Member Update on Microbial Intervention Validation for Spices
February 2019

1. Background

The Preventive Controls for Human Food (PCHF) rule, implemented under the Food Safety Modernization Act (FSMA), requires all food companies to develop a food safety plan in which they identify hazards (e.g., *Salmonella*) and implement preventive controls to mitigate these hazards. FSMA requires validation of process preventive controls for all identified hazards requiring preventive controls, meaning spice companies are required to validate pathogen reduction processes used to control *Salmonella*.

The spice industry had a number of questions related to how to meet this requirement, including how to select an appropriate non-pathogenic surrogate for *Salmonella* to use in validation studies for spices, as well as if and how spices could be grouped for the purposes of validation studies. ASTA conducted research to evaluate the antimicrobial nature of certain spices on potential surrogates and to develop science-based groupings.

2. Legal Requirements

The PCHF rule requires that process preventive controls be validated either before the food safety plan is implemented, within the first 90 calendar days of production, or within a "reasonable timeframe" for which a Preventive Controls Qualified Individual (PCQI) provides written justification. Validation is defined as "obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards." (21 CFR § 117.160). The purpose of validation is to prove that your process preventive control is effective at controlling the identified hazard(s).

3. Responsibility for Designing and Performing Validations

Validation must be performed or overseen by a PCQI. Each food facility has an independent responsibility to ensure that their process preventive controls are validated, although they can rely on work performed by third-parties to assist in doing so. Validation can be an involved process. Each microbial intervention process is unique, and there are many variations within a process type, which is why each process must be independently validated. The specifics of how to perform validation are beyond the scope of this document. However, the American Spice Trade Association has put together a number of resources to assist the spice industry with validation.

ASTA's work on identifying an appropriate surrogate organism and grouping spices can be leveraged by ASTA members as part of developing their own validation. It is important to recognize, however, that this is only one part of the work required for validation. In other words, ASTA has not validated any of its members' preventive controls through these projects, but has provided useful tools to assist its members in further validation efforts.

4. Summary of Research Findings

Surrogate Organism

Since it is undesirable to intentionally introduce pathogenic bacteria into a production environment, a non-pathogenic bacterium that responds in a similar manner to a pathogen (e.g. *Salmonella*) can be used as a surrogate to estimate the impact of a process. Through published research, partly funded by ASTA, the bacterium *Enterococcus faecium* (*E. faecium*) has been shown to be useful in modeling the impact of various microbial interventions on *Salmonella* in spices. Furthermore, ASTA commissioned laboratory studies to determine the ability of several of spices known to have high inhibitory properties to inhibit both *Salmonella* and *E. faecium*. The results of those studies showed that *E. faecium* was inhibited to the same degree or inhibited less than *Salmonella* by these spices. This further supports that *E. faecium* is a viable surrogate for *Salmonella* in spices. The report is available from ASTA.

Spice Groupings

Spice processors commonly process many types of spices, and it would be a significant burden to validate each process for each individual type of spice. ASTA has discussed this challenge with the U.S. FDA, and the agency agreed in principle that spices with common characteristics can be grouped for purposes of validation. When appropriately supported groupings are used, validation for one spice in a group is considered to also provide validation for all of the other spices in a group.

ASTA developed proposed groupings of spices, based on their ability to inhibit microorganisms. This work was based on a review of the published literature addressing the inhibitory properties of spices. A table of the proposed spice groupings, based on their ability to inhibit bacteria, is provided below. The full report is available from ASTA.

Proposed spice groupings for validation studies

Degree of Inhibition	List of Spices
Most Inhibitory (>75%)	Garlic, onion, allspice oregano, thyme, cinnamon, tarragon, cumin, cloves, lemon grass, bay leaf, capsicums, rosemary, marjoram, mustard, *mace, *juniper, *chamomile (English, Roman, German, Hungarian), *lavender, *paprika, *vanilla balm (lemon), *chervil, *chives, *cilantro, *peppermint, *savory, *spearmint, *galangal, *horseradish, *fenugreek seed, *poppy seed, *sesame
Intermediate Inhibition (50% to 75%)	Caraway, mint, sage, fennel, coriander, dill, nutmeg, basil, parsley
Less Inhibition (<50%)	Cardamon, pepper (black/white), ginger, anise seed, celery seed, lemon/lime

**In the absence of other data, the spices which are included in the ASTA list but not in the scientific literature are placed in the "most inhibitory" category.*

In summary, it is reasonable to group spices by their ability to inhibit bacteria because all of the spices within each of these grouping has approximately the same ability to inhibit bacteria

(either *Salmonella* or *E. faecium*), and it has been shown that the surrogate is not inhibited to a greater degree by the spice than *Salmonella*.

5. How to Proceed

ASTA is providing this information to the spice industry to assist in the development of validation processes. Each company must have their own validation for their microbial reduction processes. The work ASTA has performed may be helpful for companies as they develop such validation. ASTA advises spice companies to keep this document and the corresponding technical report on file, along with their own internal validation data. This will help ensure all necessary documentation is available to both regulators and third-party auditors, as needed.