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Assessing the Performance of *Clostridium perfringens* Cooling Models for Cooked, Uncured Meat and Poultry Products

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ABSTRACT

Heat-resistant spores of *Clostridium perfringens* may germinate and multiply in cooked meat and poultry products when the rate and extent of cooling does not occur in a timely manner. Therefore, six cooling models (PMP 7.0 broth model; PMIP uncured beef, chicken, and pork models; Smith-Schaffner version 3; and UK IFR ComBase Perfringens Predictor) were evaluated for relative performance in predicting growth of *C. perfringens* under dynamic temperature conditions encountered during cooling of cooked, uncured meat and poultry products. The predicted growth responses from the models were extensively compared with those observed in food. Data from 188 time-temperature cooling profiles (176 for single-rate exponential cooling and 12 for dual-rate exponential cooling) were collected from 17 independent sources (16 peer-reviewed publications and one report) for model evaluation. Data were obtained for a variety of cooked products, including meat and poultry slurries, ground meat and poultry products with and without added ingredients (e.g., potato starch, sodium triphosphate, and potassium tetrapyrophosphate), and processed products such as ham and roast beef. Performance of the models was evaluated using three sets of criteria, and accuracy was defined within a 1- to 2-log range. The percentages of accurate, fail-safe, or fail-dangerous predictions for each cooling model differed depending on which criterion was used to evaluate the data set. Nevertheless, the combined percentages of accurate and fail-safe predictions based on the three performance criteria were 34.66 to 42.61% for the PMP 7.0 beef broth model, 100% for the PMIP cooling models for uncured beef, uncured pork and uncured chicken, 80.11 to 93.18% for the Smith-Schaffner cooling model, and 74.43 to 85.23% for the UK IFR ComBase Perfringens Predictor model during single-rate exponential chilling. Except for the PMP 7.0 broth model, the other five cooling models (PMIP, Smith-Schaffner, and UK IFR ComBase) are useful and reliable tools that food processors and regulatory agencies can use to evaluate the safety of cooked or heat-treated uncured meat and poultry products exposed to cooling deviations or to develop customized cooling schedules.

Clostridium perfringens is a gram-positive bacterium that is ubiquitous in soil and water. This bacterium is considered anaerobic, although it can tolerate low concentrations of oxygen in the environment. As with all *Clostridium* species, *C. perfringens* can be found as a metabolically active vegetative cell or as a metabolically static, heat-resistant endospore. *C. perfringens* exists at varying levels in the environment and has been detected in raw and processed meat and poultry products. The prevalence of *C. perfringens* differs across studies, but when present, the typical level of *C. perfringens* is less than 100 CFU/g *(13)*. After meat products have been cooked to achieve desired lethality for non–spore-forming pathogens, the heat-resistant spores of *C. perfringens* can germinate and grow in a nutrient-rich environment without bacterial competition. Under these conditions and at optimal temperatures, *C. perfringens* has a generation time (time for a given cell population to double) of less than 10 min, which is more rapid than most other potential foodborne pathogens *(43)*. As a result, *C. perfringens* can multiply to high levels in a relatively short time when the product is not quickly cooled below the optimum growth range of 37 to 45°C. This pathogen can be controlled in products with low pH (<5.0), water activity (a_w) below 0.93, or salt concentrations above 5% *(7, 14)*.

The U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) currently requires that establishments meet specific stabilization performance standards for producing certain ready-to-eat meat and poultry products (i.e., ready-to-eat roast beef; cooked beef and corned beef products; fully cooked, partially cooked, and char-marked meat patties; and certain partially cooked and ready-to-eat

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poultry products) to address *C. perfringens*. The requirements specify no more than 1-log multiplication of *C. perfringens* within the product *(37–39)*. The FSIS recommends that producers of meat and poultry products that are not covered under this performance standard design their processes so that no more than a 2-log growth of *C. perfringens* occurs.

Generally, an establishment's cooling procedures are set forth as a cooling critical control point (CCP) within its hazard analysis critical control point (HACCP) plan (*35*). Under the HACCP regulations, establishments are required to provide scientific support for the critical limits chosen for each CCP *(35)*. Most federally inspected meat and poultry establishments have adopted one or more of the cooling options listed in the FSIS *Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) (36)* as their cooling process schedule and have used these cooling options when designing the critical limits of their cooling CCP. The FSIS considers Appendix B cooling options (e.g., the product's maximum internal temperature should not remain between 130°F [54.4°C] and 80°F [26.7°C] for more than 1.5 h nor between 80 and 40°F [4.4°C] for more than 5 h), if followed precisely, to be validated process schedules because they contain processing methods already accepted by the FSIS as effective.

In the event of a cooling deviation, establishments can support product safety by estimating the growth of *C. perfringens* or *Clostridium botulinum* that may have occurred using a validated predictive microbial cooling model. These *C. perfringens* or *C. botulinum* growth models are specifically designed to estimate pathogen growth as product temperature continuously changes over time during the cooling of cooked or heat-treated meat and poultry products. Cooling models are the main tools used by both the meat and poultry industries and the FSIS to evaluate cooling deviations or to develop or evaluate customized cooling schedules. As stated in Attachment 1 of FSIS Directive 5000.1, revision 4 *(40),* microbial pathogen computer modeling programs can be valuable tools for establishments to use for supporting analyses, developing critical limits, and evaluating the relative severity of problems caused by process deviations. However, unless a model has been validated for meat or poultry products with similar intrinsic characteristics, it is not appropriate to rely solely on a predictive microbial modeling program to determine the safety of foods and processing systems.

Proper validation of a cooling model or any predictive microbiological growth model requires extensive comparison of predicted growth responses with those observed in food. Typically, pathogen growth data for food products are obtained from inoculation challenge studies, including those published in peer-reviewed articles. These evaluations are important for understanding the performance of the cooling model and how it might be applied effectively for evaluating cooling deviations or for developing customized cooling schedules for cooked or heat-treated meat and poultry products. By considering how models perform against different criteria for defining accurate, fail-safe, and fail-dangerous predictions, establishments and regulators can understand whether a model is more likely to under- or overpredict pathogen growth. A model that underpredicts pathogen growth may lead to consumption of unsafe food, whereas a model that overpredicts pathogen growth may lead to unnecessary destruction of safe food. Cooling model evaluations help identify the range of products, product characteristics, and chilling conditions for which predictions are sufficiently accurate to be useful and also help establishments and regulators identify the most appropriate model to use to evaluate a cooling deviation *(18)*.

The objective of this study was to evaluate the relative performance of existing cooling models. Based on the performance of each individual cooling model, a determination can be made as to whether the cooling model is reliable (i.e., validated) for evaluating cooling deviations or developing customized cooling schedules for cooked or heat-treated uncured meat and poultry products.

MATERIALS AND METHODS

Six cooling models were evaluated for their accuracy in predicting growth of *C. perfringens* in a variety of cooked, uncured meat and poultry products under dynamic cooling conditions. Performance of the models was evaluated using three sets of criteria based on different definitions for accurate, fail-safe, and fail-dangerous predictions.

The number of environmental parameters (i.e., intrinsic and extrinsic factors) included in the evaluated cooling models varied from one to three. All six of the models took into account the effect of temperature on the growth of *C. perfringens* during chilling of cooked, uncured product. Only one of the cooling models included additional intrinsic factors (pH and salt concentration) that can affect the growth of *C. perfringens* in cooked, uncured meat and poultry products during chilling (Table 1).

Data for evaluating predictive models. Data for model evaluation represented a variety of cooked products, including meat and poultry slurries, ground meat and poultry products with and without added ingredients (e.g., potato starch, sodium triphosphate, and potassium tetrapyrophosphate), and processed products such as ham and roast beef. Data were collected from 17 independent sources (16 publications and one agency report) *(3, 4, 9–11, 16, 23, 25, 26–30, 32, 41, 42, 44)*. The same three-strain cocktail of *C. perfringens* (NCTC 8238, NCTC 8239, and NCTC 10240; or NCTC 8238, NCTC 8239, and ATCC 10388) was used to inoculate products in all 16 published studies. A five-strain cocktail of *C. perfringens* (5146-97, 3011-98, 3511-98, 5796-97, and 5810-97) was used to inoculate products described in the agency report *(23)*. In most cases, observed growth was obtained directly from the reported data. In the few cases in which observed growth was not reported, the data were obtained from the studies' authors.

One hundred eighty-eight sets of time-temperature cooling profiles, product intrinsic factors, and corresponding growth responses of *C. perfringens* in cooked, uncured meat and poultry products were collected to analyze the performance of six cooling models for growth of this pathogen (Table 2). Most (176 of 188) of the time-temperature profiles represented single-rate exponential cooling (i.e., cooling occurs at one rate during the entire cooling process); 12 of the time-temperature profiles *(30)* represented dual-rate exponential cooling (i.e., cooling occurs at two different rates in the first and second parts of the cooling process). For the

TABLE 1. *Characteristics of cooling models of* C. perfringens *growth evaluated*

Model	Development (matrix; temp)	Primary; secondary models	Specific parameters considered in the model		
			Temp	pH	Salt concn
ARS PMP 7.0[a]	Broth; isothermic	Gompertz equation; Ratkowsky et al. square root	Yes	No	No
PMIP (on-line ARS PMP)	Ground beef, chicken, pork; isothermic	Baranyi and Roberts; Ratkowsky et al. square root	Yes	No	No
Smith-Simpson and Schaffner, version 3 *(33)*	Ground beef; dynamic	Baranyi and Roberts; Ratkowsky et al. square root	Yes	No	No
UK IFR ComBase Perfringens Predictor[b]	Broth, product, beef slurry; isothermic	Baranyi and Roberts; Ratkowsky et al. square root	Yes	Yes (pH 5–8)	Yes (0–4%)

[a] Agricultural Research Service pathogen modeling program.
[b] ComBase Perfringens Predictor validated by the United Kingdom Institute of Food Research.

time-temperature profiles representing single-rate exponential cooling, the collected data were divided into meat types: beef ($n = 99$), pork ($n = 45$), and poultry ($n = 32$) products. All time-temperature profiles representing dual-rate exponential cooling were for ground beef ($n = 12$).

The pH and salt (NaCl) concentration data were collected for each experiment when reported. For 36 of the 92 experiments in which pH was reported, the mean ($\pm$standard deviation) pH was reported in the publication, and the upper 95% confidence limit was used for model evaluation purposes. For 118 of the 188 experiments, one or both of the relevant parameters were not reported. For 96 experiments, a pH of 6.2 was assumed because this is a common pH for cooked or heat-treated meat and poultry products *(18)*. In 107 experiments, NaCl was not added to the products.

The United Kingdom Institute of Food Research (UK IFR) has validated the ComBase Perfringens Predictor (http://modelling.combase.cc/ComBase_Predictor.aspx) cooling model for cooked, cured and uncured meat and poultry products, and time, temperature, pH, and NaCl concentration were used for evaluation of this model in the present study. The uncured product option in the model was applied. For the Smith-Simpson and Schaffner cooling model *(33)*, the ARS PMP (Agricultural Research Service pathogen modeling program) 7.0 cooling model in beef broth, and the ARS PMIP (on-line predictive microbiology information portal) cooling models in cooked, uncured beef, pork, and chicken, time and temperature were the only parameters used for evaluation. All models were evaluated by comparison of observed and predicted growth of *C. perfringens* under various exponential chilling regimes. All 188 experiments were used to evaluate performance of each of the six models with the exception of the three ARS PMIP cooling models in cooked, uncured beef, pork, and chicken, for which data from the corresponding meat types were used.

Model 1: PMP 7.0 broth model. Details on this cooling model has been published previously *(12)*. For the three strains of *C. perfringens* used, NCTC 8238 (Hobbs serotype 2), NCTC 8239 (Hobbs serotype 3), and NCTC 10240 (Hobbs serotype 13), spores were prepared using the procedure developed by Juneja et al. *(5)*. About 2 to 3 log spores per ml were heat shocked (75°C for 20 min) and inoculated into 50 ml of the growth medium Trypticase–peptone–glucose–yeast extract (TPGY) broth, and 50 ml was dispensed into 250-ml trypsinizing flasks equipped with a rubber septum inserted in the side arm sampling port. All flasks were incubated under isothermal conditions of 15 to 50°C at 2°C increments. Samples were collected periodically, serially diluted, and plated on Shahidi-Ferguson *perfringens* agar supplemented with egg yolk, and *C. perfringens* counts were determined after 48 h of anaerobic incubation at 37°C. Logistic function was used to determine the two parameters: germination, outgrowth, and lag (GOL) time and exponential growth rate (EGR). The EGR and the reciprocal of the GOL time were fitted to the square root Ratkowsky et al. four-parameter model *(24)* to evaluate the effect of temperature on growth rate. Multivariate statistical procedures were applied to determine confidence intervals for the predicted growth at a given temperature.

Models 2, 3, and 4: PMIP uncured beef, chicken, and pork models. Details on these cooling models have been published previously *(6)*. For the three strains of *C. perfringens* used NCTC 8238 (Hobbs serotype 2), NCTC 8239 (Hobbs serotype 3), and NCTC 10240 (Hobbs serotype 13), spores were prepared using the procedure developed by Juneja et al. *(5)*. Individually packaged ground meat samples (5 g) were inoculated with a spore cocktail to obtain ~3.0 log CFU/g. Inoculated samples were heat shocked at 75°C for 20 min and then incubated in a constant temperature water bath stabilized at selected temperatures between 10 and 51°C to obtain isothermal growth curves. To enumerate the *C. perfringens,* samples were properly mixed, serially diluted, and surface plated with a spiral plater on tryptose-sulfite-cycloserine (TSC) agar.

The Baranyi and Roberts model *(1)* was used as primary model to fit the growth curves. To estimate specific growth rates, data from isothermal experiments were used to develop a secondary model based on the Ratkowsky et al. four-parameter equation (as used in model 1). For the dynamic cooling experiments, samples were submerged in a water bath programmed to decrease linearly at various cooling rates from 54.4 to 27°C and from 27 to 4°C. For $t <$ 0 h (10 min), the temperature was assumed to be constant. To estimate dynamic growth, the differential form of the primary model was numerically solved for different temperature conditions *(2, 17)*.

Model 5: Smith-Simpson and Schaffner model. Details on the Smith-Simpson and Schaffner version 3 cooling model have been published elsewhere *(33)*. Three strains of *C. perfringens,* NCTC 8238 (Hobbs serotype 2), NCTC 8239 (Hobbs serotype 3), and NCTC 10240 (Hobbs serotype 13), were maintained and prepared according to procedures described by Juneja et al. *(8)* and inoculated into ground beef (25% fat) obtained at a retail store. Three grams of inoculated ground beef was aseptically weighed into sterile bags and vacuum sealed. Samples were heat activated at 75°C for 20 min and subjected to various exponential cooling rates. Samples were collected at various times, diluted, mixed, pour plated on TSC agar with egg yolk emulsion, and incubated at 37°C

TABLE 2. *Characteristics of studies included in the evaluation of cooling model performance*

Study no.	Reference	Product	No. of observations	Inoculation cocktail[a]	Temp range (°C)	Chill time(s) (h)	% salt	pH	% phosphate
1	*10*	Marinated ground turkey breast	3	1	54.5–7.2	15, 18, 21	0.85	5.94	0.2
2	*27*	Restructured roast beef	1	2	54.4–4.4	18	1.5	5.82	0.5
3	*26*	Ground beef (73% lean)	3	2	54.5–7.2	15, 18, 21	1.5	6.2[b]	0.5
4	*9*	Ground roast beef	2	1	54.5–7.2	18, 21	0.85	5.61	0.2
5	*28*	Ground roast beef	5	2	54.5–7.2	9, 12, 15, 18, 21	1	6.2[b]	0.2
6	*11*	Ground beef (75% lean)	4	2	54.5–7.2	12, 15, 18, 21		6.2[b]	
7	*41*	Injected turkey breast	6	2	54.5–7.2	6.5, 9, 12, 15, 18, 21	0.85	5.84	0.2
8a	*4*	Ground beef (93% lean)	17	2	54.5–7.2	12, 15, 18, 21		6.2[b]	
8b	*4*	Lean ground chicken	17	2	54.5–7.2	12, 15, 18, 21		6.2[b]	
8c	*4*	Lean ground pork	17	2	54.5–7.2	12, 15, 18, 21		6.2[b]	
9	*42*	Injected pork	6	1	54.5–7.2	7, 9, 12, 15, 18, 21	0.85	6.13	0.2
10a	*29*	Normal pork	6	1	54.4–4	7, 9, 12, 15, 18, 21	1	5.8	
10b	*29*	DFD pork[c]	6	1	54.4–4	7, 9, 12, 15, 18, 21	1	5.92	
10c	*29*	PSE pork[d]	6	1	54.4–4	7, 9, 12, 15, 18, 21	1	5.31	
11a	*44*	Ground beef (75% lean)	3	1	54.4–8.5	15, 18, 21		6.2[b]	
11b	*44*	Ground beef (75% lean)	3	1	54.4–8.5	15, 18, 21	1	6.2[b]	
12a	*32*	Ground beef (75% lean)	7	1	54.4–4.4	6.5, 9, 12, 15, 18, 21, 24		6.2[b]	
12b	*32*	Ground beef (75% lean)	12	1	54.4–4.4	Dual rate		6.2[b]	
13	*3*	Ground beef (93% lean), high and low inoculum	11 high inoculum; 11 low inoculum	1	54.5–7.2	18, 21		6.5, 5.6, 5.5, 5.4, 5.3, 5.2	
14	*30*	Ground beef (75% lean)	8	1	54.4–4.4	18, 21		6.2[b]	
15	*25*	Ham	2	1		15	1.5	6.22	0.2
16a	*16*	Ground roast beef	6	1	54.4–4.4	6.5, 9, 12, 15, 18, 21	1	5.73	0.3
16b	*16*	Ground roast beef	6	1	54.4–4.4	6.5, 9, 12, 15, 18, 21	1.5	5.76	0.3
16c	*16*	Ground roast beef	6	1	54.4–4.4	6.5, 9, 12, 15, 18, 21	2	5.79	0.3
17a	*23*	Beef slurry	6	3	54.4–7.2	12	0.5–3.0	5.5–6.3	
17b	*23*	Turkey slurry	6	3	54.4–7.2	15	0.5–3.0	5.5–6.2	
17c	*23*	Pork slurry	2	3	54.4–7.2	12	1.0–2.0	5.6, 5.7	

[a] *C. perfringens,* cocktail 1: NCTC 8238 (ATCC 12916), NCTC 8239 (ATCC 12917), and NCTC 10240; cocktail 2: NCTC 8238 (ATCC 12916), NCTC 8239 (ATCC 12917), and ATCC 10388; cocktail 3: 5146-97, 3011-98, 3511-98, 5796-97, and 5810-97.

[b] No pH was reported, but for modeling purposes a pH of 6.2 was assumed.

[c] DFD, dark, firm, and dry.

[d] PSE, pale, soft, and exudative.

under anaerobic conditions. Single cooling rate and dual cooling rate experiments were performed, and growth curves were fit to the Baranyi and Roberts model *(1)* using the DMFit 1.0 Microsoft Excel add-in program (Institute of Food Research, Norwich Research Park, Norwich, UK). Only curves with growth greater than 1 log CFU/g with R^2 values greater than 0.90 were used for development of the model.

Because the temperature was constantly changing over the course of every experiment, each growth curve was viewed as a series of observations taking place at a series of temperatures. Every observation of *C. perfringens* level has an associated temperature. Every pair of observations can be thought to have occurred at an effective temperature, which is the temperature of the sample at the effective time. Effective time is the average of the two times when the *C. perfringens* level was measured. An effective temperature was calculated for each consecutive pair of data points from the DMFit output within the exponential growth phase of the curve. EGRs were determined from the slope of a linear regression line between the two subsequent points. The square root model *(17)* was used to describe the relationship between the square root of the average EGR and the effective temperature.

Model 6: UK IFR ComBase Perfringens Predictor. The ComBase Perfringens Predictor is a Web-based application that provides the user with a prediction of *C. perfringens* growth in meat products under specified dynamic cooling (temperatures changing over time) conditions. After estimation or prediction of growth based on the parameters specified (NaCl concentration and pH of the product), the software provides an interpretation of the estimated *C. perfringens* growth and compares it with the FSIS performance standard of no more than 1 log CFU growth.

The underlying primary models were generated from the data available in the ComBase database, including 64 isothermal experiments with an additional 17 isothermal experiments conducted to extend the parameters for growth for higher concentrations of NaCl and higher pH of the product *(15)*. The isothermal data were collected for different concentrations of NaCl and different pH values (with one variable remaining constant), with pH ranging from 4.7 to 7.9 at a specific NaCl concentration (0.5%) and NaCl concentrations ranging from 0.5 to 6.0% at a constant pH of 6.2. The a_w of the product was calculated from the NaCl concentration (wt/vol) by formula. An additional 24 dynamic (nonisothermal) temperature profiles representing those used in the industry and abusive cooling profiles were used to validate the *C. perfringens* growth predictions.

The dynamic model was developed in three steps. The primary model was developed as a function of temperature, a_w (NaCl concentration), and pH of the product. The primary models were fitted with the DMFit 2.0 Microsoft Excel add-in program, assuming a maximum level of 10^9 CFU/ml, and the maximum specific growth rate for each set of variable parameters (temperature, a_w, and pH) was calculated. A secondary model was generated using the maximum specific growth rate (from each set of 81 primary models) as a function of temperature, a_w, and pH.

Criteria used for assessing cooling model performance. Various researchers have proposed specific approaches for validation of predictive microbial models. Three sets of criteria based on different definitions for accurate, fail-safe, and fail-dangerous predictions were used to evaluate model performance in this study. Criterion 1 defined an accurate prediction as when the residual (observed value minus predicted value) is −1.0 to +0.5 log unit, a fail-safe prediction as when the residual is less than −1.0 log unit, and a fail-dangerous prediction as when the residual is greater than +0.5 log unit. This criterion was used to evaluate model performance based on the acceptable prediction zone (APZ) method *(20),* where the ''A'' in ''APZ'' represents ''accurate'' rather than ''acceptable'' as in the original definition by Oscar *(20),* and a residual measurement that falls into this range is then defined as accurate. The fail-dangerous boundary (i.e., +0.5 log unit) of the APZ is based on an evaluation of the standard deviation (variation) of log counts among replicate experiments. The fail-safe boundary (i.e., −1.0 log unit) was set at twice the level of the fail-dangerous boundary (i.e., +0.5 log unit) because greater prediction error can be tolerated in the fail-safe direction than in the fail-dangerous direction when a model is used to predict food safety based on the APZ method *(21, 22).*

The boundaries for criterion 2 were based on the level of microbial growth that we would not consider significant: an accurate prediction is when the residual is −1.0 to +1.0 log unit, a fail-safe prediction is when the residual is less than −1.0 log unit, and a fail-dangerous prediction is when the residual is greater than +1.0 log unit. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) *(19)* used growth of <1 log unit as the criterion for determining the absence of measurable growth of pathogens of concern in its publication on microbial challenge studies.

The boundaries for criterion 3 were based on the fact that a 0.5-log resolution limit is generally accepted for microbial testing, where resolution is the ability to distinguish between two sets of results: an accurate prediction is when the residual is −0.5 to +0.5 log unit, a fail-safe prediction is when the residual is less than −0.5 log unit, and a fail-dangerous prediction is when the residual is greater than +0.5 log unit. The NACMCF *(19)* also noted that a difference of >0.5 log CFU/g may be an appropriate criterion for determining microbial growth, depending on the food, inoculum level, and method of pathogen enumeration. Criterion 3 is the same as that used by Thurette et al. *(34)* to determine the accuracy of predicted values obtained from two *Listeria monocytogenes* growth models.

RESULTS

Model 1: PMP 7.0 broth model. The performance of the ARS PMP 7.0 cooling model of *C. perfringens* in beef broth as determined by the percentage of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 are given in Tables 3 and 4. The results were based on 176 observations during single-rate exponential cooling experiments and 12 observations during dual-rate exponential cooling experiments in cooked, uncured meat or poultry products. The percentage of accurate, fail-safe, and fail-dangerous predictions differed based on which criterion was used to evaluate the data set. The performance of the ARS PMP 7.0 cooling model based on 188 observations (experiments) in cooked, uncured meat and poultry products when single-rate and dual-rate exponential cooling data sets were considered together are given in Table 5. The ARS PMP 7.0 cooling model had low combined percentages of accurate and fail-safe predictions (34.04% for criteria 1 and 3; 42.55% for criterion 2) but a high percentage of fail-dangerous predictions (57.45% for criterion 2; 65.96% for criteria 1 and 3) in cooked, uncured meat and poultry products during single-rate and dual-rate exponential cooling. This cooling model produced the lowest percentages of combined accurate and fail-safe predictions and the

TABLE 3. *Performance of the cooling models during single-rate exponential chilling*

Cooling model	No. of observations	% accurate predictions	% fail-safe predictions	% fail-dangerous predictions	% of accurate and fail-safe predictions
Criterion 1[a]					
PMIP cooked, uncured beef	99	1.01 (1/99)	98.99 (98/99)	0.00 (0/99)	100.0 (99/99)
PMIP cooked, uncured pork	45	22.22 (10/45)	77.78 (35/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	6.25 (2/32)	93.75 (30/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	176	7.39 (13/176)	92.61 (163/176)	0.00 (0/176)	100.0 (176/176)
PMP 7.0 in beef broth	176	22.73 (40/176)	11.93 (21/176)	65.34 (115/176)	34.66 (61/176)
ComBase Predictor	176	48.29 (85/176)	26.14 (46/176)	25.57 (45/176)	74.43 (131/176)
ComBase Predictor[b]	176	50.00 (88/176)	27.27 (48/176)	22.73 (40/176)	77.27 (136/176)
Smith-Schaffner	176	43.18 (76/176)	36.93 (65/176)	19.89 (35/176)	80.11 (141/176)
Criterion 2[c]					
PMIP cooked, uncured beef	99	1.01 (1/99)	98.99 (98/99)	0.00 (0/99)	100.0 (99/99)
PMIP cooked, uncured pork	45	22.22 (10/45)	77.78 (35/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	6.25 (2/32)	93.75 (30/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	176	7.39 (13/176)	92.61 (163/176)	0.00 (0/176)	100.0 (176/176)
PMP 7.0 in beef broth	176	30.68 (54/176)	11.93 (21/176)	57.39 (101/176)	42.61 (75/176)
ComBase Predictor	176	59.09 (104/176)	26.14 (46/176)	14.77 (26/176)	85.23 (150/176)
ComBase Predictor[b]	176	60.80 (107/176)	27.27 (48/176)	11.93 (21/176)	88.07 (155/176)
Smith-Schaffner	176	56.25 (99/176)	36.93 (65/176)	6.82 (12/176)	93.18 (164/176)
Criterion 3[d]					
PMIP cooked, uncured beef	99	0.00 (0/99)	100.00 (99/99)	0.00 (0/99)	100.0 (99/99)
PMIP cooked, uncured pork	45	2.22 (1/45)	97.78 (44/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	0.00 (0/32)	100.00 (32/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	176	0.57 (1/176)	99.43 (175/176)	0.00 (0/176)	100.0 (176/176)
PMP 7.0 in beef broth	176	17.05 (30/176)	17.61 (31/176)	65.34 (115/176)	34.66 (61/176)
ComBase Predictor	176	40.91 (72/176)	33.52 (59/176)	25.57 (45/176)	74.43 (131/176)
ComBase Predictor[b]	176	42.61 (75/176)	34.66 (61/176)	22.73 (40/176)	77.27 (136/176)
Smith-Schaffner	176	30.68 (54/176)	49.43 (87/176)	19.89 (35/176)	80.11 (141/176)

[a] Accurate prediction is when the residual is −1.0 to +0.5 log unit; fail-safe prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.
[b] A salt concentration of 1% was used for modeling for those products with a salt concentration of 0.85% to improve model performance.
[c] Accurate prediction is when the residual is −1.0 to +1.0 log unit; fail-safe Prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +1.0 log unit.
[d] Accurate prediction is when the residual is −0.5 to +0.5 log unit; fail-safe prediction is when the residual is less than −0.5 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.

highest percentages of fail-dangerous predictions of any of the six cooling models evaluated in this study (Table 5).

When criterion 1 was used to evaluate the performance of this cooling model, most of the time (90.63%; 58 of 64 observations) when the cooling model provided an accurate or fail-safe prediction, the actual growth of *C. perfringens* observed in product was 1.00 log unit or less (50.00%; 32 of 64 observations) or for the 18- or 21-h chilling profiles (66.67%; 40 of 64 observations) (Fig. 1; Table 5). Further analysis of the fail-safe predictions for this model based on the use of criterion 1 to assess model performance (21 observations; Tables 3 and 5) indicated that these predictions were associated with product with intrinsic factors (e.g., pH, salt concentration, and phosphate concentration) that have an inhibitory effect on the growth of *C. perfringens* in the meat or poultry products. For example, 19 of the fail-safe predictions were observed for ground beef or turkey with a pH of 5.6 to 5.2 (Fig. 2). Generally, the only time that the ARS PMP 7.0 cooling model provided an accurate prediction was when minimal growth (≤1.0 log CFU/g) or appreciable growth (≥3.89 log CFU/g) of *C. perfringens* was observed in cooked, uncured meat and poultry products (data not shown).

Models 2, 3, and 4: PMIP uncured beef, chicken, and pork models. The performance of the cooling models for cooked, uncured ground beef, pork, and chicken as determined by the percentages of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 are given in Table 3. The results were based on 99, 45, and 32 observations (or experiments) in cooked, uncured beef, pork, and chicken products, respectively, during single-rate exponential cooling. The percentage of accurate, fail-safe, and fail-dangerous predictions differed based on which criterion was used to evaluate the data set for the

TABLE 4. *Performance of the cooling models during dual-rate exponential chilling*

Cooling model	No. of observations	% accurate predictions	% fail-safe predictions	% fail-dangerous predictions	% accurate and fail-safe predictions
Criterion 1[a]					
PMIP cooked, uncured beef	12	75.00 (9/12)	16.67 (2/12)	8.33 (1/12)	91.67 (11/12)
PMP 7.0 in beef broth	12	25.00 (3/12)	0.00 (0/12)	75.00 (9/12)	25.00 (3/12)
ComBase Predictor	12	8.33 (1/12)	0.00 (0/12)	91.67 (11/12)	8.33 (1/12)
ComBase Predictor[b]	12	8.33 (1/12)	0.00 (0/12)	91.67 (11/12)	8.33 (1/12)
Smith-Schaffner	12	41.67 (5/12)	0.00 (0/12)	58.33 (7/12)	41.67 (5/12)
Criterion 2[c]					
PMIP cooked, uncured beef	12	83.33 (10/12)	16.67 (2/12)	0.00 (0/12)	100.00 (12/12)
PMP 7.0 in beef broth	12	41.67 (5/12)	0.00 (0/12)	58.33 (7/12)	41.67 (5/12)
ComBase Predictor	12	50.00 (6/12)	0.00 (0/12)	50.00 (6/12)	50.00 (6/12)
ComBase Predictor[b]	12	50.00 (6/12)	0.00 (0/12)	50.00 (6/12)	50.00 (6/12)
Smith-Schaffner	12	58.33 (7/12)	0.00 (0/12)	41.67 (5/12)	58.33 (7/12)
Criterion 3[d]					
PMIP cooked, uncured beef	12	58.34 (7/12)	33.33 (4/12)	8.33 (1/12)	91.67 (11/12)
PMP 7.0 in beef broth	12	25.00 (3/12)	0.00 (0/12)	75.00 (9/12)	25.00 (3/12)
ComBase Predictor	12	8.33 (1/12)	0.00 (0/12)	91.67 (11/12)	8.33 (1/12)
ComBase Predictor[b]	12	8.33 (1/12)	0.00 (0/12)	91.67 (11/12)	8.33 (1/12)
Smith-Schaffner	12	41.67 (5/12)	0.00 (0/12)	58.33 (7/12)	41.67 (5/12)

[a] Accurate prediction is when the residual is −1.0 to +0.5 log unit; fail-safe prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.
[b] A salt concentration of 1% was used for modeling for those products with a salt concentration of 0.85% to improve model performance.
[c] Accurate prediction is when the residual is −1.0 to +1.0 log unit; fail-safe Prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +1.0 log unit.
[d] Accurate prediction is when the residual is −0.5 to +0.5 log unit; fail-safe prediction is when the residual is less than −0.5 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.

cooling model. The combined percentage of accurate and fail-safe predictions was 100.00% for all three performance criteria (Table 3). For the beef cooling model based on 12 dual-rate exponential cooling experiments, the percentages of accurate predictions were 75.00, 83.33, and 58.34%, the percentages of fail-safe predictions were 16.67, 16.67, and 33.33%, and the percentages of fail-dangerous predictions were 8.33, 0.00, and 8.33% for performance criteria 1, 2, and 3, respectively (Table 4).

The combined performance of the three cooling models (i.e., cooked, uncured ground beef, pork, and chicken) produced percentages of accurate predictions of 7.39, 7.39, and 0.57%, percentages of fail-safe predictions of 92.61, 92.61, and 99.43%, and percentages of fail-dangerous predictions of 0.00, 0.00, and 0.00% for performance criteria 1, 2, and 3, respectively (Table 3). The results were based on 176 observations (experiments) in cooked, uncured meat and poultry products during single-rate exponential cooling. The combined percentage of accurate and fail-safe predictions were 100.00% for all three performance criteria. The percentages of accurate, fail-safe, and fail-dangerous predictions differed based on which criterion was used to evaluate the data set for the cooling model.

When single-rate and dual-rate exponential cooling data sets were considered together (Table 5), the combined performance of the three cooling models (i.e., cooked, uncured ground beef, pork, and chicken) produced percentages of accurate predictions of 11.70, 12.23, and 4.26%, percentages of fail-safe predictions of 87.77, 87.77, and 95.21%, and percentages of fail-dangerous predictions of 0.53, 0.00, and 0.53% for performance criteria 1, 2, and 3, respectively, based on 188 observations (experiments). The combined percentages of accurate and fail-safe predictions were 99.47, 100.00, and 99.47% for performance criteria 1, 2, and 3, respectively.

Overall, the three PMIP cooling models produced a low percentage of accurate predictions (0.00 to 22.22%) but a high percentage of fail-safe predictions (77.78 to 100.00%) in cooked, uncured meat and poultry products during single-rate and dual-rate exponential cooling (Table 5), depending on the cooling model and the criteria used to assess model performance. Consequently, the three cooling models generally appear to be fail-safe predictive microbial models. The combined percentages of accurate and fail-safe predictions were 99.10 or 100% for uncured beef, 100% for uncured pork, and 100% for uncured chicken (Table 5).

Model 5: Smith-Simpson and Schaffner model. The performance of the Smith-Schaffner cooling model as determined by the percentages of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 are given in Table 3. The results were based on 176 observations (or experiments) in cooked, uncured meat and poultry products during single-rate exponential cooling (Table 3). The percentages of accurate, fail-safe, or

TABLE 5. *Performance of the cooling models during single-rate and dual-rate exponential chilling*

Cooling model	No. of observations	% accurate predictions	% fail-safe predictions	% fail-dangerous predictions	% accurate and fail-safe predictions
Criteria 1[a]					
PMIP cooked, uncured beef	111	9.01 (10/111)	90.09 (100/111)	0.90 (1/111)	99.10 (110/111)
PMIP cooked, uncured pork	45	22.22 (10/45)	77.78 (35/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	6.25 (2/32)	93.75 (30/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	188	11.70 (22/188)	87.77 (165/188)	0.53 (1/188)	99.47 (187/188)
PMP 7.0 in beef broth	188	22.87 (43/188)	11.17 (21/188)	65.96 (124/188)	34.04 (64/188)
ComBase Predictor	188	45.74 (86/188)	24.47 (46/188)	29.79 (56/188)	70.21 (132/188)
ComBase Predictor[b]	188	47.34 (89/188)	25.53 (48/188)	27.13 (51/188)	72.87 (137/188)
Smith-Schaffner	188	43.09 (81/188)	34.57 (65/188)	22.34 (42/188)	77.66 (146/188)
Criteria 2[c]					
PMIP cooked, uncured beef	111	9.91 (11/111)	90.09 (100/111)	0.00 (0/111)	100.0 (111/111)
PMIP cooked, uncured pork	45	22.22 (10/45)	77.78 (35/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	6.25 (2/32)	93.75 (30/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	188	12.23 (23/188)	87.77 (165/188)	0.00 (0/188)	100.0 (188/188)
PMP 7.0 in beef broth	188	31.38 (59/188)	11.17 (21/188)	57.45 (108/188)	42.55 (80/188)
ComBase Predictor	188	58.51 (110/188)	24.47 (46/188)	17.02 (32/188)	82.98 (156/188)
ComBase Predictor[b]	188	60.11 (113/188)	25.53 (48/188)	14.36 (27/188)	85.64 (161/188)
Smith-Schaffner	188	56.38 (106/188)	34.58 (65/188)	9.04 (17/188)	90.96 (171/188)
Criteria 3[d]					
PMIP cooked, uncured beef	111	6.31 (7/111)	92.79 (103/111)	0.90 (1/111)	99.10 (110/111)
PMIP cooked, uncured pork	45	2.22 (1/45)	97.78 (44/45)	0.00 (0/45)	100.0 (45/45)
PMIP cooked, uncured chicken	32	0.00 (0/32)	100.00 (32/32)	0.00 (0/32)	100.0 (32/32)
3 PMIP cooling models (combined data)	188	4.26 (8/188)	95.21 (179/188)	0.53 (1/188)	99.47 (187/188)
PMP 7.0 in beef broth	188	17.55 (33/188)	16.49 (31/188)	65.96 (124/188)	34.04 (64/188)
ComBase Predictor	188	38.83 (73/188)	31.38 (59/188)	29.79 (56/188)	70.21 (132/188)
ComBase Predictor[b]	188	40.42 (76/188)	32.45 (61/188)	27.13 (51/188)	72.87 (137/188)
Smith-Schaffner	188	31.38 (59/188)	46.28 (87/188)	22.34 (42/188)	77.66 (146/188)

[a] Accurate prediction is when the residual is −1.0 to +0.5 log unit; fail-safe prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.
[b] A salt concentration of 1% was used for modeling for those products with a salt concentration of 0.85% to improve model performance.
[c] Accurate prediction is when the residual is −1.0 to +1.0 log unit; fail-safe Prediction is when the residual is less than −1.0 log unit; fail-dangerous prediction is when the residual is greater than +1.0 log unit.
[d] Accurate prediction is when the residual is −0.5 to +0.5 log unit; fail-safe prediction is when the residual is less than −0.5 log unit; fail-dangerous prediction is when the residual is greater than +0.5 log unit.

fail-dangerous predictions differed based on which criterion was used to evaluate the data set for the cooling model.

Percentages of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 for this cooling model based on 12 dual-rate exponential cooling experiments are given in Table 4. The Smith-Schaffner model was the second most accurate model for dual-rate cooling (behind the PMIP cooked, uncured beef model). The Smith-Schaffner model was also second in accurate and fail-safe percentage behind the PMIP cooked, uncured beef model. However, this cooling model may provide a moderate to high percentage of fail-dangerous predictions under dual-rate exponential chilling conditions.

When single-rate and dual-rate exponential cooling data sets were considered together (Tables 5), the Smith-Schaffner cooling model combined percentages of accurate and fail-safe predictions were 77.66, 90.96, and 77.66% for performance criteria 1, 2, and 3, respectively, based on 188 observations (experiments) in cooked, uncured meat and poultry products. The percentages of accurate, fail-safe, or fail-dangerous predictions differed depending upon which criteria were used to evaluate the data set for the cooling model.

For single-rate exponential cooling (Table 3), the Smith-Schaffner cooling model produced high combined percentages of accurate and fail-safe predictions (80.11% for criteria 1 and 3; 93.18% for criterion 2) and low

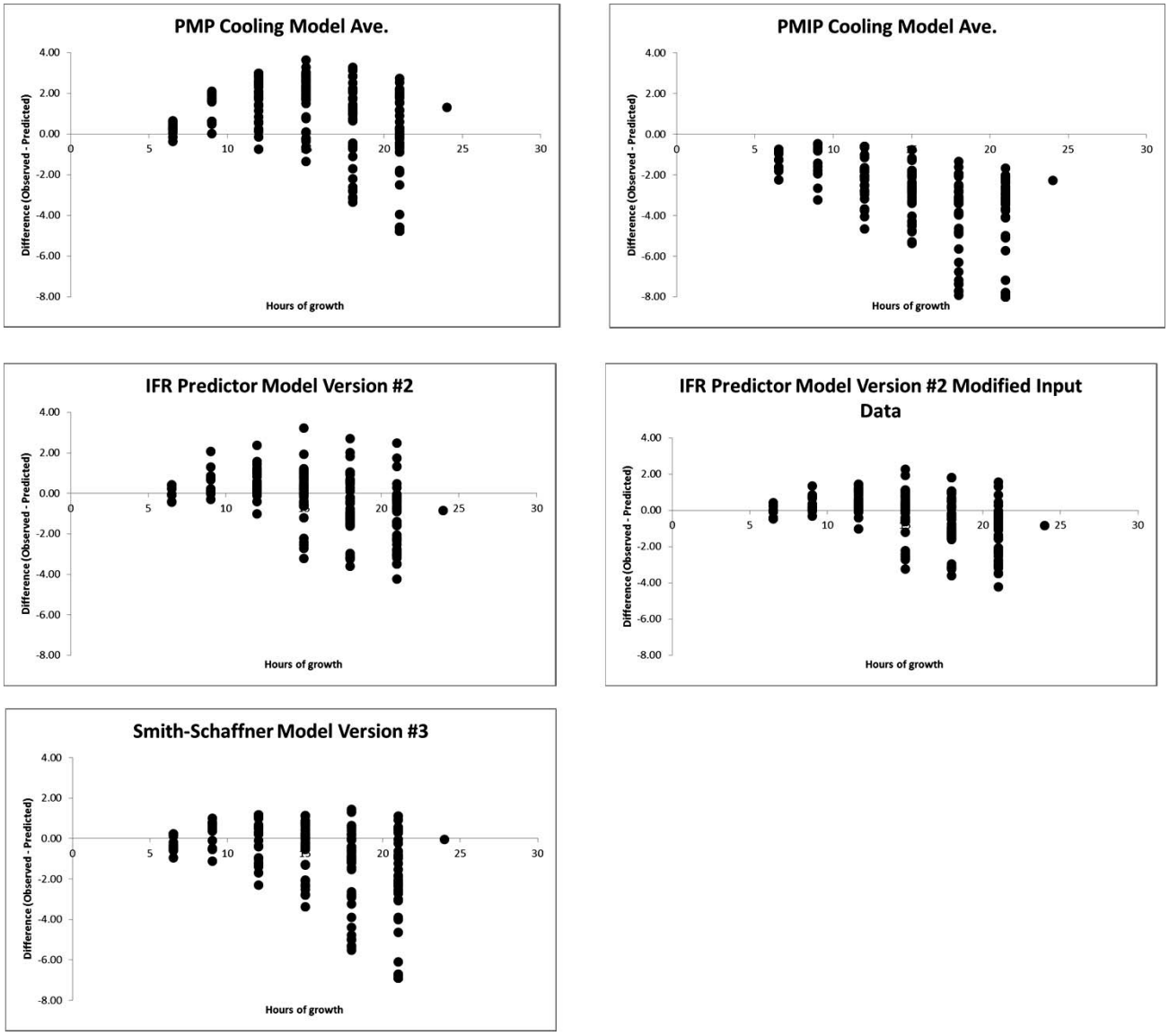

FIGURE 1. *Performance of cooling models of* C. perfringens *growth plotted by cooling time. The performance of each cooling model was determined by looking at the difference between the observed and predicted value for each time-temperature cooling profile from all studies listed in Table 2. Overpredicted residual values are negative, and underpredicted residual values are positive.*

percentages of fail-dangerous predictions (19.89% for criteria 1 and 3; 6.82% for criterion 2) in cooked, uncured meat and poultry products. Data analysis indicated that most of the time this model will provide accurate or fail-safe predictions for growth of *C. perfringens* in a cooked, uncured meat or poultry product after a cooling deviation or for a customized cooling schedule.

Model 6: UK IFR ComBase Perfringens Predictor. The performance of the UK IFR ComBase Perfringens Predictor cooling model as determined by the percentages of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 are given in Table 3. The results were based on 176 observations in cooked, uncured meat and poultry products during single-rate exponential cooling. For the 12 dual-rate exponential cooling experiments, the percentages of accurate, fail-safe, and fail-dangerous predictions for performance criteria 1, 2, and 3 are given in Table 4. The data suggest that this cooling model may provide a high percentage of fail-dangerous predictions under dual-rate exponential chilling conditions.

When single-rate and dual-rate exponential cooling data sets were considered together (Table 5), the performance of the ComBase Perfringens Predictor cooling model produced combined percentages of accurate and fail-safe predictions of 70.21, 82.98, and 70.21% for performance criteria 1, 2, and 3, respectively. These percentages are based on 188 observations in cooked, uncured meat and poultry products.

For single-rate exponential cooling (Table 3), the ComBase Perfringens Predictor cooling model produced high combined percentages of accurate and fail-safe predictions (74.43% for criteria 1 and 3; 85.23% for criterion 2) and low percentages of fail-dangerous predictions (25.57% for criteria 1 and 3; 14.77% for criterion 2) in cooked, uncured meat and poultry products. Data analysis indicated that most of the time this model will provide accurate or fail-safe prediction for growth of *C. perfringens*

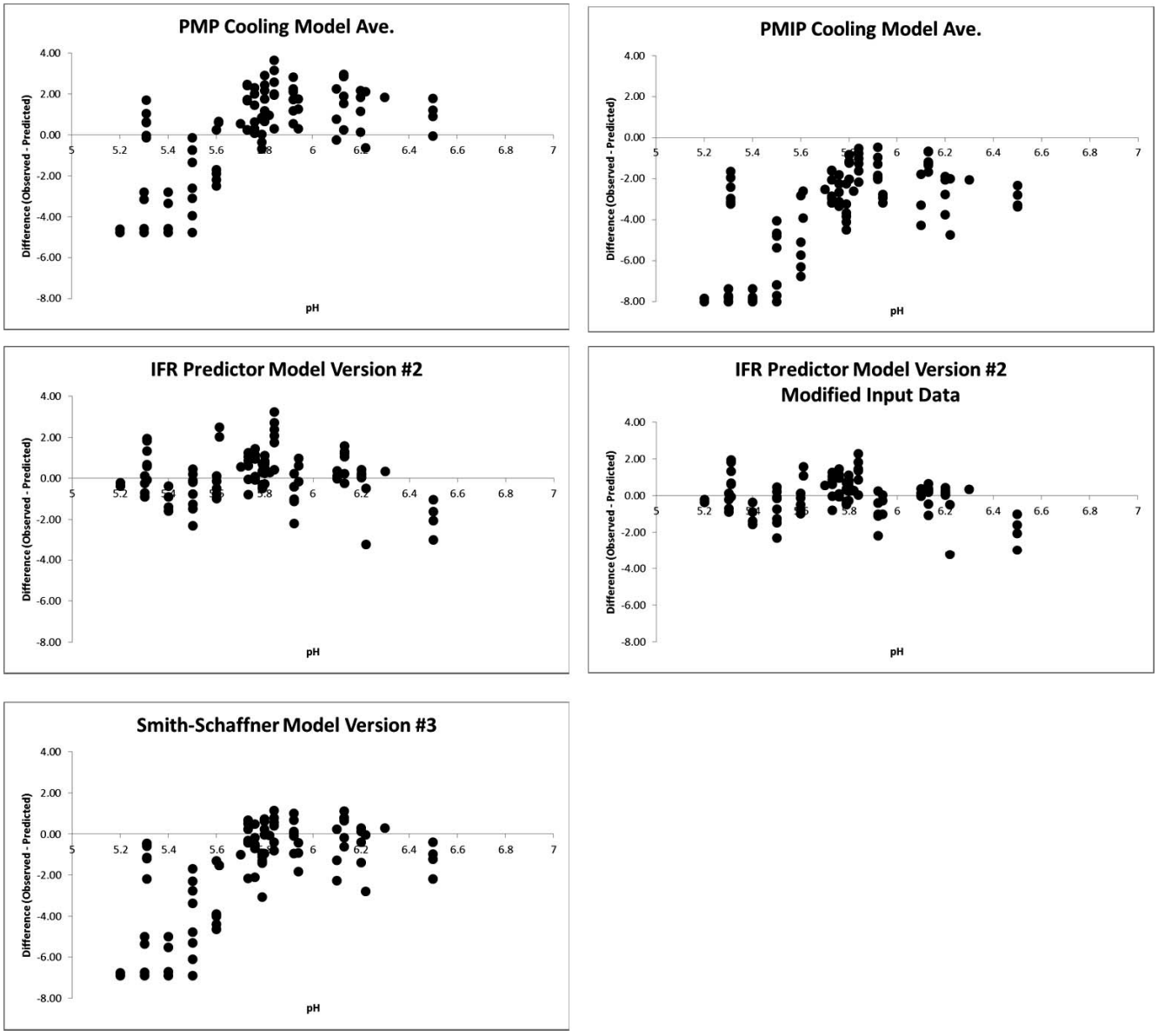

FIGURE 2. *Performance of cooling models of* C. perfringens *growth by pH of product. The performance of each cooling model was determined by looking at the difference between the observed and predicted value for each time-temperature cooling profile from all studies listed in Table 2. Only data from studies in Table 2 that specifically measured the pH of the product were used in this analysis. Overpredicted residual values are negative, and underpredicted residual values are positive.*

in a cooked, uncured meat or poultry product after a cooling deviation or for a customized cooling schedule. This cooling model also produced the highest percentage of accurate predictions, the second lowest percentage of combined accurate and fail-safe predictions, and the second highest percentage of fail-dangerous predictions of any of the six cooling models evaluated.

Further analysis revealed that most of the observations for product with 0.85% salt, based on the use of criteria 1 or 3 to assess model performance, produced a high percentage of fail-dangerous predictions (76.47%; 13 of 17 observations; Fig. 3). Using a salt concentration of 1.0% instead of 0.85% in the model for the 17 observations, discussed earlier, resulted in a decrease in the number of fail-dangerous predictions from 13 of 17 observations to 8 of 17 observations (Fig. 3), thus resulting in decreased percentages of fail-dangerous predictions of 22.73% instead of 25.57% or 11.93% instead of 14.77%, depending on which performance criteria was used to assess model performance (Table 3). The range of the residuals for the 11 worst fail-dangerous predictions changed from +1.06 to +3.22 log units to +0.18 to +2.28 log units, which also indicates improved performance of this model (Fig. 3).

DISCUSSION

Cooling models are the main tool used by both the meat and poultry industries and the FSIS to evaluate cooling deviations and to develop or evaluate customized cooling schedules. The selection of a cooling model depends on a number of factors. From the regulator's perspective, a model that produces a high percentage of accurate and fail-safe predictions provides the greatest protection of public

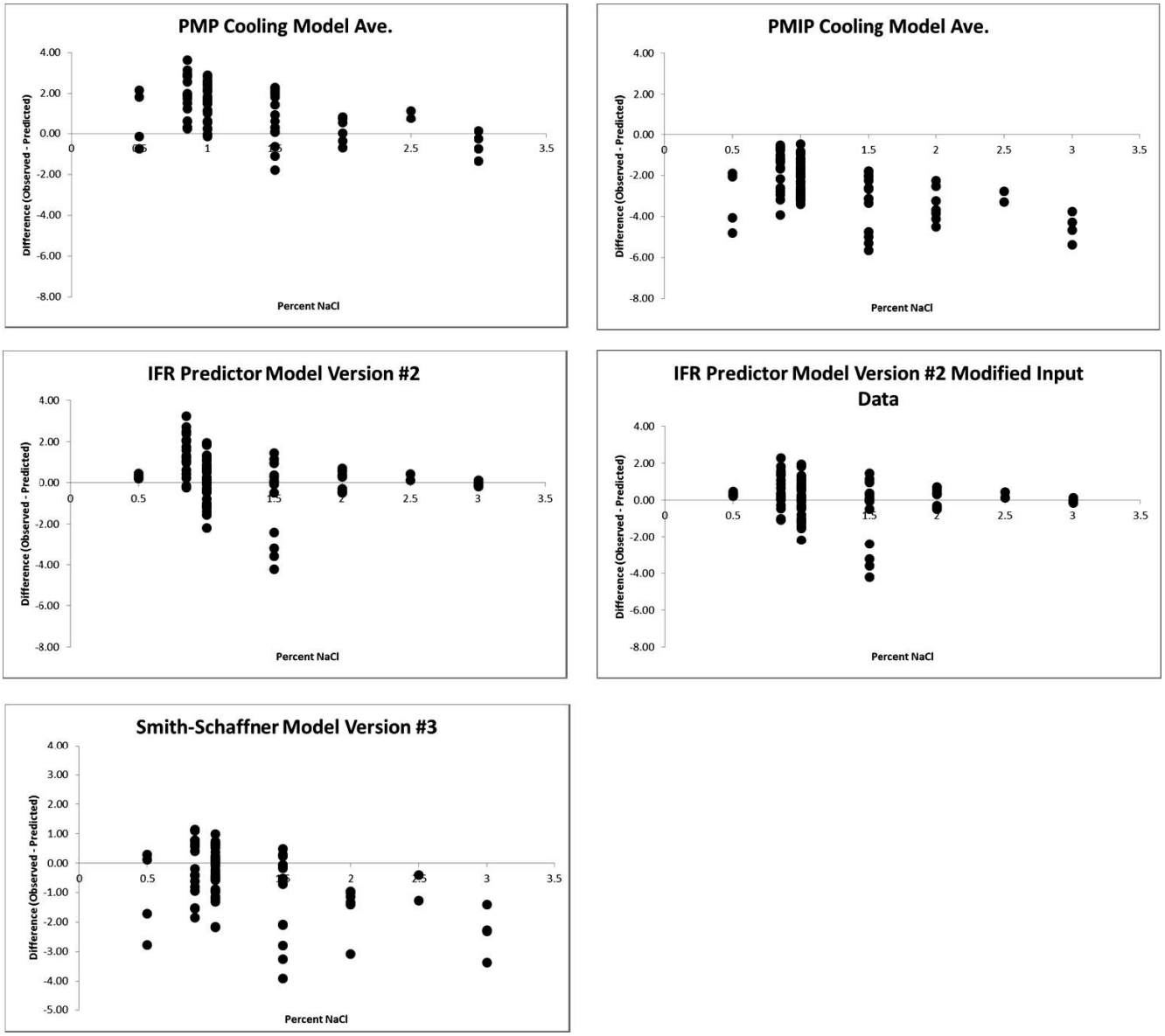

FIGURE 3. *Performance of cooling models of* C. perfringens *growth by the NaCl concentration in the product. The performance of each cooling model was determined by looking at the difference between the observed and predicted value for each time-temperature cooling profile from all studies listed in Table 2. Only data from studies in Table 2 that specifically stated the percentage of salt added to the product were used in this analysis. Overpredicted residual values are negative, and underpredicted residual values are positive.*

health. However, a model that tends to overpredict growth, resulting in a high percentage of fail-safe predictions, may have negative economic consequences for the industry and consumers because food that is safe to consume may be destroyed unnecessarily. The percentages of accurate, fail-safe, and fail-dangerous predictions for each cooling model will differ depending on the criterion used to evaluate the data set. Consensus is needed on the most appropriate criteria for evaluating model performance because standard criteria for these evaluations are not available.

The ARS PMP 7.0 cooling model for *C. perfringens* in beef broth provided the highest percentage of fail-dangerous predictions of the models studied. Although some fail-safe predictions (21 observations) were obtained for this model based on the use of criterion 1 to assess model performance, all of the fail-safe predictions were obtained for product with intrinsic factors (pH, salt concentration, and phosphate concentration) that have an inhibitory effect on the growth of *C. perfringens* in meat or poultry products (Figs. 2 and 3). Meat and poultry products with a low pH have reduced growth of *C. perfringens* during extended cooling procedures *(3)*. In this same study, in ground beef with a pH of 5.6 and beef, pork, and poultry barbeque products with a pH of $\leq$5.63 that were cooled exponentially from 54.4 to 7.2°C in 15 h or less, *C. perfringens* growth would be limited to $\leq$1 log CFU/g. Therefore, it is not surprising that the ARS PMP 7.0 cooling model of *C. perfringens* in beef broth produces fail-safe predictions under these circumstances, especially given that the model does not take into account the pH and salt concentration of the meat, which can have an inhibitory effect on the growth of *C. perfringens* in the product.

Most of the time (66.67%; 40 of 64 observations) when the ARS PMP 7.0 cooling model of *C. perfringens* in beef broth provided an accurate or fail-safe prediction, it was for 18- or 21-h chilling profiles (Fig. 1 and Table 5). These results are consistent with the research that has shown that this cooling model is fail-safe when low (<1 log CFU/ml) or high (>3 log CFU/ml) observed increases occur during exponential cooling of TPGY broth but consistently underpredicts *C. perfringens* growth at intermediate observed increases (1 to 3 log CFU/ml) *(31)*. The performance of this ARS cooling model was worst when predicting the growth of the pathogen during single- and dual-rate exponential cooling of ground beef in comparison to TPGY broth *(32)*. These same researchers also found that the cooling model may provide a high percentage of fail-dangerous predictions under dual-rate exponential chilling conditions, which sometimes occur in federally inspected meat and poultry establishments, especially during cooling deviations. However, the available data set for validation of dual-rate exponential cooling experiments is based on only 12 observations.

The 18- or 21-h chilling profiles do not reflect the typical or even worst-case cooling deviations (i.e., ≤15-h chilling profiles) seen for cooked, uncured meat or poultry products in federally inspected meat or poultry establishments. Use of a model that underpredicts pathogen growth under typical or worst-case cooling deviations may lead to consumption of unsafe food. Consequently, the usefulness of this ARS PMP 7.0 cooling model for evaluating cooling deviations of cooked, uncured meat and poultry products is questionable, especially given that other validated and reliable cooling models are currently available to the industry and the FSIS. The FSIS plans to include these findings in future guidance with other findings from the present study to assist establishments in selecting a reliable model, and the ARS will remove the PMP 7.0 model for beef broth from the ARS Web site based on the results of the present study that this cooling model underpredicts the growth of *C. perfringens* for most cooling processes.

In contrast to the ARS PMP 7.0 model in beef broth, the three ARS PMIP cooling models (cooked, uncured ground beef, pork, and chicken) produced the highest percentages of combined accurate and fail-safe predictions and the lowest percentages of fail-dangerous predictions compared with the other three cooling models evaluated in the present study, regardless of the criteria used to assess model performance. Although the three PMIP cooling models appear to be fail-safe models because they provided the highest percentage of both fail-safe predictions and combined accurate and fail-safe predictions of the six cooling models evaluated, most of the time these cooling models will overpredict the growth of *C. perfringens* in a meat or poultry product during a cooling deviation or in a customized cooling schedule. A model that overpredicts pathogen growth may lead to unnecessary destruction of safe food. Consequently, these cooling models may provide a conservative approach for evaluating cooling deviations of cooked, uncured meat and poultry products. Because the results of this study support other validated and reliable cooling models currently available to the industry and the FSIS, the results of the PMIP models should be compared with those of the ComBase and Smith-Schaffner models when assessing a cooling process deviation to prevent the unnecessary destruction of safe food.

The three PMIP cooling models for predicting the relative growth of *C. perfringens* in uncured meat and poultry products (beef, chicken, and pork) are based on parameterization of a class of models initially developed by Baranyi and Roberts *(1)*, encompassing five parameters: the Ratkowsky et al. *(24)* four parameters for specific growth rate predictions as affected by temperature and a fifth parameter (q_0), a physiological state constant that depends upon the history of the cells before initiation of growth. The estimated value of q_0 was derived using dynamic experiments for which the history of the cells was similar. In these models, observed growth was higher in beef than in pork and chicken. The maximum specific growth rate was significantly higher for beef (2.7 log CFU/h, $P < 0.001$) than for pork and poultry meat (ca. 2.2 log CFU/h).

As with the ARS PMP 7.0 model, the ARS PMIP cooling models do not consider the pH and salt concentration of the meat or whether the product is cured or uncured. These important intrinsic factors can affect the growth of *C. perfringens* in cooked meat and poultry products during cooling. Currently, the UK IFR ComBase Perfringens Predictor model is the only cooling model available that takes these important intrinsic factors into account when predicting the growth of this pathogen during cooling.

The Smith-Schaffner cooling model *(33)* was developed using data collected under dynamic temperature conditions. Smith-Simpson and Schaffner *(33)* reported accurate predictions of *C. perfringens* growth during single-rate exponential cooling; however, the model underpredicted growth when applied to dual-rate exponential cooling scenarios. The Smith-Schaffner model had a higher percentage of accuracy than did the PMP 7.0 and the PMIP cooling models but was less accurate than the ComBase Perfringens Predictor model. Given the conservative approach the authors used to develop the Smith-Schaffner model, this model had a higher fail-safe percentage than did the other models evaluated, except for the three PMIP cooling models. The Smith-Schaffner model fail-dangerous and combined accurate and fail-safe percentages were comparable to those of the ComBase Perfringens Predictor model. As with the PMP 7.0 model, a high percentage of the fail-safe predictions (58.46%; 38 of 65 observations) observed for the Smith-Schaffner cooling model, based on the use of criterion 1 to assess model performance, was found for product with intrinsic factors (e.g., pH, salt concentration, and phosphate concentration) that have an inhibitory effect on the growth of *C. perfringens* in the meat or poultry product (Figs. 2 and 3). For example, 28 of the fail-safe predictions were observed in pale, soft, and exudative pork, ground beef, and beef, turkey, or pork slurry with a pH of 5.2 to 5.61 (Fig. 2). Therefore, it is not surprising that the Smith-Schaffner cooling model produced fail-safe predictions under these circumstances, especially given that the model does not take into account the pH and

salt concentration of the meat, which have an inhibitory effect on the growth of *C. perfringens* in product.

A high percentage of the fail-dangerous predictions (65.71%; 23 of 35 observations) produced with the Smith-Schaffner cooling model, based on the use of criteria 1 or 3 to assess model performance, had residuals of +0.51 to +1.0 log unit for single-rate exponential chilling. Thus, most of the fail-dangerous predictions were just outside the boundaries for an accurate prediction based on the use of criteria 1 or 3 to assess model performance. However, when criterion 2 was used to assess model performance, the percentage of fail-dangerous predictions decreased from 19.89% (35 of 176 observations) to 6.82% (12 of 176 observations) because the fail-dangerous boundary for an accurate prediction went from +0.5 to +1.0 log unit. At the same time, the percentage of accurate predictions increased from 43.18% (76 of 176 observations) to 56.25% (99 of 176 observations) (Table 4). Consequently, the percentage of accurate predictions is a relative measure of model performance because the boundaries of an accurate prediction affect its value.

Our analysis confirmed that the ComBase Perfringens Predictor cooling model provides a reliable estimation of food safety with regard to the growth of *C. perfringens* in cooked, uncured meat and poultry products, except under those circumstances discussed here. The ComBase Perfringens Predictor cooling model has been externally validated by the UK IFR for cooked cured and uncured meat and poultry products, and consistent with these findings, the validated model produced accurate predictions of the growth of *C. perfringens* in cooked, uncured meat and poultry products in the present study. The cooling model research has been published *(15),* and a copy of the validation report is available from the Food Standard Agency (London, UK).

The ComBase Perfringens Predictor cooling model is the only model evaluated here that was developed to take into account the pH and salt concentration of the meat and whether the product is cured or uncured. These important intrinsic factors can affect the growth of *C. perfringens* in cooked meat and poultry products during cooling. However, the ComBase Perfringens Predictor model does not take into account other meat processing ingredients such as phosphate (0.4 to 0.5%) and antimicrobial agents (e.g., sodium lactate and sodium diacetate), which can have an inhibitory effect on the growth of *C. perfringens* in the product. No model for *C. perfringens* growth is currently available that takes these intrinsic factors into account.

Most of the fail-safe predictions (84.78%; 39 of 46 observations) obtained with the ComBase Perfringens Predictor cooling model, based on the use of criterion 1 to assess model performance, were found for product that was chilled to 4.4 or 7.2°C in 18 or 21 h (Fig. 1). This same trend was observed for the PMP 7.0 and the Smith-Schaffner cooling models. However, 18- or 21-h chilling profiles do not reflect the typical or even worst-case cooling deviations (≤15-h chilling profiles) for cooked, uncured meat or poultry products in federally inspected meat and poultry establishments. Nevertheless, this general trend of overprediction by the cooling models for the longer chilling times is probably due to the fact that the cooling models are predicting a higher maximum cell population than actually occurred in product in various published studies. For example, in the development of the ComBase Perfringens Predictor cooling model, the maximum cell population was assumed to be 10^9 CFU/ml during the fitting procedure for the primary models *(15),* although the maximum *C. perfringens* cell populations were 5 to 6 log CFU/g in products in the original studies.

A high percentage of the fail-dangerous predictions (42.22%; 19 of 45 observations) produced with the ComBase Perfringens Predictor cooling model, based on the use of criteria 1 or 3 to assess model performance, had residuals of +0.51 to +1.0 log unit for single-rate exponential chilling. Thus, a high percentage of the fail-dangerous predictions were just outside the boundaries for an accurate prediction based on use of criteria 1 or 3 to assess model performance. However, when criterion 2 was used to assess model performance, the percentage of fail-dangerous predictions decreased from 25.57% (45 of 176 observations) to 14.77% (26 of 176 observations) because the fail-dangerous boundary for an accurate prediction went from +0.5 to +1.0 log unit. At the same time, the percentage of accurate predictions increased from 48.29% (85 of 176 observations) to 59.09% (104 of 176 observations) (Table 4). Consequently, the percentage of accurate predictions is a relative measure of model performance because the boundaries of an accurate prediction affect its value.

In further analysis of the fail-dangerous predictions, most of the observations for product containing 0.85% salt, based on the use of criteria 1 or 3 to assess model performance, produced fail-dangerous predictions (76.47%; 13 of 17 observations; Fig. 3), and most of these fail-dangerous predictions (85.62%; 11 of 13 observations) had residuals of +1.06 to +3.22 log units for product during single-rate exponential chilling (Fig. 3). Thus, under these conditions the model may provide a prediction that results in an inappropriate product disposition decision by federally inspected establishments for cooked, uncured meat and poultry products during cooling deviations. Use of a modified input of 1% salt for products with a salt concentration >0.5% and <0.95% provides more accurate predictions. During the development of the ComBase Perfringens Predictor cooling model, physiological state (α_0) values of 10^{-3} and 10^{-2} were used in the model for NaCl concentrations of <1% and ≥1%, respectively. The α_0 was an order of magnitude higher in meat media with ≥1.0% NaCl than in meat media with 0.5% NaCl. The higher α_0 value is probably due to the higher salt concentration in product, which may be protective of spores, leading to less thermal damage and a shorter lag time *(15).* Consequently, the cooling model uses the smaller α_0 value for product with 0.85% NaCl to predict the growth of *C. perfringens* during cooling. However, no actual tests were conducted for product with >0.5% and <1.0% salt to estimate the α_0 values *(15).* Therefore, product with >0.5% but <1.0% NaCl may actually have an estimated α_0 value of 10^{-2} instead 10^{-3}, especially given the strong tendency

for the model to greatly underestimate the growth of *C. perfringens* in product with 0.85% NaCl during cooling.

In conclusion, the ARS PMP 7.0 cooling model of *C. perfringens* in beef broth produced the highest percentage of fail-dangerous predictions of the six cooling models evaluated in this study. This PMP model underestimated the growth of *C. perfringens* in cooked, uncured meat and poultry products during chilling most of the time (57.39 to 65.96%). The three ARS PMIP cooling models appear to be fail-safe models because they provided the highest percentages of both fail-safe predictions (77.78 to 100.00%) and combined accurate and fail-safe predictions (99.10 to 100.00%) of the six cooling models. The PMIP cooling models will generally overpredict the growth of *C. perfringens* in an uncured meat or poultry product during chilling, but these models have the advantage of being meat type specific. The Smith-Schaffner cooling model produced high combined percentages of accurate and fail-safe predictions (77.66 to 93.18%) and low percentages of fail-dangerous predictions (6.82 to 22.34%). The ComBase Perfringens Predictor model provided the highest percentages of accurate predictions (38.83 to 59.09%) of the six cooling models evaluated. The ComBase Perfringens Predictor model also produced high combined percentages of accurate and fail-safe predictions (70.21 to 85.23%) and low percentages of fail-dangerous predictions (14.77 to 29.79%). The ComBase Perfringens Predictor cooling model has the added advantage of taking into account the pH and salt concentration of the meat and whether the product is cured or uncured.

The three PMIP, Smith-Schaffner, and ComBase Perfringens Predictor cooling models are useful and reliable models for estimating the growth of *C. perfringens* in cooked or heat-treated uncured meat and poultry products during cooling deviations. However, the ARS PMP 7.0 cooling model of *C. perfringens* in beef broth is a fail-dangerous model and thus is not a useful model for evaluating cooling deviations of cooked, uncured meat and poultry products, especially given that there are other validated and reliable cooling models currently available to the industry and the FSIS. More research should be conducted to further improve the accuracy of the available cooling models used to assess the growth of *C. perfringens* in meat and poultry product during cooling deviations to protect public health but prevent unnecessary destruction of safe food. The models also should incorporate the effect of meat processing ingredients such as nitrite, phosphates, sodium chloride, and organic acid salts, which are frequently used in the manufacture of processed, ready-to-eat meat and poultry products.

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