risk and inform risk management decisions regarding transportation of cold food without temperature control. In this document, I describe the development of science-based means to manage the food safety risks associated with the transportation of cold food without temperature control. I start with a review of the 2009 U.S. Food and Drug Administration (FDA) Model Food Code requirements for using time as a public health control for ready-to-eat foods that are removed from cold holding and stored without temperature control, including the FDA position paper on this topic from Annex 3 of the Food Code. I then expand upon the approach used in the Food Code and show the use of mathematical models for bacterial growth in food under changing temperature conditions. I develop a mathematical model-based risk management strategy, validate the models used in that strategy, summarize published and newly collected data on food temperature rise during transport, and conclude with some practical implications of the work. This project was designed to serve as an aid to risk managers and customers of wholesale cash and carry food service suppliers. The results are also relevant to anyone interested in assessing and managing the risks posed by holding cold foods out of temperature control, including those concerned with safe transport and holding of foods in supermarkets, delis, restaurants, cafeterias, and homes.

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USING TIME AS A PUBLIC HEALTH CONTROL IN THE FDA MODEL FOOD CODE

The 2009 FDA Model Food Code (section 3-501.19, entitled ''Using Time as a Public Health Control'') states that potentially hazardous food (time and temperature control for safety) that is ready-to-eat has an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control and can be stored without temperature control for up to 4 h, after which it must be discarded or consumed. The Food Code also states that this time limit is up to 6 h as long as the food temperature does not exceed 21.1°C (70°F) after that time.

In the ''Annex 3: Public Health Reasons/Administrative Guidelines'' of the ''Supplement to the 2005 Food Code,'' in section 3-501.19, titled ''Holding Cold Food without Temperature Control,'' the FDA expounds upon some of the risks that may develop when a food is removed

from refrigerated storage and begins to warm to room temperature. Note that text in the current 2009 Food Code is unchanged from the 2005 supplement. The annex also notes that the 2000 Conference for Food Protection (CFP) meeting recommended that the FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control (section 3-501.19). It goes on to state that the FDA (in consultation with the U.S. Department of Agriculture, Food Safety and Inspection Service [USDA FSIS]) determined that there was sufficient scientific information available to support the current provision in the Food Code without requesting consideration by NACMCF. The FDA then provides a position paper on using time alone as a public health control.

REVIEW OF FDA POSITION PAPER

The position paper makes a number of statements that refer to evidence in the scientific literature in support of the Food Code guidance. The position paper states that *Listeria monocytogenes* is a primary organism of concern when food will be held out of temperature control, at least in part because *L. monocytogenes* grows more rapidly than *Salmonella* spp. at refrigeration and room temperatures. This statement is not supported by predictions using the ComBase Predictor modeling program, assuming pH 7 and 0.5% NaCl. Under these conditions, *L. monocytogenes* will outgrow *Salmonella* spp. at temperatures less than ~17°C; but, at temperatures greater than ~17°C, *Salmonella* spp. have a faster predicted growth rate. Given the faster growth rates of *Salmonella* spp. and their lower median infectious dose, it would appear prudent to consider both *L. monocytogenes* and *Salmonella* spp. in any consideration of risk posed by foods held out of temperature control.

The position paper also states that conditions are permitted in the Food Code that would allow *L. monocytogenes* cells 1 log of growth (3.3 generations). While no specific citation to the exact portion of the code is provided that would document allowance of a 1-log increase in *L. monocytogenes,* this level of increase is consistent with other expert reports that discuss risk in this context *(8, 16).* Setting a specific risk target such as a 1-log increase is also quite useful in efforts to manage risk in a quantitative manner.

The position paper states that for food refrigerated at 5 or 7.2°C (41 or 45°F) and then transferred to an ambient temperature of 24°C (75°F) for 4 h, the growth rate of *L. monocytogenes* remains slow enough to ensure that the critical limit of 1-log growth is not reached. It appears that an assumption is being made that the food temperature changes instantaneously to 24°C (75°F) at the start of the 4-h period. Implicit in any discussion about foods held out of temperature control are assumptions about how the food temperature rises in the ambient environment. It is well known that the rate of temperature change of a food in response to its environment is proportional to the driving force (i.e., the temperature differential between the food and its environment) *(18).* This means that the rate of temperature change is greatest when the food is first placed in the environment and gradually slows as the food and environmental temperatures converge.

The position paper also states that published generation times at 24°C (75°F) for *L. monocytogenes* in food were not found, but that published values at 20°C (68°F) and 21.1°C (70°F) in egg and milk products confirmed slow *L. monocytogenes* growth at room temperatures. While no citations are provided in support of these statements, predictions from ComBase Predictor (again assuming pH 7 and 0.5% NaCl) show doubling times of 1.37 h (20°C [68°F]), 1.22 h (21.1°C [70°F]), and 0.95 h (23.9°C [75°F]). As noted above, predicted doubling times for *Salmonella* spp. would be slightly more rapid than those for *L. monocytogenes*. Furthermore, a query of the ComBase database (a systematically formatted database of quantified microbial responses to the food environment with more than 50,000 records), which is related to, but separate from the ComBase Predictor models, shows more than 200 *L. monocytogenes* data sets in food for the temperature range in question. A more detailed analysis of those data sets follows below.

The position paper supports some of its claims using the models available in the USDA Pathogen Modeling Program (PMP). The position paper states that when the PMP uses the optimum conditions (pH 6.8, 0.5% NaCl, 0.0% nitrite), *L. monocytogenes* would require more than 4 h to grow 1 log at 24°C (75°F). The position paper does not state which version of PMP was used to make these predictions. When the PMP on-line models (http://pmp.arserrc.gov/ PMPOnline.aspx) or when PMP v. 7.0 are used, they predict a 0.42-log increase in *L. monocytogenes* in 4 h for the conditions above, when the organism is assumed to undergo a lag phase. This assumption of the existence of a lag time is a very critical one, however, since when no lag time is assumed, the model predicts a 1.84-log increase. ComBase Predictor models for these conditions show more modest growth but a pattern generally consistent with PMP predictions: 0.14-log increase in 4 h, assuming a typical physiological state (i.e., lag time) and a 1.29-log increase, assuming no lag time.

One of the limitations noted in the position paper was that there were no models available at the time that could consider changing temperatures when predicting growth. While not exactly true (dynamic models did exist at the time *(5)*), such models were not easily usable or broadly applicable. This is not the case today. ComBase Predictor models allow dynamic temperature predictions in a relatively easy and user-friendly manner: the user selects intrinsic characteristics (pH, water activity [a_w], etc.) and then the temperature profile over which growth is to be modeled.

The position paper then concludes by noting that the conservative nature of the 4-h limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 24°C (75°F). While, indeed, the 4-h limit is conservative and does provide a margin of safety, it is a safety margin of unknown and variable size. In the analysis below, additional statements from ''Annex 3: Public Health Reasons/Administrative Guidelines, Supplement to the 2005 Food Code,''

TABLE 1. *Predictions from different models of time periods needed for a 1-log increase in growth for* Listeria monocytogenes[a]

Product temp		PMP		ComBase[b]	
°F	°C	Annex 3 (h)[c]	Version 7 (h)[d]	With lag time (h)	No lag time (h)
41	5.0	88	81	127	47
45	7.2	54	55	80	29
50	10.0	35	35	49	19
70	21.1	5	8	11	4
95	35.0	3	3	5	2

[a] PMP, Pathogen Modeling Program.
[b] ComBase models: pH 6.8, 0.5% NaCl, 0% CO_2, with and without lag time.
[c] As reported in Annex 3, Supplement to the 2005 Food Code.
[d] pH 6.8, 0.5% NaCl, 0.0% nitrite, with lag time.

section 3-501.19, are discussed with the intent of more fully characterizing the risks posed by holding foods out of temperature control.

The Annex cites the 2004 CFP report, which states that the USDA PMP program could be used as a tool to estimate time periods for a 1-log increase in growth for *L. monocytogenes* in ideal (laboratory media) growth conditions. Using this modeling approach, several estimates are given and are reported in Table 1. While the Annex does not provide the assumptions needed to reproduce the predictions, nor does it state the version of PMP used to make the predictions, a reasonably similar set of predictions are shown in Table 1, using PMP version 7, assuming pH 6.8, 0.5% NaCl, and 0.0% nitrite and assuming that lag time does occur. Using essentially identical assumptions, predictions were also made using ComBase, both with and without the assumption of a lag time. When lag times are assumed to occur, the ComBase predictions for time to a 1-log increase of *L. monocytogenes* are longer than the PMP predictions; they are shorter when lag time is not considered.

The Annex then cites the 2004 CFP report as recommending that food could safely be held for up to 6 h without external temperature control as long as the food temperature did not exceed 21.1°C (70°F). Furthermore, the Annex states that, based on findings from the FDA *Listeria* risk assessment for ready-to-eat foods *(19),* foods that require time and temperature control for safety can be stored up to 6 h without temperature control if the food temperature does not exceed 21.1°C (70°F) and if the food is discarded or consumed after 6 h. Since the PMP data predictions given in the 2004 CFP report show that a 1-log increase in *L. monocytogenes* occurs in 5 h at 21.1°C (70°F), and the relevant data from the FDA *Listeria* risk ranking are not indicated, the science in support of the 6-h recommendation is not clear.

The Annex then turns to a discussion of consumer handling practices and notes that data from a 1999 Audits International study *(2)* were used to assess risk from purchasing food at retail and transporting the food home. The Annex authors assume a temperature of 18.3°C (65°F) for all predictions. They also added 2 h to all times (4 or 6 h) to factor in transportation time (per the Audits International public health control recommendations). The Annex indicates that the USDA PMP was used to predict growth (Log CFU per gram) of several pathogens for 6 or 8 h, at 18.3°C (65°F). Predictions were made using the PMP broth models (pH 6.8), with the minimal NaCl (unspecified, but likely 0.5%) and no sodium nitrite. The pathogens used were *Bacillus cereus* (vegetative cells), *Escherichia coli, L. monocytogenes, Salmonella* spp., *Shigella flexneri,* and *Staphylococcus aureus*. These predictions are shown in Table 2. Although the PMP modeling conditions were generally specified (temperature 18.3°C [65°F], pH 6.8, etc.), it was not possible to match those predictions using either PMP version 7 or the current on-line version of the PMP, possibly because the predictions made in the Annex were using an older unidentified version of the PMP. The current PMP predictions as well as the ComBase predictions are also shown in Table 2. The predictions from the Food Code Annex are higher in 7 of 12 conditions (shown in

TABLE 2. *Predictions from the FDA Model Food Code Annex*[a]

	Food Code Annex		PMP version 7		ComBase	
	6 h	8 h	6 h	8 h	6 h	8 h
Bacillus cereus	**0.62**	**0.87**	0.42	0.71	0.01	0.02
Escherichia coli	0.35	0.52	0.28	0.52	**0.60**	**0.75**
Listeria monocytogenes	**0.47**	**0.71**	0.28	0.52	0.11	0.21
Salmonella spp.	**0.25**	0.41	0.11	0.23	0.24	**0.47**
Shigella flexneri	**0.26**	**0.34**	0.10	0.16	0.06	0.09
Staphylococcus aureus	0.38	0.51	**0.54**	**0.73**	0.11	0.21

[a] Predictions used USDA Pathogen Modeling Program (PMP), PMP version 7, and ComBase for growth (Log CFU per gram) of several pathogens for 6 or 8 h, at 65°F using pH 6.8, 0.5% NaCl, and no sodium nitrite. Fastest growth for a given set of pathogen and time conditions is shown in bold.

bold), higher in 2 of 12 conditions for PMP v. 7, and higher in 3 of 12 conditions for ComBase. The differences in the predictions shown in Table 2 highlight the challenges of using computer models, especially where predicted levels of growth are less than 1 log CFU.

One of the key limitations of the approach used in the Food Code Annex is the assumption about food starting temperature. The temperatures of foods that start at refrigeration temperatures rise over time. As mentioned above, one of the limitations noted in the FDA position paper was that there were no models that could consider changing temperatures when predicting growth. While not strictly true (see, for example, Baranyi et al. *(5)*), such models were not widely available, easily usable, or broadly applicable, but this has changed over the past 20 years.

REVIEW OF GROWTH MODELS FOR FLUCTUATING CONDITIONS

Much of the published research detailing the development of mathematical models for the growth of bacteria under changing temperature conditions shows that such models are generally accurate and that models that include lag time are more accurate than models that do not. Research with the meat spoilage organism *Brochothrix thermosphacta,* which studied fluctuating temperatures between 4 and 12°C (39.2 to 53.6°F) where a temperature shift occurred over a 12-h time period, showed no extra induced lag time *(14).* Additional research from this same lab showed no induced lag for exponentially growing cultures of *B. thermosphacta* for a temperature shift-down from 17 to 25°C (62.6 to 77°F) to 5°C (41°F), and model fit was better when the lag was included rather than ignored *(5).* Alavi et al. *(1)* developed a model for *L. monocytogenes* growth in sterile, whole milk and validated that model under changing temperature profiles in which temperature repeatedly fluctuated between 10 and 20°C (50 and 68°F) over a 2-h time period. The authors noted that the data for *L. monocytogenes* growth were within the range predicted by the model. Augustin and Carlier *(3)* built a model to describe the influence of the temperature and the duration of preincubation on the lag time for regrowth of *L. monocytogenes* at low temperature. These researchers did not observe a temperature history effect, and they noted that this implies an instantaneous metabolic adjustment during the lag phase. Bovill et al. *(7)* studied the growth of *L. monocytogenes* and *Salmonella* spp. in a variety of media and foods during fluctuating temperature conditions and compared those with model predictions. The investigators studied conditions that included a 20°C (36°F) rise from 10 to 30°C (50 to 86°F) over 4 or 5 h, and they concluded that the accuracy of a prediction under fluctuating temperatures was generally similar to that under constant temperature conditions. This same research team went on to study the growth of *L. monocytogenes* and *Salmonella* spp. with more rapid rates of increase and decrease in temperature to and from the minimum for growth, e.g., 15 to 20°C (27 to 36°F) temperature shifts over 2 h *(6).* They noted that growth was little affected by even the most rapid changes, injury or lag was not observed, and the model originally proposed by Baranyi et al. *(5)* generally held true. Koseki and Isobe *(12)* studied the growth of *E. coli* O157:H7, *Salmonella* spp., and *L. monocytogenes* on iceberg lettuce under fluctuating temperature conditions. The conditions that were studied included a 10°C (18°F) rise in 5 h, and the authors concluded that the observed viable counts for each pathogen corresponded with predictions in most cases. Xanthiakos et al. *(20)* modeled the growth of *L. monocytogenes* in commercial pasteurized whole milk and evaluated the model under four different dynamic temperature conditions, with temperature changes from 2 to 16°C (35.6 to 60.8°F). The authors confirmed that the models were generally accurate, and relative errors between the observed and the predicted growth of *L. monocytogenes* were less than 10% in each scenario tested. Gougouli et al. *(11)* investigated the behavior of *L. monocytogenes* in ice cream mixes under dynamic warming and freezing conditions. They developed a model under static conditions and validated it under dynamic chilling and dynamic chilling-freezing conditions, using four different temperature change scenarios. The model accurately predicted the growth of *L. monocytogenes* in both chilling and chilling-freezing scenarios. Muñoz-Cuevas et al. *(15)* applied the dynamic model of Baranyi and Roberts *(4)* to model lag period and exponential growth of *L. monocytogenes* under fluctuating temperature and a_w. They noted that scenarios in which exponential growth was halted by a sudden change in the temperature and/or a_w were in good agreement with predictions and that when a population that was already in a lag period was subjected to environmental fluctuations, the system was reset with a new lag phase. They concluded that the predictions were considerably more accurate when lag phase was included in the model.

In some cases, models for the growth of bacteria under changing temperature conditions are less accurate. Some of the earliest research done with modeling the effect of temperature changes on microbial growth was done using the milk spoilage organism *Pseudomonas fragi,* studying temperature transitions between 4 and 16°C (39.2 and 60.8°F) *(10, 13).* This research showed that, as the temperature changed, additional lag times beyond those expected from temperature alone were induced by the temperature shift. This implies that any models used would make fail-safe or conservative predictions. This is similar to research by Baranyi et al. *(5)* that showed generally no induced lag for a temperature shift from optimal condition to 5°C (41°F) but that did show a significant lag for a shift to 3°C (37.4°F). Alavi et al. *(1)* also noted that lag-phase modeling under dynamic conditions was problematic, as the effect of the magnitude of the temperature shift may not be considered. A similar observation was made by Swinnen et al. *(17),* who developed models in which *E. coli* was exposed to sudden temperature upshifts. These authors noted that, for large, rapid temperature shifts, i.e., larger than 8°C (14.4°F), the work to be done increases with increasing temperature shift amplitudes.

The literature on predictive modeling under dynamic conditions can generally be summarized as follows:

dynamic models have generally been shown to be accurate, and lag times should be included. Conditions under which models have been found to be less accurate are those in which rapid, large temperature shifts occur; and, in those circumstances, model predictions are fail-safe.

MODEL FOR RISK MANAGEMENT

As noted above, the purpose of this work is to develop a tool to assist in the management of the risk posed by rising temperatures during food transport. The approach outlined below builds upon the logic described above but also strives to make the assumptions more realistic with manageable additional complexity.

A number of assumptions were made to perform the model calculations. First, it was assumed that the starting food temperature was 4.4°C (40°F). One of the shortcomings of earlier approaches was the assumption regarding starting temperature. Earlier approaches assumed that the food in question spent the entire time at the abuse temperature. In an effort to make my approach more realistic, I assumed that food temperature would rise in a linear manner over time. While the principles and theories that govern food temperature change over time are well understood *(18),* there is scant published data documenting the application of those principles, especially when looking at short-term temperature abuse that might occur in food transport from a retail establishment to a home or restaurant. Data on temperature rise during transport are presented and further discussed below.

One important decision in any computer modeling application is the selection of organisms. For this application, I determined that *Salmonella* spp. and *L. monocytogenes* were the logical organisms to use. *Salmonella* spp. were selected because these pathogens are associated with a wide variety of foods and have a relatively rapid growth rate, especially at higher temperatures (>17°C or 62°F) as noted above. For purposes of model validation, *Salmonella* spp. were assumed to be in a ground beef matrix. While the choice of a food matrix is somewhat arbitrary, *Salmonella* spp. are known to exist in ground beef; and ground beef is a permissive matrix for pathogen growth, as it has a high pH and high a_w, contains adequate nutrients, and has no known growth inhibitors.

L. monocytogenes was selected as the second organism to use because of its frequent isolation from the food processing environment, its use in prior analyses discussed above, and its rapid growth relative to other pathogens at temperatures of less than 17°C (62°F). For purposes of model validation, *L. monocytogenes* was assumed to be in a processed (i.e., luncheon) meat matrix. *L. monocytogenes* is known to be associated with luncheon meats, and this represents a high-risk food-pathogen pairing *(19).*

A wide variety of computer models are available for *Salmonella* spp. and *L. monocytogenes,* but ComBase was selected due to its ease of use, especially for making predictions under changing temperature conditions. Another important factor in the use of computer models is the selection of conditions other than temperature for model predictions. The two most important of these factors (after temperature) are pH and a_w. Optimal conditions for *Salmonella* spp. and *L. monocytogenes* growth were assumed: pH 6.5, a_w 0.997 and pH 6.8, a_w 0.995, respectively. Because the computer model only allows temperature predictions in a certain range, but growth can occur above and below those model limits, it was assumed that, below or above the limit, the growth rate was the same as at the limit. Although the above analysis indicates that lag times generally occur in these changing temperature conditions, the decision about whether to include them or not is a risk management decision. In the development of this tool, bacterial lag times were conservatively assumed to be zero.

As noted above, the FDA position paper cited in the Food Code notes that a 1-log increase in *L. monocytogenes* would be allowed by some practices in the Food Code. This level of increase for both *Salmonella* spp. and *L. monocytogenes* is consistent with other expert reports that discuss risk in this context *(8, 16).* In implementing the approach developed in my analysis, a 1-log CFU increase was considered to represent a ''red'' or danger situation, consistent with those other expert reports. Additionally, as I wished to provide feedback on future risk management decision-making, I classified a 0.6-log increase (two doublings) as representing a ''yellow'' or caution situation.

Table 3 shows the relationship between the time to transport (in hours) and its temperature on arrival, assuming optimal growth conditions (pH 6.5, a_w 0.997), no lag time, a linear temperature increase, and a 1-h cooling time to the predicted increase in *Salmonella* spp. according to ComBase Predictor. These data show that, even for very long transport times, as long as the product temperature does not rise above 12.8°C (55°F), the *Salmonella* spp. risk is minimal. Even longer transport times (5 h) pose minimal risk if the product temperature does not rise above 21.1°C (70°F). The safety transport times for minimal risk are considerably smaller when product temperatures rise to 29.4°C (85°F), i.e., ~1 h. When product temperatures rise to 32.2°C (90°F) or higher, even a 1-h transport time shows the yellow or caution risk area, indicating that the predicted pathogen level has more than doubled. Note that assumptions about cooling times (here assumed to be 1 h) will result in different predictions. As with the discussion about lag times, the choice of cooling times assumptions is a risk management decision.

Table 4 shows the same type of predictions for *L. monocytogenes* under its most permissive conditions (pH 6.8, a_w 0.995). The same basic trend is evident: lower temperature rises pose minimal risk even for long transport times, and risks are higher for higher temperatures and shorter transport times. However, Table 4 shows some important contrasts relative to Table 3 and points out the importance of considering *Salmonella* spp., pathogens that grow optimally at higher temperatures, as well as *L. monocytogenes,* a pathogen that grows well at lower temperatures. Table 4 shows that even products that reach high temperatures (32.2 to 37.8°C [90 to 100°F]) after 1-h transport pose minimal risk from *L. monocytogenes* (less than two doublings), in contrast to the same conditions for *Salmonella* spp. in Table 3. Conversely, transport times

TABLE 3. *Predicted 1-log CFU increases in* Salmonella *spp.*[a]

Time to transport (h)	Product temp on arrival, °C (°F):								
	15.6 (60)	18.3 (65)	21.1 (70)	23.9 (75)	26.7 (80)	29.4 (85)	32.2 (90)	35.0 (95)	37.8 (100)
0.0									
0.5							***0.52***	***0.52***	***0.59***
1.0						***0.53***	0.64	0.69	0.79
1.5						0.62	0.76	0.87	0.99
2.0					***0.55***	0.70	0.88	**1.04**	**1.18**
2.5					0.65	0.82	**1.03**		
3.0				***0.53***	0.74	0.94			
3.5				0.61	0.83	**1.06**			
4.0				0.68	0.92				
4.5				0.75	**1.02**				
5.0			***0.59***	0.82					
5.5			0.64	0.89					
6.0			0.69	0.96					
6.5			0.74	**1.03**					
7.0			0.79						
7.5		***0.58***	0.84						
8.0	***0.35***	0.62	0.89						

[a] Predictions assume pH 6.5, a_w 0.997, a linear temperature rise during transport, no lag time, and 1 h to cool. Increases of less than 0.60 log CFU are shown in italic bold, and increases of more than 1.00 log CFU are shown in bold.

and temperatures that showed minimal risk for *Salmonella* spp., 12.7°C (55°F) after 16 h, showed considerably greater risk for *L. monocytogenes*. Transport times and temperatures that are intermediary, 23.9°C (75°F) after 3 h, are judged to be of minimal risk by both model predictions.

VALIDATION OF COMBASE MODELS

The model predictions shown above represent worst-case optimal predictions from ComBase, but it is important to know if these predictions are valid for pathogen growth in actual foods. Validation could be accomplished in a variety of ways. Experiments could be conducted in the laboratory, and the results compared with the predictions above. Such experiments are time-consuming but are currently under way in our laboratory. Another, more expedient, means would be to use the data contained in the ComBase database for validation. ComBase is a set of more than 40,000 data sets from the published and unpublished literature that can be queried and compared with ComBase predictor.

ComBase contains 168 potential data sets on *Salmonella* spp. growth in beef. From those 168 data sets (growth curves), 80 showed growth or were in the range encompassed

TABLE 4. *Predicted 1-log CFU increases in* Listeria monocytogenes[a]

Time to transport (h)	Product temp on arrival, °C (°F):								
	15.6 (60)	18.3 (65)	21.1 (70)	23.9 (75)	26.7 (80)	29.4 (85)	32.2 (90)	35.0 (95)	37.8 (100)
0.0									
0.5									
1.0								***0.51***	***0.54***
1.5							***0.56***	0.64	0.68
2.0						***0.58***	0.67	0.76	0.82
2.5					***0.56***	0.67	0.78	0.89	0.96
3.0				***0.54***	0.65	0.77	0.89	**1.01**	**1.10**
3.5				0.60	0.73	0.87	**1.01**		
4.0				0.66	0.81	0.96			
4.5			***0.58***	0.73	0.89	**1.06**			
5.0			0.63	0.79	0.97				
5.5			0.68	0.86	**1.05**				
6.0		***0.56***	0.73	0.93					
6.5		0.61	0.78	1.00					
7.0		0.65	0.84	**1.06**					
7.5		0.70	0.89						
8.0	***0.56***	0.74	0.94						

[a] Predictions assume pH 6.8, a_w 0.995, a linear temperature rise during transport, no lag time, and 1 h to cool. Increases of less than 0.60 log CFU are shown in italic bold, and increases of more than 1.00 log CFU are shown in bold.

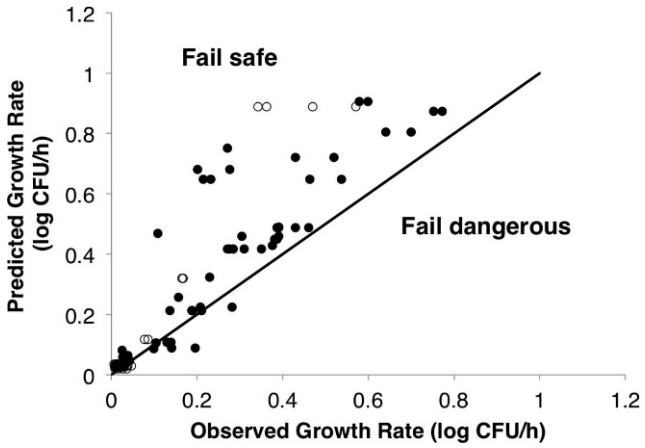

FIGURE 1. *Observed versus predicted growth rates from ComBase for* Salmonella *spp. growth in beef, expressed as growth rate only (closed circles) or as microbial count data (open circles).*

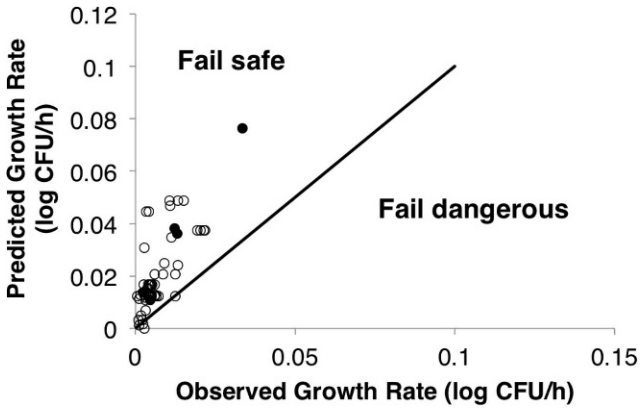

FIGURE 2. *Observed versus predicted growth rates from ComBase for* Listeria monocytogenes *growth in processed meats, expressed as growth rate only (closed circles) or as microbial count data (open circles).*

by the model. Of the 80 points, 58 represent growth rate only data (closed circles), while 23 represent microbial count data (open circles), as shown in Figure 1. It is clear from Figure 1 that almost every data set shows that the model gives a conservative or fail-safe prediction, in which the predicted growth rate is faster than the observed growth rate. Fail-safe predictions lie above the diagonal line of equivalence. In those few cases in which the model prediction was not fail-safe, the growth rates were low (less than 0.3 log CFU/h) and were generally very close to the diagonal line of equivalence.

ComBase contains 153 potential data sets on *L. monocytogenes* in processed meats. From those 153 data sets (growth curves), 68 showed growth or were in the range encompassed by the model. Five of the 68 observations are growth rate only data (closed circles), whereas 63 represent microbial count data (open circles), as shown in Figure 2. The data points are clustered at the low-growth end of the scale (compared with Fig. 3) because research on *L. monocytogenes* growth in processed meats has typically focused on low-temperature, slow-growth conditions. As with *Salmonella* spp. validation above, almost every data set shows that the model gives a conservative or fail-safe prediction. Fail-safe predictions lie above the diagonal line of equivalence. In those few cases where the model prediction was not fail-safe, the growth rates were very low.

In general the results of both the *Salmonella* spp. and *L. monocytogenes* model validations are quite promising and indicate that the models are reliably fail-safe in their predictions when compared to bacterial growth in the targeted food systems.

PUBLISHED DATA ON TEMPERATURE RISE DURING TRANSPORT

There is a clear lack of published or publicly available data on the temperature changes encountered by foods as they are being transported to restaurants and retail establishments, which could be used to estimate the temperature changes that such foods undergo. One publicly available data set that might represent an approximation for the transportation of perishable foods from wholesale cash and carry food service suppliers is the EcoSure 2007 Cold Temperature Database, available on FoodRisk.org *(9)*. This database was created by EcoSure, a division of Ecolab, and it served to update the 1999 Audits International database *(2)* of food temperatures from the retail sources during travel to consumers' home refrigerators or freezers. Among many other observations, the EcoSure 2007 database contains data on more than 900 luncheon meat (prepackaged 170 to 225 g [6 to 8 oz]) and fresh meat (ground beef, 450 g [~1 lb]) product temperatures and other important details during transportation to over 900 consumers' homes. While the retail stores surveyed are different from wholesale cash and carry food service suppliers and typical consumers are not wholesale cash and carry food service customers, the EcoSure database represents the most comprehensive and relevant data set available for this type of food safety assessment. As noted above, more than 900 consumers were surveyed, and data on many types of foods were collected; although, for purposes of this research only the data collected for prepackaged luncheon meat and ground beef were used. For each of the 900+ food items of each type, a starting time

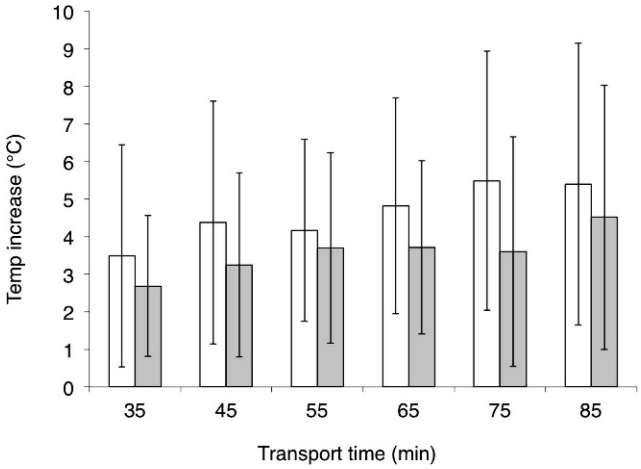

FIGURE 3. *Average temperature increase for ranges of transport times from the EcoSure database for prepackaged luncheon meat (white bars) and ground beef (gray bars). Error bars represent standard deviations around the mean.*

and temperature, an ending time and temperature, and other relevant data for further analysis were extracted.

The EcoSure data set shows that most travel times are at least 30 min and less than 2 h, with the majority between 1 and 1.5 h. The mean transport time for ground beef was 65 min (±26 min), and 70 min for prepackaged luncheon meats (±27 min). It should be noted that these times are measured from when the food is picked up from the refrigerated case in the store until it is placed in the home refrigerator; they are not the door-to-door driving time. Analysis of the EcoSure data set showed that the average temperature rise for ground beef during transport is 3.7°C (6.7°F), with a standard deviation of 2.8°C (5.1°F), while the average temperature rise for prepackaged luncheon meats during transport is 4.9°C (8.9°F), with a standard deviation of 3.3°C (6.0°F).

The average temperature increase for ranges of transport times from the EcoSure database for prepackaged luncheon meat and ground beef were calculated and plotted and are shown in Figure 3. This figure shows that the average temperature rise is greater for prepackaged luncheon meat than for ground beef and that this trend holds true for a range of transport times. While the exact dimensions of the prepackaged luncheon meats studied in the EcoSure 2007 Cold Temperature Report are not specified, the average package weight was 225 g (0.5 lb), and more than 85% of all samples had this weight. The weight of the ground beef product from the EcoSure study was specified to be 450 g (~1 lb), although the exact weights were not recorded. It seems likely that these temperature increase differences shown in Figure 3 were due to both the smaller mass of the luncheon meats and the typical geometry of luncheon meats versus ground beef. This figure also shows that, as transport time increases, the average temperature also increases. The rate of increase is about 0.29°C (0.5°F) per min for ground beef and about 0.39°C (0.69°F) per min for luncheon meat, with moderately good correlation coefficients (r^2 values > 0.8). The standard deviations around the averages are large relative to the increases, ±1.7 to ±3.3°C (3 to 6°F), with the standard deviation also tending to increase with transport time.

Figure 4 shows the effect of transport time on average temperature rise for luncheon meats (the more temperature-sensitive food) as grouped by external (outside) temperature on the day of transport. It is clear from Figure 4 that, while external temperature plays a role (especially for longer transport times and the highest external temperature), the relationship is by no means straightforward and unambiguous. The results in Figure 4 are no doubt confounded by a number of factors, including the use of vehicle air conditioning on the warmest days, product placement in shopping bags, etc.

COLLECTED DATA ON TRANSPORT TIME AND TEMPERATURE

The data extracted from the EcoSure study and presented in Figures 3 and 4 do encompass some of the conditions in Tables 3 and 4. However, the masses of the foods used are not representative of a typical wholesale cash and carry food service supplier, and the conditions represent neither the worst-case temperature stresses, nor optimal recommended transport conditions. To address these concerns, data on temperature rise during storage at elevated ambient temperatures were also collected, specifically as part of this study. The products studied were of two geometries. Some products were of large mass and roughly oblong in shape: ground beef (4.5-kg [10-lb] package), roast chicken or block cheddar cheese (both 2.25 kg [5 lb]), or unsliced luncheon meat (1.8 kg [4 lb]). Other products were of smaller mass and roughly flat in shape: sliced luncheon meat or sliced cheese (both 608 g [1.5 lb]). All items were stored in an ambient temperature environment of ~37.8°C (100°F). Foods were stored either in an uninsulated canvas bag or in a double-layer polyester fiberfill insulated bag with three frozen gel packs per item. Temperature data loggers (Lascar Electronics, Erie, PA) with K-type probes were used to monitor ambient temperatures, bag temperatures, and product temperatures; the product measurement was made using a probe located ~1 cm from the surface of the food. Foods were moved from a controlled temperature environment (~4.4°C [40°F]) into the treatment environment (~37.8°C [100°F]), and temperatures were logged for at least 2 h.

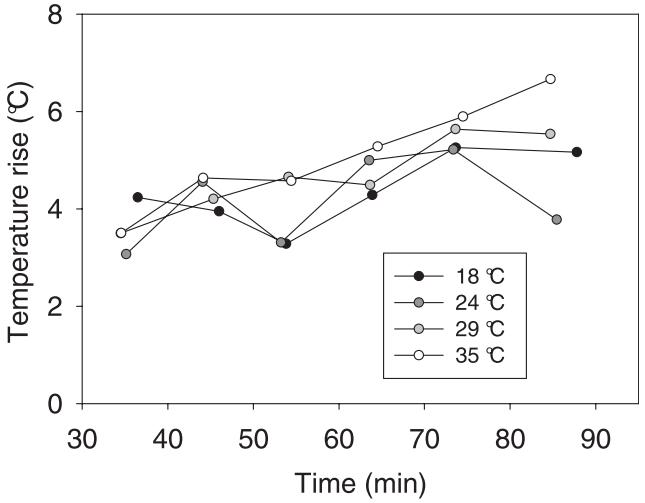

FIGURE 4. *The effect of transport time on average temperature rise for luncheon meat was grouped by external (outside) temperature; outside temperatures are grouped into ranges centering on 18 (darkest shade), 24, 29, and 35°C (lightest shade).*

Figure 5 shows the temperature change during simulated transport for all products stored in an uninsulated bag. The temperature increases for ground beef, roast chicken, block cheddar cheese, and unsliced luncheon meat products are remarkably similar, all rising by about 8.3°C (15°F) in 1 h, which is approximately within one standard deviation of the consumer transport observation in Figure 3. The large-mass products experienced a 16.6°C (30°F) rise in 2 h. The temperature increase for the sliced cheese and sliced luncheon meat products was, in contrast, about 25°C (45°F) in 1 h and 33.3°C (60°F) in 2 h. Experiments using the insulated bags with frozen gel packs (data not shown) exhibited only minimal temperature increases for all products: 1.1°C/h (2°F/h) even over longer times (>6 h). It is clear from the data presented in Figure 5 that product mass

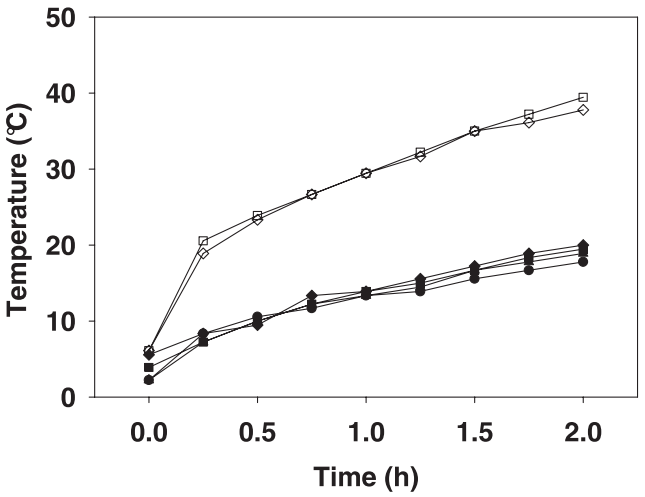

FIGURE 5. *Temperature change during simulated transport for all products stored in an uninsulated bag at 37°C. Products were ground beef (solid circle), roast chicken (solid triangle), block cheddar cheese (solid square), luncheon meat chub (solid diamond), sliced cheese (open square), and sliced luncheon meat (open diamond).*

and, more likely, product shape appear to play a key role in determining temperature rise over time when stored at ambient or elevated temperatures. The large-mass products would meet an acceptable risk level even after 2 h according to Tables 3 and 4; however, small-mass, flat-shaped products would represent an unacceptable risk from *Salmonella* spp. (1.18-log CFU increase, Table 3) and a borderline risk from *L. monocytogenes* (0.82-log CFU increase, Table 4).

CONCLUSIONS AND PRACTICAL APPLICATIONS

It is clear from Figure 5 that smaller and, more critically, thinner food items require greater care in handling. Even the surface of larger food masses will warm slowly due to the cooling effects of the adjacent colder portions. While refrigerated transport is ideal, an important risk reduction can be obtained by insuring that any sensitive foods are placed in the air-conditioned portion of a vehicle, rather than in an un–air-conditioned trunk or in a warmer location in the vehicle. Even when small, geometrically thin food products are placed in a very warm environment, as long as they are properly packed in an appropriate insulated bag with frozen gel packs, their temperature rise will be minimal.

The analysis developed builds on the foundation established in the 2009 FDA Model Food Code, section 3-501.19, ''Holding Cold Food without Temperature Control,'' and the FDA position paper contained in Food Code Annex 3 Public Health Reasons/Administrative Guidelines. The analysis uses publicly available ComBase models for *Salmonella* spp. and *L. monocytogenes,* organisms selected because of their ubiquitous nature and relatively rapid growth rates above and below 17°C (62°F), respectively. The model predictions under static temperature conditions were fail-safe when compared with the ComBase database observations in real foods, and many articles in the published literature support the application of such models under changing temperature conditions. The times and temperature changes encompassed by the predictions are consistent with data on consumer food transport to the home from the grocery store and on data for representative foods from a wholesale cash and carry food service supplier collected as part of this project. The resulting predictions should be a useful aid to risk managers and customers of wholesale cash and carry food service suppliers in managing the microbial risks associated with holding cold food without temperature control.

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