

Technical Brief

Surrogates

By Peter Slade, Ph.D., NCFST/IIT

Use of the word surrogate(s) has not been customarily entered as a key word in the literature relating to bacterial agents used as proxies in food production environments. Anyone that has worked in food microbiology for any length of time has, however, invariably worked with “surrogates.” It’s just that the term hasn’t been routinely coined until recently.

Surrogate microorganisms are those organisms, usually bacteria but sometimes yeasts or molds, that are used in challenge or process validation studies in situations where where a target pathogen would not be used. Obviously, in a pilot plant, and sometimes even at the bench, it is undesirable to inoculate food, equipment, or the production environment with high levels of pathogens when trying to assess the efficacy of various new or experimental intervention strategies. The survival of just a few pathogens can compromise the safety of workers or the integrity of the processing environment. So surrogates are used instead. Historically, one of the best examples is the putrefactive anaerobe, *Clostridium sporogenes* PA 3679, a known spoilage agent, used as a proxy in studies investigating the heat resistance of the pathogen *Clostridium botulinum*. The literature is replete with other examples, but they just don’t line up under the banner headline of “surrogates on parade”!

In a guidance document for the juice industry, FDA defined a surrogate microorganism as “any non-pathogenic microorganism that has acid-tolerance, heat resistance, or other relevant characteristics similar to pertinent microorganisms (i.e., pathogens of concern). Food-grade lactic acid bacteria that have GRAS (generally recognized as safe) status are a possible option if their characteristics are similar to the pertinent microorganisms” (<http://vm.cfsan.fda.gov/~dms/juicguid.html>).

Later, in its technical white paper on “Kinetics of Microbial Inactivation for Alternative Food Processing Technologies”, FDA defined a surrogate microbe, as “a non-pathogenic species and strain responding to a particular treatment in a manner equivalent to a pathogenic species and strain. The surrogate allows biological verification of the treatment without introducing pathogens into a food processing area” (<http://vm.cfsan.fda.gov/~comm/ift-glos.html>).

Guidance on the use of microbial surrogates for the validation of treatment effectiveness was recently issued in an Institute of Food Technologists’ (IFT) report (1). In selecting surrogates, this report suggested that the following characteristics are desirable:

- Nonpathogenic
- Inactivation characteristics and kinetics that can be used to predict those of the target organism
- Behavior similar to target microorganisms when exposed to processing parameters (for example, pH stability, temperature sensitivity, and oxygen tolerance)
- Stable and consistent growth characteristics
- Easily prepared to yield high-density populations
- Once prepared, population is constant until utilized
- Easily enumerated using rapid, sensitive, inexpensive detection systems
- Easily differentiated from other microflora

NCFST has conducted surrogate research the past two years. The large range of candidate surrogate strains originally under consideration has been narrowed to include a handful of non-sporeforming bacteria for use in validation and challenge studies. These strains, among them generic *Escherichia coli*, *Listeria innocua* and *Enterococcus faecium* strains, have been

assessed in the first comprehensive study of its kind to match certain resistance traits of target pathogens (*E. coli* O157:H7, *Salmonella* spp., and *Listeria monocytogenes*). This battery of strains has been evaluated with respect to thermal inactivation, sensitivity to reduced water activity (a_w) and low pH, and desiccation resistance following attachment to surfaces.

There is still much to do. Combination treatments and resistance to sanitizers and commonly used antimicrobials and preservatives need to be considered. However, the foundation has been laid, and NCFST is eager to work with industry scientists to broaden the knowledge base in other applications concerning process validation. Results of initial studies will soon be published, and not long thereafter, an electronic key word search for bacterial surrogates that may be used in food challenge investigations studies should lead to a comprehensive array of data and information. Much of this information is the result of the collaborative research supported by industry members at NCFST.

Reference:

(1)Institute of Food Technologists (IFT). 2002. IFT Expert Report on Emerging Microbiological Food Safety Issues – Implications for Control in the 21st Century. IFT, Washington, DC.

For further information on surrogate studies at NCFST, contact either of the project principal investigators, Sue Keller, Ph.D., NCFST/FDA, at 708-728-4140 susanne.keller@cfan.fda.gov, or Peter J. Slade, NCFST/IIT, at 708-563-8172 or slade@iit.edu.