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Dear Ms. Scott,

On September 21, ASTA representatives met with FDA officials to discuss questions from the FDA related to business practices in the spice industry to control pathogens.

During this meeting, FDA asked ASTA a number of questions about treatment facilities that control pathogens, including which entities generate and own validation data, and how spices move between entities. ASTA has consolidated the following responses to these questions from a number of ASTA members.

FDA QUESTION: What various business relationships exist between spice companies and facilities that are applying a pathogen control treatment?

Answer: There are many different business relationships that exist between companies who import and process spices and contract facilities that apply microbial reduction treatments to control pathogens.

Some of the most common scenarios are:

- The product may be treated at origin before entering the U.S. by either a processor or contract treatment facility applying a pathogen control
- The product may be treated by a pathogen control treatment facility after it is imported but before physically going to the spice company
- A spice company may acquire untreated spices and then send them to a contract facility for pathogen treatment
- A spice company may treat the spices in their own facility
- The entire process may be contracted including import, pathogen treatment, further processing, etc.

FDA QUESTION: What types of pathogen treatments do contract facilities apply to spices?

Answer: Contract facilities can perform a variety of treatments including steam, ethylene oxide (EtO), propylene oxide (PPO) or irradiation.

FDA QUESTION: Which entity owns the spice product throughout the process?

Answer: Once in the U.S., the product is typically owned by the spice company throughout the entire process. Contract facilities never own the product, even in scenarios when the product is shipped directly to the treatment facility before the spice company takes physical possession of it. As the contract facility does not own the product, they are rarely the last stop in the full process. The treated product may be shipped to the spice company or it may go to the next contracted party (e.g. seasoning blender, third party packer, customer).

FDA Question: How are spices packaged during pathogen treatment?

Answer: Spices are packaged in a variety of ways depending on the spice and the type of treatment. During batch type steam treatment, or ETO/PPO treatment, the spice can be packed in bulk boxes, poly or burlap bags or other packaging materials that are concurrently treated. If a continuous steam process is used, spices will be free flowing through the equipment with no packaging. Spices may be packaged in any form of packaging during irradiation treatment.

FDA Question: Who develops the validation process?

Answer: The facility applying the pathogen control treatment is responsible for making sure that the product is correctly treated and that the process is validated. Sometimes spice companies work with contract facilities to develop a specific validation process for their products. Otherwise, the contract facility typically provides a certificate of the processes performed and an executive summary on the process, but the contract facility retains any proprietary information.

FDA Question: Who has the validation data? Is it reasonable to expect companies relying on a contract facility for a preventive control to have or be able to gain access to this information? Should FDA be directed to obtain this information directly from the treatment facility?

Answer: Validation data is usually proprietary, and the company that pays for the validation study and the resulting data typically owns the data. Spice companies take responsibility to understand the pathogen control process being used and ensure that the validation is effective and minimum validation protocols have been implemented and utilized during the study. In terms of documentation, spice companies typically receive a statement that the treatment parameters have been validated to show a 5-log decrease of *Salmonella* (or suitable surrogate). Additionally, treatment facilities typically provide a certificate of the processes performed and an executive summary describing the process. More detailed (and proprietary) information is available from the facility applying the pathogen control treatment.

FDA Question: What information do importers obtain from foreign suppliers when relying on overseas facilities to apply a pathogen control?

Answer: Importers obtain various types of information and/or conduct onsite audits of overseas suppliers who are treating spices for pathogens. The type of information collected depends on a variety of factors such as the specific spice, how the spice is being processed, and the end use. Many importers use supplier questionnaires and request GFSI audits and documentation related to the food safety plan and validation. For validations, importers have the same expectations for foreign suppliers that are required from U.S. treatment facility and are requesting similar information – either the full validation report and an agreement that the validated parameters are the minimum used, or a certificate of process and executive summary from the validation. Treatment certificates include confirmation of the number of bags treated and identifying information on the bags such as vendor lot# or PO#.

FDA Question: What guidance would be helpful from FDA as it relates to the most expeditious process of obtaining validation data and related documentation in these scenarios?

Answer: Spice companies would like more information about the data requirements for validation procedures. The spice industry relies on the best available scientific data to ensure that pathogen control treatments are effective. Due to the vast amount and types of spices products, it would be helpful to understand if and how it is appropriate to group validations studies of similar type

products. It would also be helpful for FDA to outline expectations of the documentation that spice companies should receive from the facility applying the pathogen treatment.

If you have any additional questions or would like to discuss any of the information provided by ASTA, please don't hesitate to contact ASTA with any follow up questions.

Sincerely,

Laura Shumow
Executive Director
American Spice Trade Association