USDA
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One Team, One Purpose

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness

Food Safety and Inspection Service:

Office of Public Health Science

Evaluating Cooling Deviations in Cooked/Heat-Treated Meat and Poultry Products

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Food Safety and Inspection Service

Topics to be Covered

- Biological hazards associated with stabilization (cooling)
- FSIS requirements or policy concerning stabilization
- FSIS policy concerning *C. perfringens* and *C. botulinum* levels
- Available Cooling Models
- General Comments on Cooling Models
- Using Cooling Models in HACCP Plans/Food Safety Systems
- Cooling Models and Product Safety: One Scenario

Hazards associated with Stabilization (Cooling)

- Lethality treatment kills vegetative cells, but spores may survive
- During stabilization (cooling), spores may germinate and grow
- Spore-formers of concern in meat and poultry products include:
  - *Clostridium botulinum*
  - *Clostridium perfringens*
  - *Bacillus cereus*
- *C. perfringens* is the target, because the other pathogens grow more slowly

Foodborne Illnesses Associated with *C. perfringens*

- Estimated mean domestic:
  - Illnesses: 965,958
  - Hospitalizations: 438
  - Deaths: 26
- Illnesses are largely attributed to food served at institutions/events and not FSIS regulated products
- Toxins release as bacteria make spores in the gut - causes diarrhea, abdominal cramps, vomiting, and fever
- Illness onset: 8 to 18 hours
- **High** Infectious Dose: 10^6 CFU

Number of foodborne illnesses associated with *C. botulinum*

- Estimated mean domestic:
  - Illnesses: 55
  - Hospitalizations: 42
  - Deaths: 9
- Illnesses primarily attributed to improper canning of low acid canned foods
- Preformed neurotoxin mediated - leads to muscle paralysis and suffocation
- Illness onset: 12 to 36 hours
- Infectious dose: As little as 1 ng/kg of body

Control Measures for *C. perfringens* and *C. botulinum* Growth

- Limiting the amount of time products are held at temperatures conducive to growth is the primary means of control that establishments use to ensure spores do not germinate and grow to high levels
  - *C. perfringens* growth limit: 6°C and 52° C (43°F and 126°F)
  - *C. botulinum* growth limit: 10°C and 50 °C (50 °F and 122 °F)

Stabilization (Cooling) Performance Standard

- For cooked beef, roast beef, cooked corned beef, cooked meat patties (318.17(a)(2) and 318.23(c)(1)), partially cooked meat patties, char-marked meat patties (318.23(c)(1)), and fully cooked poultry products, partially cooked poultry breakfast strips, partially cooked small mass poultry products (318.150(b)), during cooling, the critical limit must be designed such that:
  - There can be no multiplication (growth) of toxigenic microorganisms such as *C. botulinum*, and
  - No more than a 1-$\log_{10}$ multiplication (growth) of *C. perfringens* within the finished product

Other Products

- For products that do not fall under the performance standards, the Agency guidance is that the critical limit should be designed so that:
  - There can be no multiplication (growth) of toxigenic microorganisms, such as *C. botulinum*, and
  - No more than a 1-$\log_{10}$ multiplication (growth) of *C. perfringens* within the finished product

FSIS Guidance: Appendix B

- Option 1
  - Internal temperature:
    - 130 – 80 °F ≤ 1.5 hours (optimum growth range)
    - 80 – 40 °F ≤ 5 hours
- Option 2
  - Chilling within 90 minutes of cooking
  - Internal temperature:
    - 120 – 55 °F ≤ 6 hours
    - 120 – 80 °F ≤ 1 hr (optimum growth range)
    - Less than 40 °F before shipping
- Option 3
  - FOR NITRITE (i.e., ≥ 100 ppm) AND SODIUM ERYTHORBATE OR ASCORBATE (i.e., ≥ 250 ppm) CONTAINING PRODUCTS ONLY
  - Internal temperature:
    - 130 – 80 °F ≤ 5 hrs (optimum growth range)
    - 80 – 45 °F ≤ 10 hrs

Corrective Actions - Cooling Deviations

- In the event of a deviation, the establishment must ensure (9 CFR 417.3(a)):
  - The cause of the deviation is identified and eliminated;
  - The CCP will be under control after the corrective action is taken;
  - Measures to prevent recurrence are established; and
  - No product that is injurious to health enters commerce.

What support can an establishments use to demonstrate product safety?

- It is up to the establishment to determine disposition and support the safety of their products

- Product **on-hold** may be salvaged (released as is, recooked, or condemned depending on the results) using:
  - Pathogen modeling programs
    - Past cooling deviations
    - Current cooling deviations
  - Other scientific supporting documentation
  - Sampling

Agency Policy Concerning *C. perfringens* and *C. botulinum* Levels

- Based on modeling:
  - If no more than 1 log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log), then the process meets the stabilization performance standard or Agency policy and the product can be released.

  - If there is greater than a 1 log growth of *C. perfringens* or other supportable stabilization target (e.g., 2-log growth) **and > 0.30 log increase of *C. botulinum***, then product should be destroyed

Agency Policy Concerning *C. perfringens* and *C. botulinum* Levels

- Based on modeling:
  - If there is more than a 1 log growth of *C. perfringens*, **no *C. botulinum* growth** (mean net growth ≤ 0.30 log), less than 3.0-log growth of *B. cereus*, and the establishment does not have support that spore levels in the product are low, then product may be either:
    - Recooked or
    - Microbiologically tested (N ≥ 10) or
    - Destroyed
  - Establishments may also be able to support **release** of product if other supporting documentation is provided

Evaluating Cooling Deviations Using Predictive Microbial Models

- Valuable tools for establishments evaluating the relative severity of problems caused by process deviations

- It is not possible or appropriate to rely solely upon a predictive microbial model to determine the safety of foods and processing systems unless the model has been validated for the product and process in question

Cooling Models Available

- Cooling Models currently available:
  - ARS PMP 7.0 and PMP 8.0 Cooling Models
  - ARS Predictive Microbiology Information Portal (PMIP)
    - Cooling of cooked uncured beef, pork, and chicken and cooked cured pork
  - UK IFR ComBase *Perfringens* Predictor Model
  - Smith-Schaffner Model version #3

Cooling Models

- Websites with free cooling models:
  - http://ars.usda.gov/Services/docs.htm?docid=6786
  - http://portal.arserrc.gov/
  - http://www.ifr.ac.uk/safety/growthpredictor/

PMP 7.0 *C. perfringens* in beef broth model

- Consistently under predicts *C. perfringens* growth (1 to 3 log CFU/ml)
- Not validated for cooked, uncured meat and poultry products
- Results may be used in combination with other scientific supporting documentation (for example, in-plant data showing *C. perfringens* in their finished products is low, etc.)

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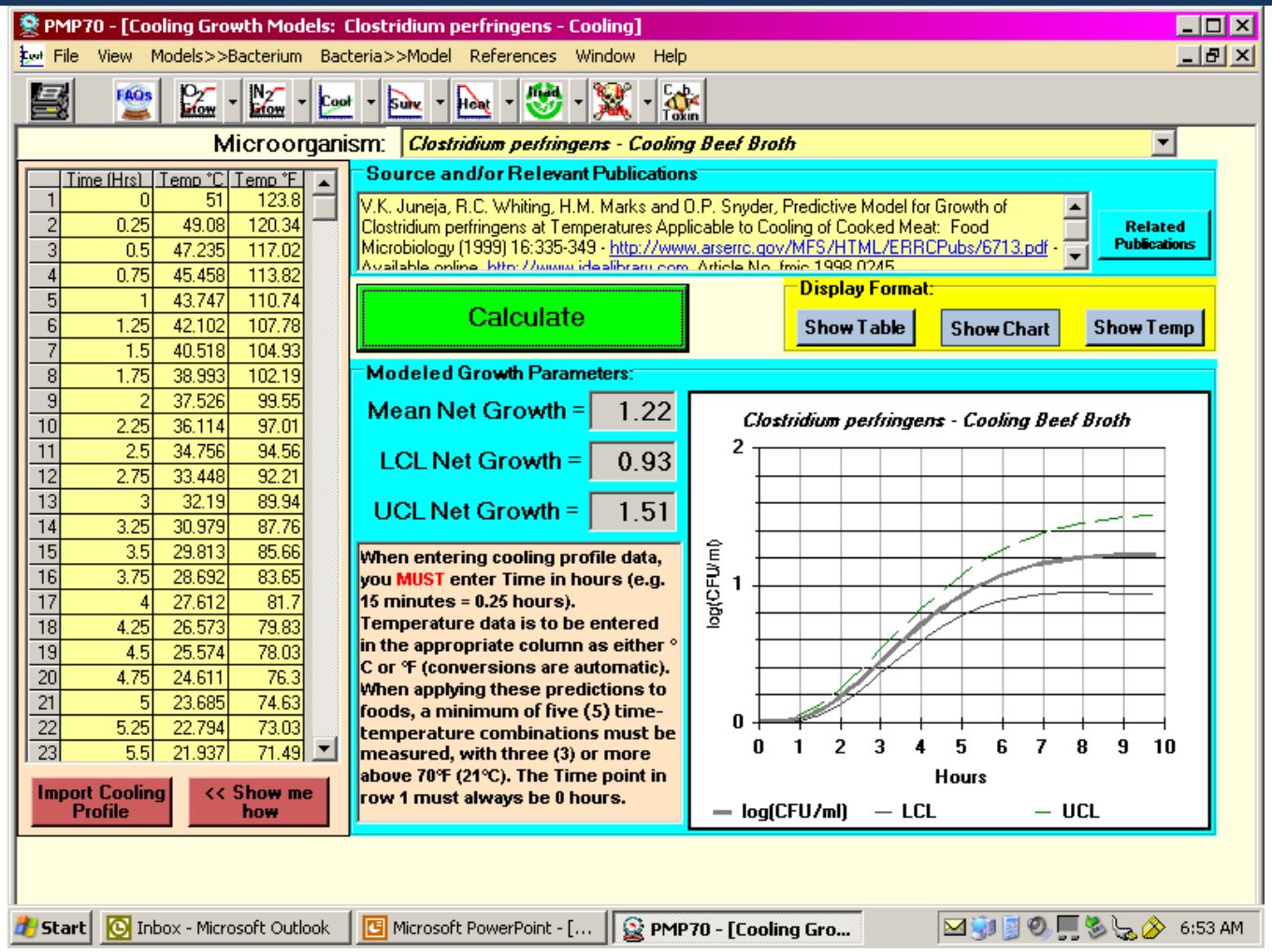

Proteolytic *Clostridium botulinum* in Beef Broth *Clostridium perfringens* in Beef Broth *Clostridium perfringens* – Cooling Cured Beef *Clostridium perfringens* – Cooling Cured Chicken

ARS PMP 7.0 & 8.0 Cooling Model's Requirements

- When entering cooling profile data, you must enter time in hours (e.g., 15 minutes = 0.25 hours)

- Temperature data is to be entered in the appropriate column as either °C or °F (conversions are automatic)

ARS PMP 7.0 & 8.0 Cooling Model's Requirements

- When applying these predictions to foods, a minimum of 5 time-temperature combinations must be measured, with 3 or more above 70° F (21° C)
  - At least 5 time-temperature combinations are needed to sufficiently define the shape of cooked product cooling profile.
  - The shape of cooked product cooling profile impacts on the amount of growth of *C. perfringens* and *C. botulinum*

The PMIP *C. perfringens* Models

- For the cooling of cooked, uncured beef, pork, and chicken
  - Analysis shows that these three cooling models significantly over predict the growth of *C. perfringens* that occurs in cooked, uncured meat and poultry products
  - These models are all considered validated for predicting the growth of *C. perfringens* in cooked or heat-treated uncured meat and poultry products

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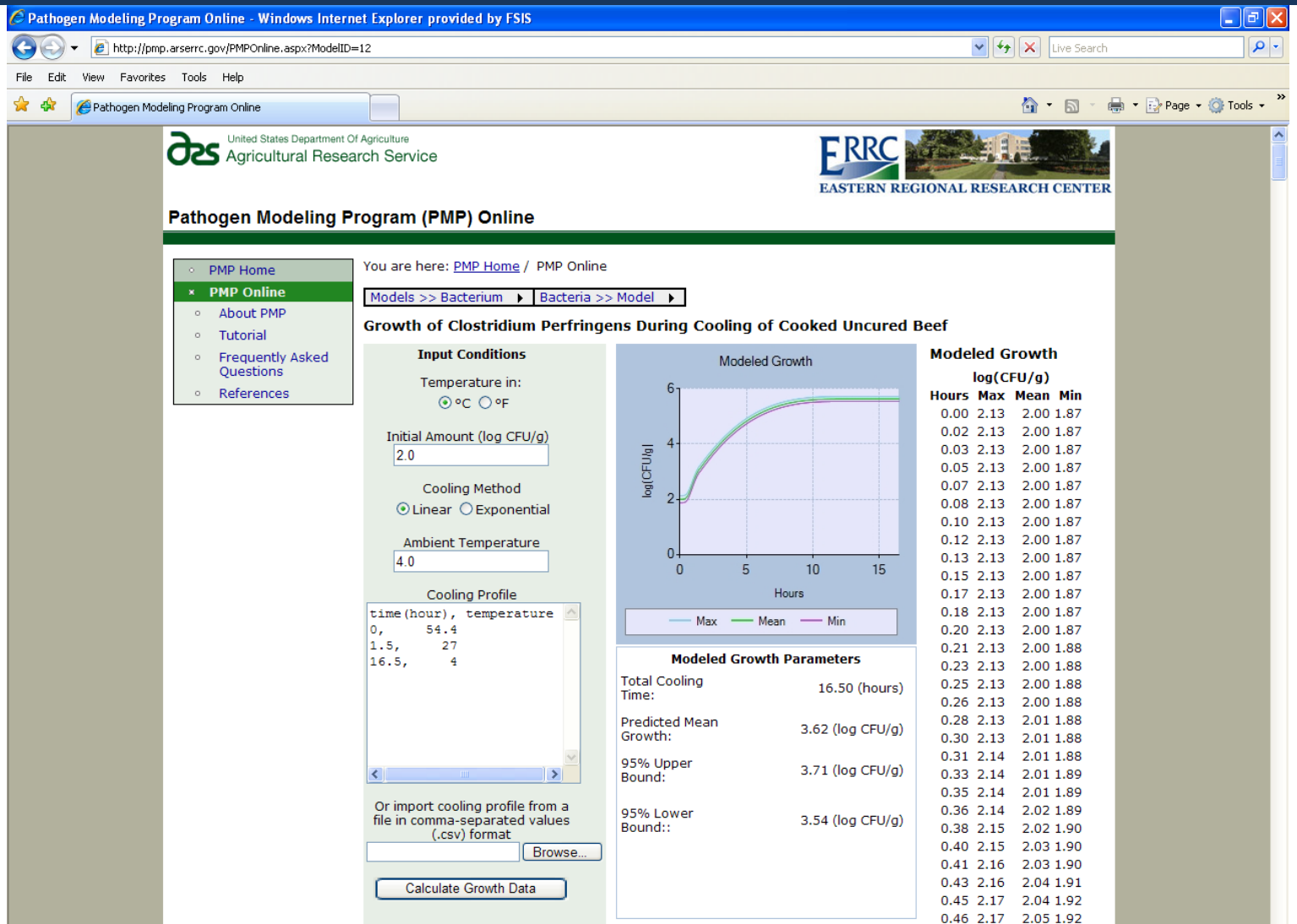
PMIP Cooling Model – Cooked, Uncured Beef



The other PMP & PMIP Cooling Models

- *C. perfringens* in cooked, cured beef, pork, and chicken – these models have not been validated and should not be used alone
- *C. botulinum* in beef broth
  - Only cooling model available for *C. botulinum*
  - The model has not been validated
  - The best tool available at this time
  - FSIS does not object to its use

The ComBase *Perfringens* Predictor Model

- Validated for cooked, cured and uncured meat and poultry products
- Provides a good estimation of the growth of *C. perfringens* in cooked, cured and uncured meat and poultry products

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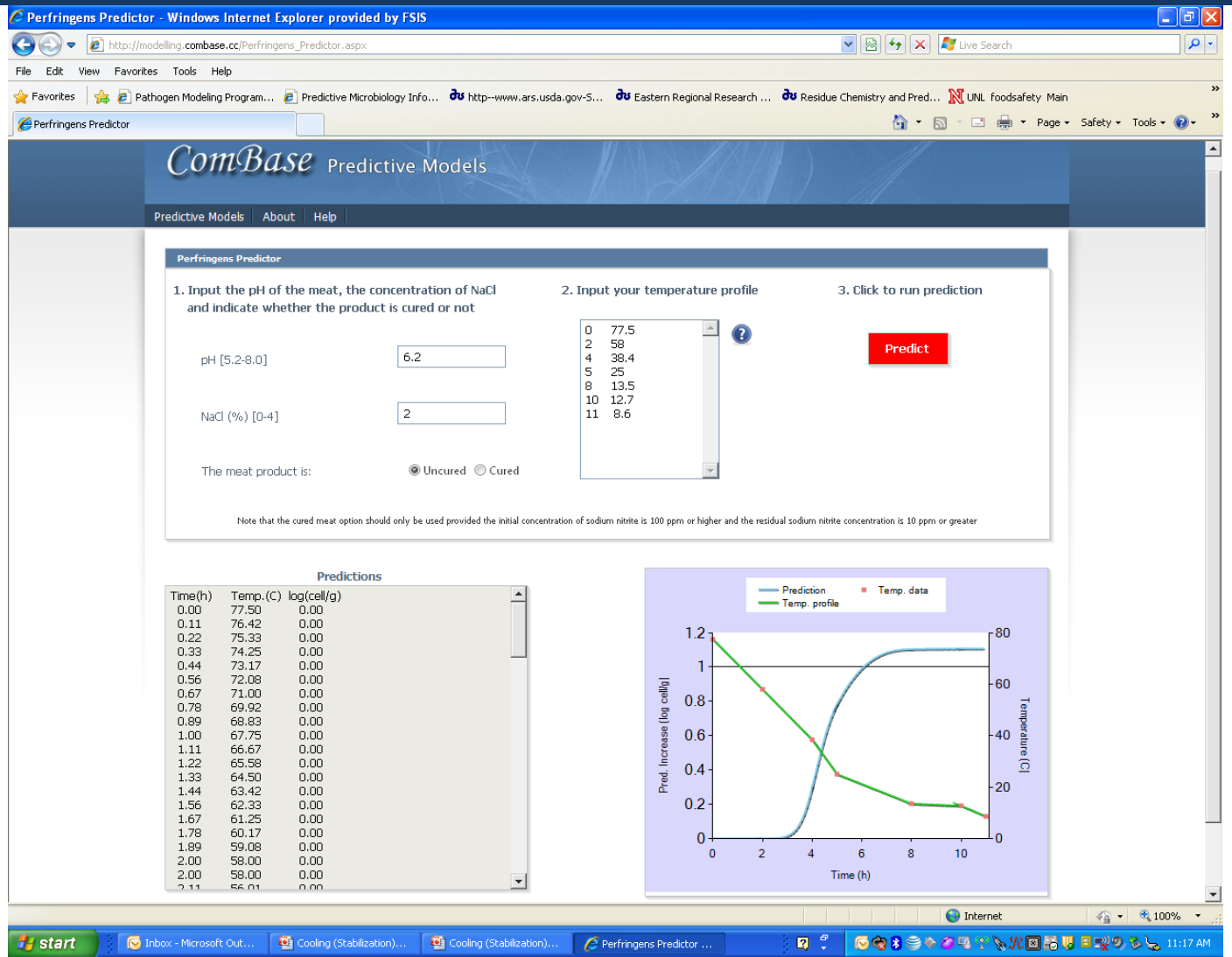
The ComBase *Perfringens* Predictor Model



ComBase *Perfringens* Predictor Model's Requirements

- The time unit is hours, and the temperature unit is degrees centigrade (°C)
- A minimum of 5 and a maximum of 100 points (time versus temperature) records in the cooling profile
- The temperature values must be between 0 and 95°C
- The records must be recorded in chronological order
- The first time-point must be zero
- The final temperature must be less than 15°C.

The Smith-Schaffner Version #3 Model

- Analysis shows that this cooling model provides a reliable estimation of the growth of *C. perfringens* in cooked, uncured meat and poultry products
- Relatively high percentage of accurate and fail-safe predictions (Mohr et al, 2015)
- Considered validated for predicting the growth of *C. perfringens* in cooked or heat-treated uncured meat and poultry products

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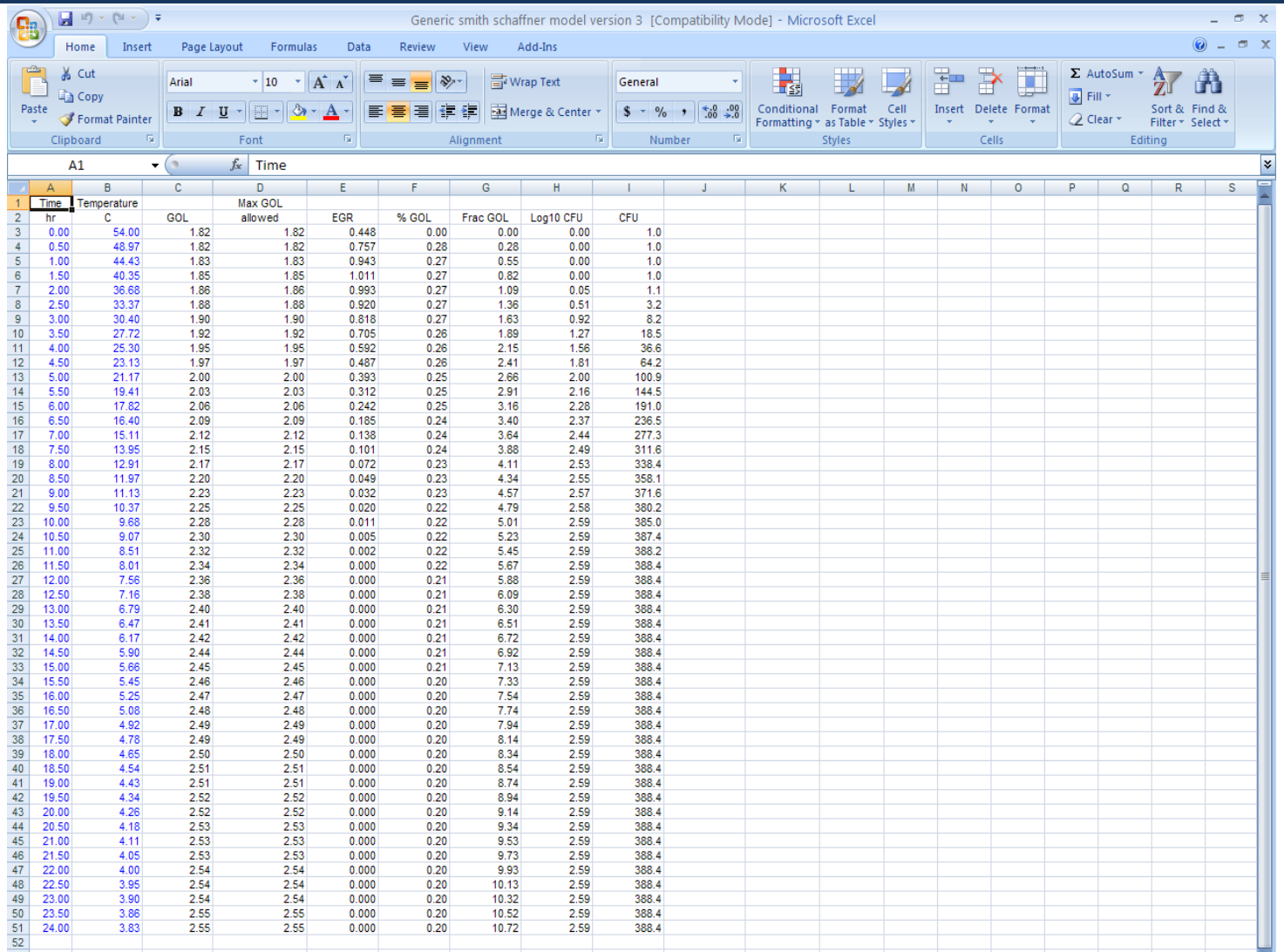
The Smith-Schaffner version #3 Model



Time	Temperature		Max GOL					
hr	C	GOL	allowed	EGR	% GOL	Frac GOL	Log10 CFU	CFU
0.00	54.00	1.82	1.82	0.448	0.00	0.00	0.00	1.0
0.50	48.97	1.82	1.82	0.757	0.28	0.28	0.00	1.0
1.00	44.43	1.83	1.83	0.943	0.27	0.55	0.00	1.0
1.50	40.35	1.85	1.85	1.011	0.27	0.82	0.00	1.0
2.00	36.68	1.86	1.86	0.993	0.27	1.09	0.05	1.1
2.50	33.37	1.88	1.88	0.920	0.27	1.36	0.51	3.2
3.00	30.40	1.90	1.90	0.818	0.27	1.63	0.92	8.2
3.50	27.72	1.92	1.92	0.705	0.26	1.89	1.27	18.5
4.00	25.30	1.95	1.95	0.592	0.26	2.15	1.56	36.6
4.50	23.13	1.97	1.97	0.487	0.26	2.41	1.81	64.2
5.00	21.17	2.00	2.00	0.393	0.25	2.66	2.00	100.9
5.50	19.41	2.03	2.03	0.312	0.25	2.91	2.16	144.5
6.00	17.82	2.06	2.06	0.242	0.25	3.16	2.28	191.0
6.50	16.40	2.09	2.09	0.185	0.24	3.40	2.37	236.5
7.00	15.11	2.12	2.12	0.138	0.24	3.64	2.44	277.3
7.50	13.95	2.15	2.15	0.101	0.24	3.88	2.49	311.6
8.00	12.91	2.17	2.17	0.072	0.23	4.11	2.53	338.4
8.50	11.97	2.20	2.20	0.049	0.23	4.34	2.55	358.1
9.00	11.13	2.23	2.23	0.032	0.23	4.57	2.57	371.6
9.50	10.37	2.25	2.25	0.020	0.22	4.79	2.58	380.2
10.00	9.68	2.28	2.28	0.011	0.22	5.01	2.59	385.0
10.50	9.07	2.30	2.30	0.005	0.22	5.23	2.59	387.4
11.00	8.51	2.32	2.32	0.002	0.22	5.45	2.59	388.2
11.50	8.01	2.34	2.34	0.000	0.22	5.67	2.59	388.4
12.00	7.56	2.36	2.36	0.000	0.21	5.88	2.59	388.4
12.50	7.16	2.38	2.38	0.000	0.21	6.09	2.59	388.4
13.00	6.79	2.40	2.40	0.000	0.21	6.30	2.59	388.4
13.50	6.47	2.41	2.41	0.000	0.21	6.51	2.59	388.4
14.00	6.17	2.42	2.42	0.000	0.21	6.72	2.59	388.4
14.50	5.90	2.44	2.44	0.000	0.21	6.92	2.59	388.4
15.00	5.66	2.45	2.45	0.000	0.21	7.13	2.59	388.4
15.50	5.45	2.46	2.46	0.000	0.20	7.33	2.59	388.4
16.00	5.25	2.47	2.47	0.000	0.20	7.54	2.59	388.4
16.50	5.08	2.48	2.48	0.000	0.20	7.74	2.59	388.4
17.00	4.92	2.49	2.49	0.000	0.20	7.94	2.59	388.4
17.50	4.78	2.49	2.49	0.000	0.20	8.14	2.59	388.4
18.00	4.65	2.50	2.50	0.000	0.20	8.34	2.59	388.4
18.50	4.54	2.51	2.51	0.000	0.20	8.54	2.59	388.4
19.00	4.43	2.51	2.51	0.000	0.20	8.74	2.59	388.4
19.50	4.34	2.52	2.52	0.000	0.20	8.94	2.59	388.4
20.00	4.26	2.52	2.52	0.000	0.20	9.14	2.59	388.4
20.50	4.18	2.53	2.53	0.000	0.20	9.34	2.59	388.4
21.00	4.11	2.53	2.53	0.000	0.20	9.53	2.59	388.4
21.50	4.05	2.53	2.53	0.000	0.20	9.73	2.59	388.4
22.00	4.00	2.54	2.54	0.000	0.20	9.93	2.59	388.4
22.50	3.95	2.54	2.54	0.000	0.20	10.13	2.59	388.4
23.00	3.90	2.54	2.54	0.000	0.20	10.32	2.59	388.4
23.50	3.86	2.55	2.55	0.000	0.20	10.52	2.59	388.4
24.00	3.83	2.55	2.55	0.000	0.20	10.72	2.59	388.4

A Validated Cooling Model

- A valuable tool to support:
  - the selection of time and temperature critical limits at the cooling CCP, and
  - corrective actions for a cooling process deviation

Cooling Models

- The cooling/growth model can be used for cooling deviations if:
  - The model is validated for the specific cooked RTE meat/poultry product; or
  - Other credible scientific documentation (e.g., finished product testing for *C. perfringens*) is provided to support modeling results if model is not validated

Cooling Deviation

- **Scenario:**
- The plant has a cooling CCP CL

  "product's maximum internal temperature should not remain between 130° F and 80° F for more than 1.5, nor between 80° F and 40° F for more than 5 hours"
- For this cooling deviation, the cooked, uncured perishable product took approximately 4 hours to reach an internal temperature of 80° F and then another 11 hours to reach an internal temperature of 40° F.

Cooling Deviation

- **Scenario (cont.):**
- The plant plans to use the validated ComBase *Perfringens* Predictor Model and the PMP 7.0 cooling model for *C. botulinum* to estimate the growth of *C. perfringens* and *C. botulinum* , respectively, that occurred in their affected product.
- The plant has documentation on the pH (6.0) and salt concentration (1.5%) for their affected product.

Cooling Deviation

- **Scenario (cont.):**
- **The company recorded the following time/temp data as the product cooled down:**

Time (Hr)	Temp (F)	Time (Hr)	Temp (F)	Time (Hr)	Temp (F)
0.0	129.92	6.0	65.48	12.0	44.24
1.0	110.12	7.0	60.26	13.0	42.44
2.0	97.34	8.0	55.76	14.0	40.82
3.0	87.26	9.0	52.16	15.0	39.56
4.0	78.80	10.0	49.10		
5.0	71.60	11.0	46.58		

Cooling Deviation

- Scenario - Results from ComBase and PMP 7.0 Cooling Models
  - *C. perfringens*
    - Mean Net Growth = 2.10 log increase
  - *C. botulinum*
    - Mean Net Growth = 0.19 log increase
    - LCL Net Growth = - 0.08 log increase
    - UCL Net Growth = 0.29 log increase

Cooling Deviation

- **Scenario - Product Disposition**
- Product can be recooked because:
  - The predicted growth for *Clostridium perfringens* is a 2.1 log increase which exceeds the Agency performance standard/policy of no more than 1.0 log increase for the pathogen; and
  - The predicted mean net growth for *Clostridium botulinum* is 0.19 log which is not more than a 0.3 mean log increase indicating there was no multiplication of the pathogen thus meeting the Agency's performance standard/policy
- Plant may elect to microbiologically test or destroy affected product instead of recooking the product

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THANK YOU!

DO YOU HAVE ANY QUESTIONS?