Appendix B

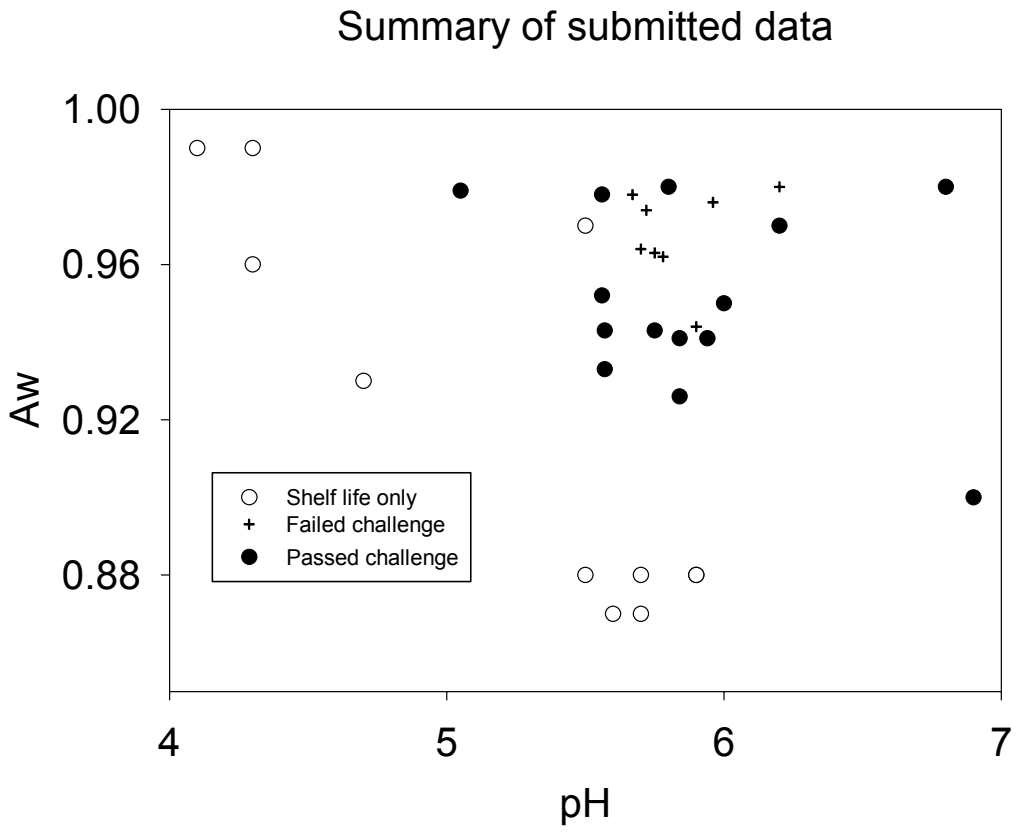
Data from Industry and Trade Organizations

The panel conducted a survey among industry and trade organizations on their approaches to temperature control for safety (see below). More than 60 individuals and organizations submitted information, and from this data, the results of 35 challenge studies were graphed as shown below. Seven submissions included no data; seventeen submissions did not include water activity measurements; three submissions included no pH or water activity measurements; and two submissions did not include appropriate time data. Eight of the respondents' observations were from failed challenge studies, and the remaining 27 observations were for products that passed challenge studies. It should be noted that the challenge test design and criteria were those proposed by the submitters, not the panel and that some data is based on studies using total plate counts and not challenge organisms.

The figure below summarizes the challenge study data submitted to the panel for consideration. Only the data for products where pH and a_w was available and challenge studies were performed are represented in the graph below. Products that failed or passed the microbial challenge study are indicated. The x and y coordinates show the corresponding pH and water activity values associated with the foods used in those challenge tests.

It is clear that factors other than pH and water activity influence the safe storage times of these foods at room temperature. For instance, some of the formulations include preservatives such as sorbic acid, sodium propionate, and phosphoric acid which may result in a product that does not need time/temperature control for safety, even though its pH and aw may suggest differently. For example, one product failed its challenge study after only 24 h; whereas another product, with more permissive pH and water activity values, was judged safe for 4320 h. It is also evident that many (14 out of 21) products with pH and water activity values greater than 4.6 and 0.85, respectively, can be safety held at ambient temperatures for lengthy periods of time.

Note that the challenge test design and criteria were those proposed by the submitters, not the panel and that some data is based on studies using total plate counts and not challenge organisms.


Summary of submitted data
1.00
0.96
0.92
0.88
Aw
4
5
6
7
pH
Shelf life only
Failed challenge
Passed challenge

Evaluation & Definition of Potentially Hazardous Foods

IFT Scientific & Technical Panel for FDA Task Order No. 4

Request for Information

The IFT Scientific & Technical Panel on Evaluation & Definition of Potentially Hazardous Foods seeks information to support a thorough scientific evaluation of the FDA Food Code 1999 definition of Potentially Hazardous Foods. Specific interest is in foods that might be considered potentially hazardous under the definition, but are demonstrated to be safe at room temperature through testing or other means.

We are interested in contributions in any format. You may answer the General Considerations below, provide more specific information and data using the attached form, and/or provide a copy of results or protocols that you have on file. All information will be blinded prior to delivering to the panel to maintain confidentiality unless requested otherwise.

We would appreciate your response within 30 days; however if more time is necessary due to extenuating circumstances, please let us know. We would be happy to accept data up to March 30th.

Send information to the soliciting organization (e.g., trade association, testing lab, etc.) or directly to IFT at the following address:

Frank Busta
Department of Science & Technology Projects
Institute of Food Technologists
1025 Connecticut Avenue NW, Suite 503
Washington DC 20036

For questions contact:
Maria Oria
Phone: 202-466- 5980 or mporia@ift.org

General Considerations (Attach additional information if needed)

1. How do you determine if a specific food product requires refrigeration for safety? List specific criteria (e.g., pH, water activity, time, history, etc.) and provide examples as appropriate.

2. Do you use computer modeling (e.g., USDA Pathogen Modeling Program, Food Micro Model, etc.) in determining the need for refrigeration for safety? If so, how? What pass/fail criteria do you use? Please attach an example if available.

3. Do you use challenge testing in determining the need for refrigeration for safety? If so, how? What pass/fail criteria to you use? Attach general or specific protocol(s) if available.

4. How do you determine appropriate pathogens to consider for challenge testing or modeling? Do you use surrogates for specific organisms?

5. If you use challenge testing or modeling, how do you determine which pathogens or surrogate organisms to use?

Specific Product Example

Example type: ☐ Challenge study ☐ Computer modeling ☐ Both

Product Description	
Ingredients (e.g., package ingredient declaration)	
Intrinsic factors:	
- pH	
- Water activity	
- Preservatives	
- Other	
Extrinsic factors:	
- Processing	
- Packaging	
- Distribution temperature	
- Other	
Intended use	
Shelf-life	
Data validating safety of room temperature use or storage	Attach data (table or chart) and describe the following, as appropriate. Method protocol may also be attached.
- Initial inoculum level	
- Inoculation method & preparation	
- Organism(s)	
- Incubation temperature(s)	
- Enumeration methods	
- Pass/fail decision criteria	