

Appendix C

Scientific Data Used to Develop Framework

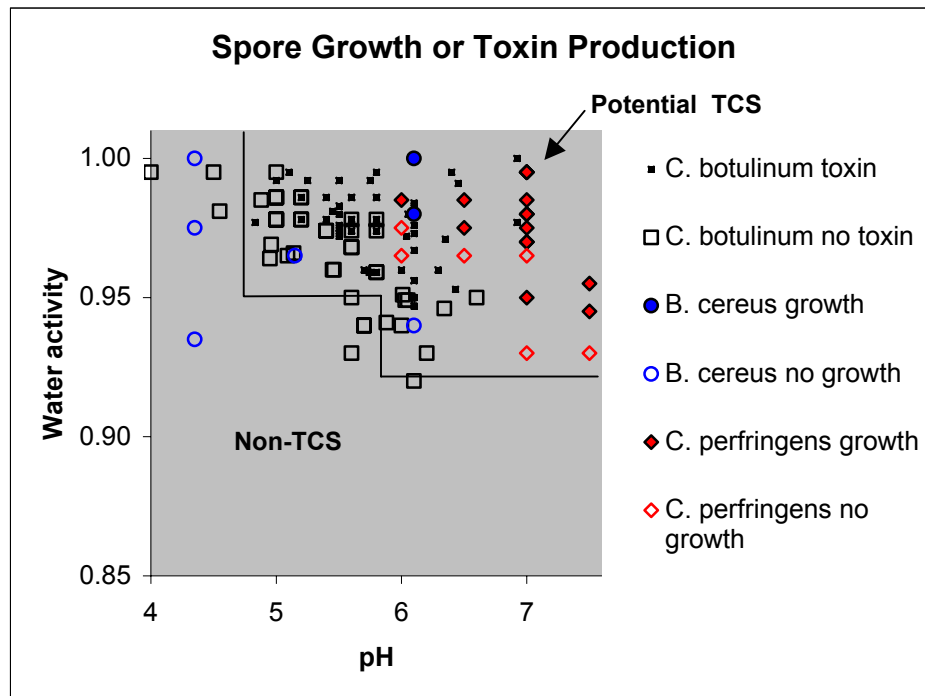
1. Determination of pH and water activity limits for TCS foods

To determine pH and water activity limits for TCS foods, as they are presented in the framework (see Chapter 8) the panel used data from the literature and from the results of the survey (see appendix B). Data for products with identified preservative systems were not included to assure that conservative data were used to determine limits. Professional judgement of the panel was used to omit unrealistic data. For example, studies using artificially high inoculum levels in laboratory media with no competitive microflora, using mild humectants (for example, glycerol) or acidulants (for example, HCl) were not used if results varied significantly with substantial data in food systems.

While numerous studies have been done on growth of foodborne pathogens, many studies do not report the pH and water activity of the growth medium. As a result, only limited data are available to study the interaction of pH and a_w on the growth of foodborne pathogens. **The panel strongly encourages researchers to include pH and water activity data in scientific publications to assist the incorporation of data into analyses such as the one being performed here.**

1.1. Spores

Data on water activity and pH interaction effects on growth or toxin production of foodborne pathogenic sporeformers are illustrated below. The lines indicate the parameter limits that the panel considered to develop the framework.



For foods that are treated to inactivate vegetative foodborne pathogens, the panel concluded that the following parameters effectively control the growth of sporeforming foodborne pathogens:

- $pH \leq 4.6$, or
- $a_w \leq 0.92$, or
- $pH \leq 5.6$ and $a_w \leq 0.95$

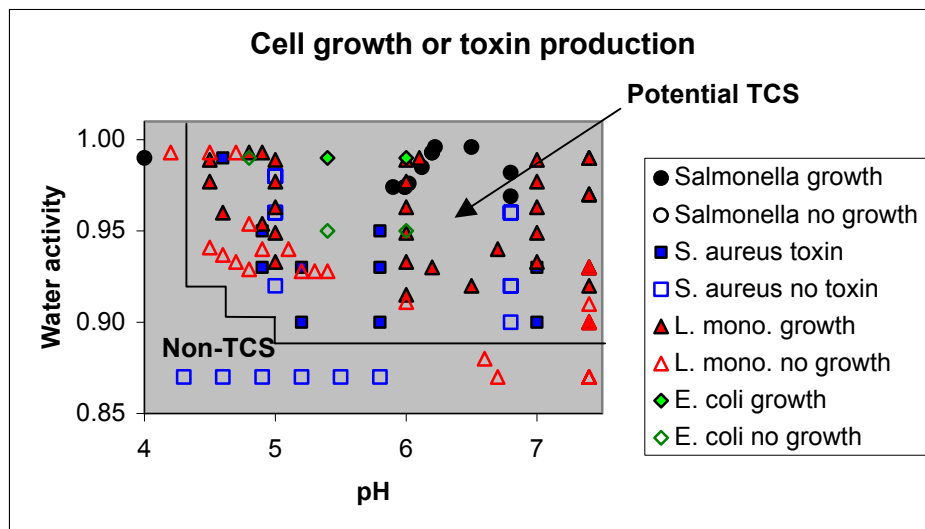
The panel believes that these parameters are conservative since numerous studies demonstrated lack of growth and/or toxin production above these levels. Products that fall in the non-TCS area should be considered in a "safe-harbor" that does not require time/temperature control. Products that fall in the potential TCS region may be stable depending on shelf life expectations, presence of preservatives, temperature, and other factors affecting growth (see Chapter 3). Challenge studies may be performed for foods in the high pH and a_w ranges and/or for those foods with extended shelf life expectations.

An equation to fit the data could also be used to identify pH and a_w combinations that would inhibit sporeforming pathogen growth; however, panel members believe that this would be more difficult to implement and/or communicate to non-technical users of the information.

1.2. Vegetative cells

Literature data on interaction of pH and water activity on control of vegetative pathogens is more limited than that for spore-formers. Published studies and modeling programs generally use broth media or foods with high a_w that are not near the minimum for growth. Studies conducted for short shelf life products are relevant to foodservice operators who are primarily interested in the potential for pathogen growth in hours or a few days; however, these studies may not be applicable to extended shelf life products.

The following data were considered in developing the framework for vegetative pathogen control, in addition to the minimum pH and a_w values for vegetative pathogen growth (see Chapter 3). However, the panel believes that intended shelf life must be considered in addition to pH and a_w in determining the need for time/temperature control. The lines indicate the parameter limits that the panel considered to develop the framework.



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