ASTA Regulatory Workshop 2019

Case Study: Dehydrated Garlic Validation on Salmonella Control

Scott Klinger
Director of Quality Assurance and Technical Services

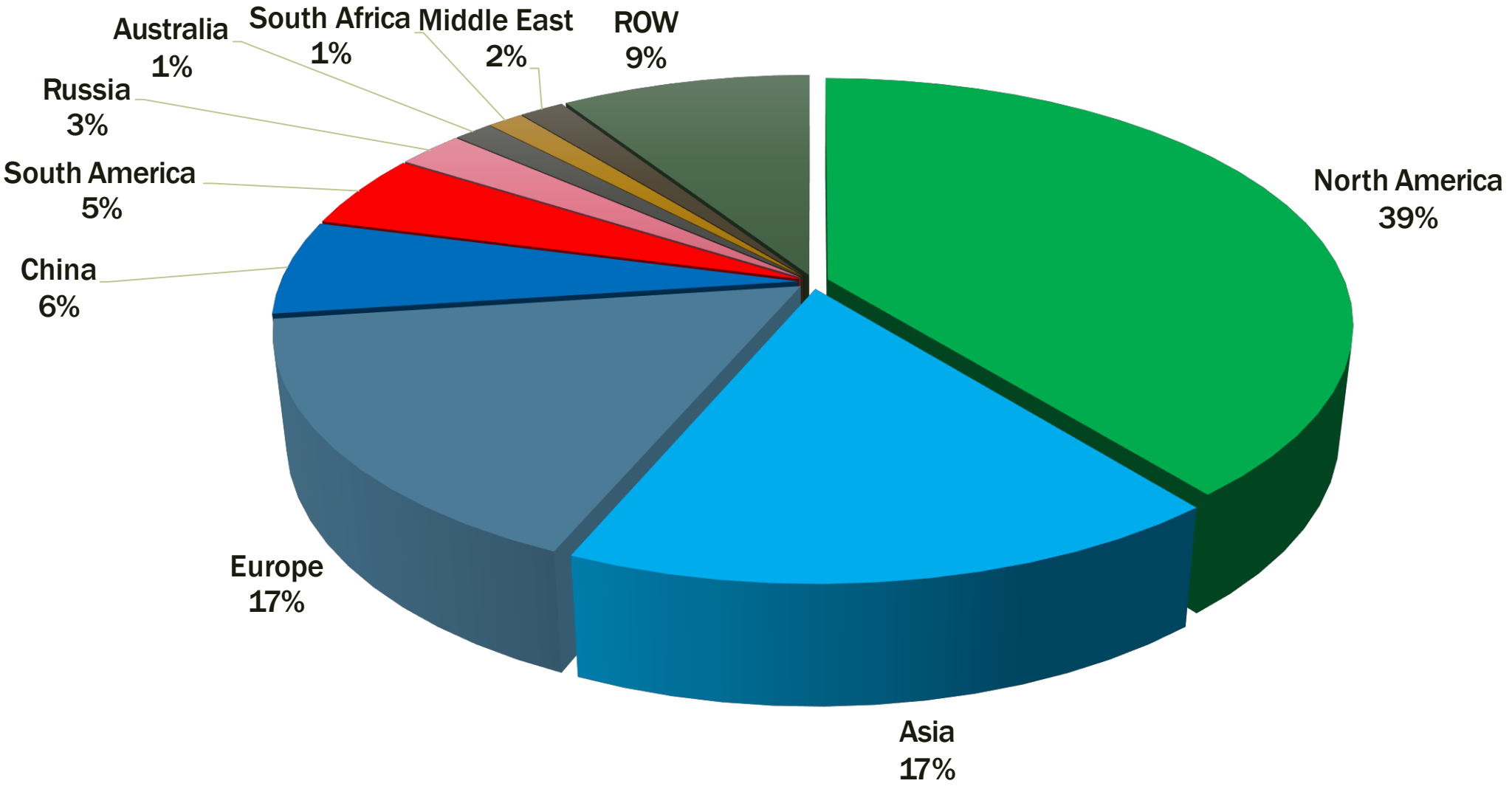
BCFoods

Agenda

- Global Usage
- Main Growing Areas
- Garlic Season
- Background of Micro Profile of Dehydrated Garlic
- Validation Steps for Study on Garlic
- Results of Validation on Dehydrated Garlic
- References

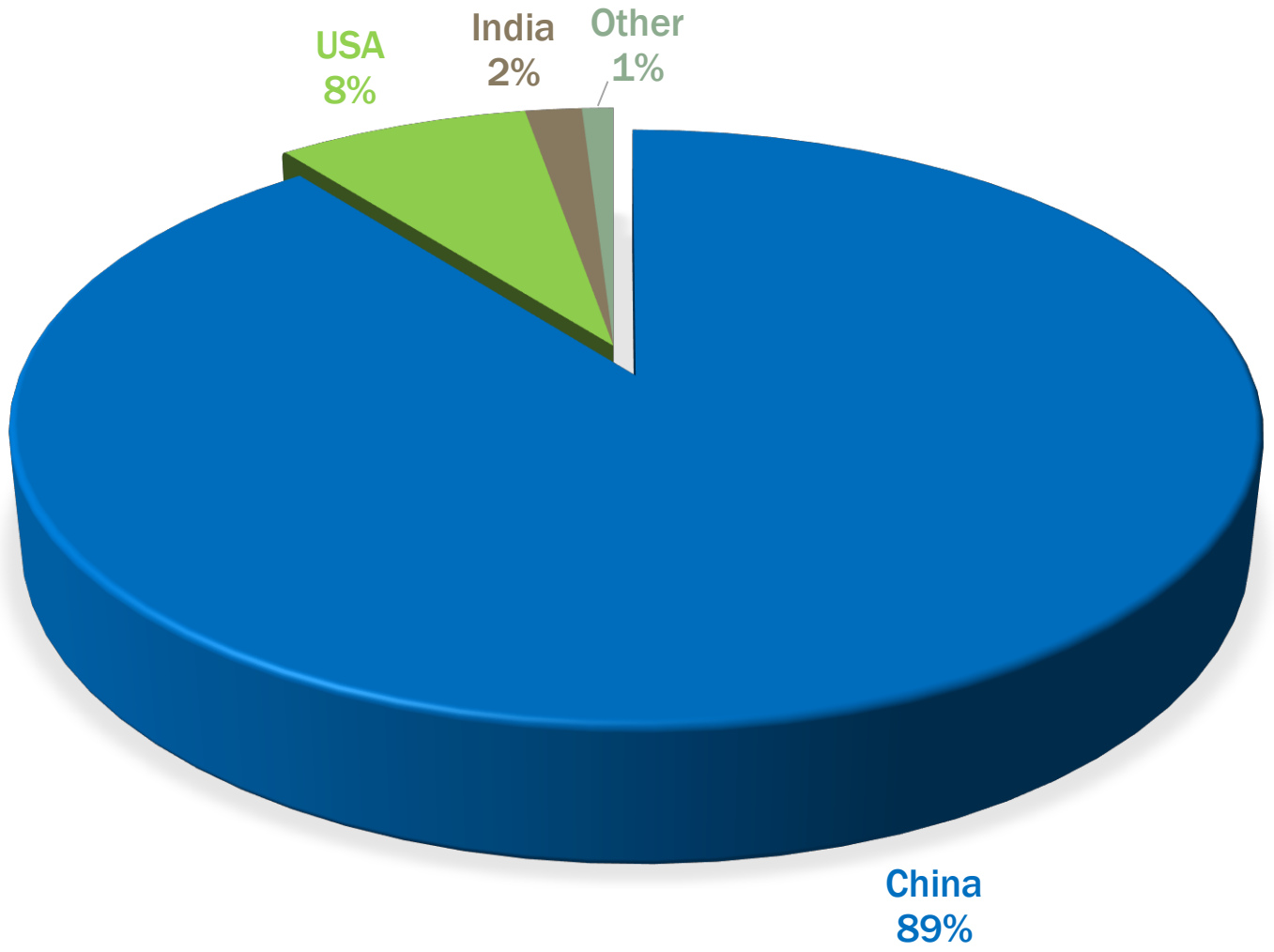
Global Usage

Global Dehydrated Garlic Demand: Based est. 250,000 MT volume



Main Growing Areas

Dehydrated Garlic Production Countries: Based est. 250,000 MT volume



Garlic Season

Chinese Garlic Season

9/30/2018

10/20/2018

2/24/2019

4/15/2019

5/10/2019

Garlic flower stalk

Late May: harvesting

Background of Micro Profile of Dehydrated Garlic

Typical Dehydrated Garlic Microbial background for “Standard Grade” specification

- Data collected from 2017 and 2018 crop

Bacteria:	Average Result:	Specification Limit:
TPC:	127,000 cfu/g	500,000
Coliform:	<3 mpn/g	500
Water Activity:	0.2901	0.6
Moisture:	4.70%	6.5%

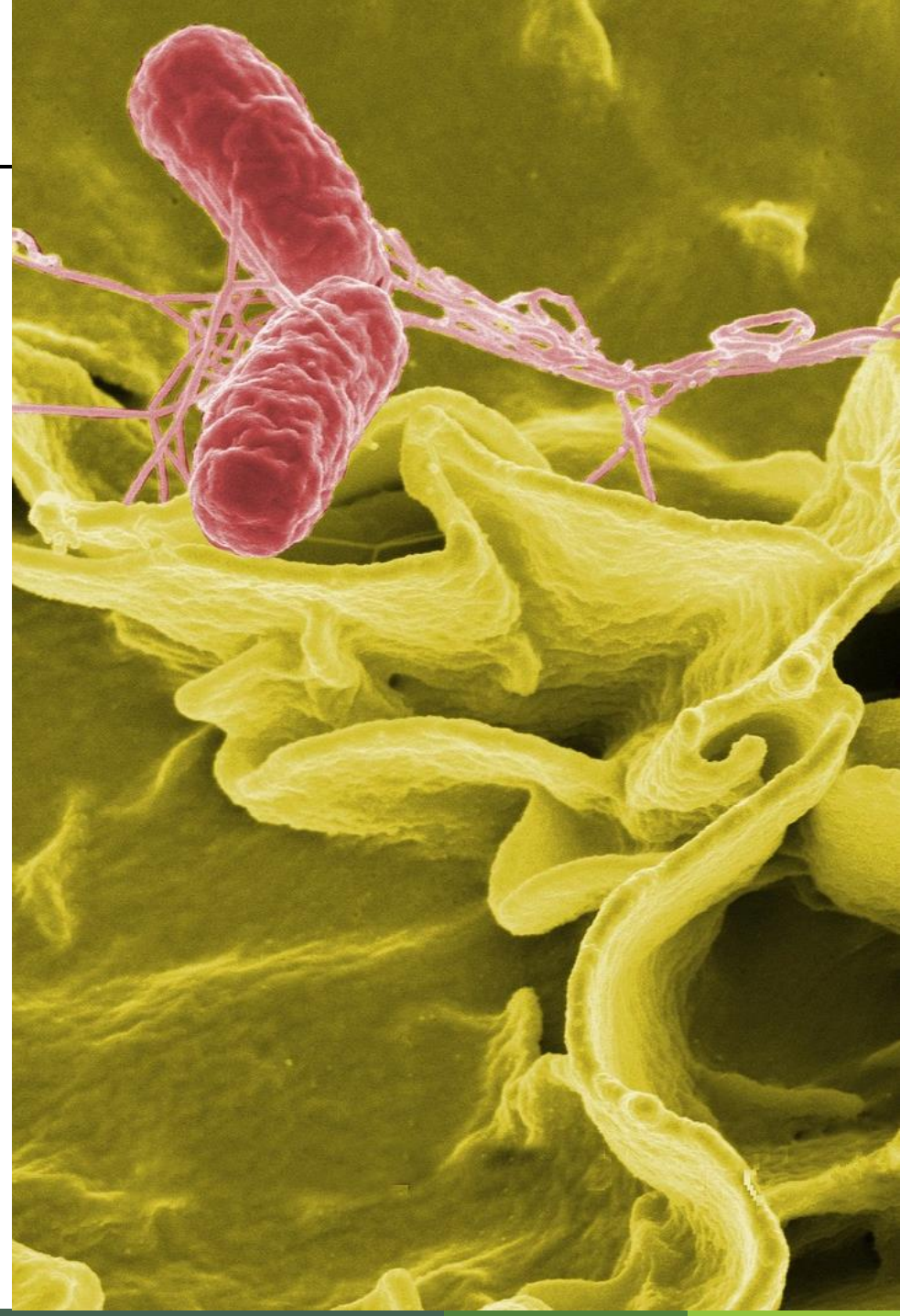
We tested over 1500 lots for pathogen with zero findings.

- Tests included Salmonella spp. Listeria Monocytogenes, Generic E. coli.
- Due to the growing process and natural characteristics of garlic, the chances for pathogen are extremely low, vs. a more susceptible product like a leafy product or fresh product.

Validation Steps for Study on Garlic:

1. Define Validation Criteria:
    a. Use Guidelines that are published for industry
    b. Type of Study:
        a. Growth inhibition
        b. Inactivation
        c. Combination of both

2. Approach Model:
    a. Create a team and include a microbiologist
    b. ID target organism to control
    c. Research scientific data used for the design of the study
    d. Understand the capabilities of your process



Validation Steps for Study on Garlic:

Before the study:

- What are the background bacteria on the product to be used?
- Based on the Approach results, will the control or process achieve the required limit?
- Identify the Surrogate to use and confirm it's appropriate for your product
  - Scientific and challenge study to identify a surrogate
  - Surrogate preparation for the study and control during transportation
- Understand the water activity of the product your challenging
- It has also been suggested that product variability be considered in the preparation of the study

Validation Steps for Study on Garlic:

The Study:

- Inoculation procedure
- The surrogate must be evenly distributed over the product samples
- Samples of the inoculated material must be pulled prior to introduction to the process as a control
- Product used in the study should demonstrate worse case characteristics
- Process control steps must be under normal parameters to mimic the actual production conditions
- It is also important to identify worst-case areas such as cold spots or transfer sections
- Consider the quantity of samples to inoculate and test – in this case, the more the merrier.
  Minimum of 10 should be considered

Validation Steps for Study on Garlic:

Testing the treated product:

Don’t only test the surrogate

Conclusion and reporting:

Document every step that is done, even if you think it’s not important.

Your report shall include the following:

- Critical processing steps or conditions that were used to achieve the result
- Record of all data collected by your laboratory and the raw data on the individual samples tested, methods used, any assumptions, etc.
- Science-based justification for your approach to the study
- All data collected regarding the surrogate used
- Have available the actual production data from the study

Results of Validation on Dehydrated Garlic

- Surrogate used Enterococcus faecalis
- Background results were <10 average
- Results of a study (examples)

3.1 10^7 CFU/ml *Enterococcus faecalis* culture suspension inoculation verification micro test data:

Sample name	Sample traceable number	CFU/g	Log CFU/g
Standard *Enterococcus faecalis* sample	**128-2019-00004898**	**3200000**	**6.51**
	128-2019-00004899	**3400000**	**6.53**
	Average Log CFU/g		**6.52**

3.4 10^7 CFU/ml *Enterococcus faecalis* inoculated AD garlic Flakes after the heat treatment test data

Sample name	Sample traceable number	CFU/g	Log CFU/g	
Samples after the heat treatment Trial	**128-2019-00004814**	**<10**	**1**	Calculated as 1
	128-2019-00004815	**<10**	**1**	Calculated as 1
	128-2019-00004816	**<10**	**1**	Calculated as 1
	128-2019-00004817	**<10**	**1**	Calculated as 1
	128-2019-00004818	**<10**	**1**	Calculated as 1
	Average Log CFU/g		**1**	

4 . AD garlic Flakes processing line microbiological validation summary result:

Its heating process for the AD garlic Flakes product can achieve 5.0 log reduction target in this Trial .

4.1 For 10^7 CFU/ml *Enterococcus faecalis* inoculated AD garlic Flakes, after the Trial , it achieved **5.52** log reduction

4.2 For 10^8 CFU/ml *Enterococcus faecalis* inoculated AD garlic Flakes, after the Trial , it achieved **6.38** log reduction

4.3 For 10^9 CFU/ml *Enterococcus faecalis* inoculated AD garlic Flakes, after the Trial , it achieved **7.24** log reduction

Thank You

Scott Klinger
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