EXTRU-TECH, INC.

The Extru-Technician

April 2013

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KILL STEP VALIDATION OF LOW-MOISTURE EXTRUSION – EXTRU-TECH, INC.

The Food and Drug Administration has had a zero tolerance policy for *Salmonella* since 2010, which is why the pet food industry has experienced a dramatic increase in recalls over the past two years.

story continues on page 4

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WELCOME LETTER

EXTRU-TECH LEADS INDUSTRY BY SCIENTIFICALLY PROVING THE KILL STEP OF THE EXTRUSION PROCESS

In this issue of *The Extru-Technician*, we are excited to announce the results of our exhaustive scientific validation study proving the lethality step of the extrusion process in our private level 2 bio-safety extrusion lab.

With product recalls as one of the foremost concerns of the food and feed markets, manufacturers continue to refine programs to reduce microbiological contamination and to ultimately kill pathogens, such as *Salmonella*. While others have tried to prove validation of the extrusion process without using an extruder, we took a different approach and set up a real-world manufacturing process.

Contents

Our extrusion lab was designed to mimic as close as possible real-world extrusion based processing conditions for the manufacture of low moisture foods and feeds. We then took it a step further by inoculating the raw ingredients of a typical extrusion based formula with a cocktail of natural pathogens at levels not normally experienced in even the worst of conditions.

Our exacting plan and detailed research was designed and implemented by a team of microbiologists and technical experts. The scheme and results were scientifically documented to record the parameters that were required and realized to kill the subject pathogens at the extruder. The ultimate goal was to scientifically validate that Extru-Tech's full line of continuous cook extruders provide effective pathogen lethality to fulfill the food safety validation requirements of our clients and more so to assist them in the manufacture of safe, high-quality products – and we were successful.

We hope you find this issue of *The Extru-Technician* informative as we detail our ground-breaking validation for extruded pet food safety systems. Please continue to share your comments and thoughts with us; we appreciate the feedback and look forward to offering solutions.

Sincerely,

R. Scott Krebs
Executive V.P., C.O.O.
Extru-Tech, Inc.

INDUSTRY EVENTS

PETFOOD FORUM 2013
April 15-17, 2013
Renaissance Schaumburg Convention Center Hotel
Schaumburg, Illinois

MEXICO PET EXPO
June 26-28, 2013
Guadalajara Mexico

PET FOOD INSTITUTE/NATIONAL GRAIN & FEED JOINT INDUSTRIES MEETING
September 24 - 26, 2013
JW Marriott Indianapolis Downtown
Indianapolis, Indiana

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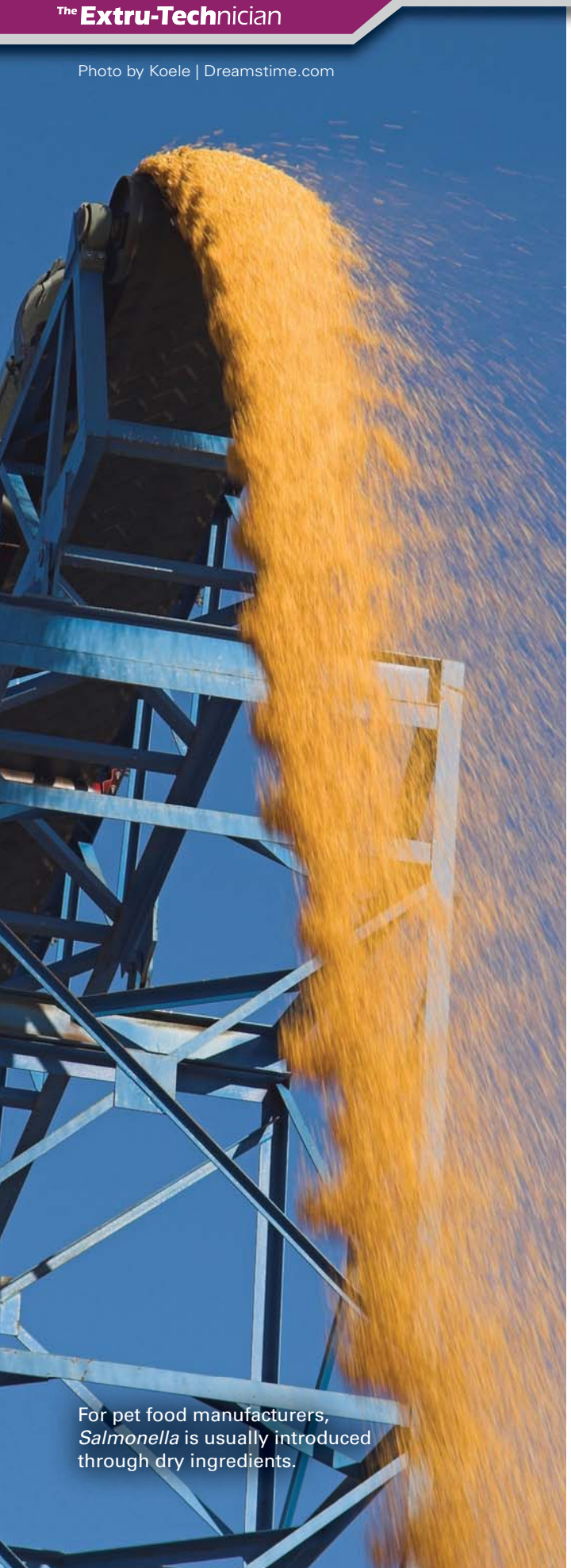


For pet food manufacturers, *Salmonella* is usually introduced through dry ingredients.

Continued from cover

In many of these pet food recalls, *Salmonella* was found in the plant (commonly found in raw materials used to make pet food) and even though no pets or people were sickened, the manufacturer decided to recall all batches produced at that time. It's better to be safe than sorry, but these recalls undermine consumer confidence, damage brands and impact the entire industry.

While every manufacturer strives for products that are 100 percent pathogen free, applicable and validated scientific studies to support properly designed pet food safety systems weren't available … until now.

Kill step validation

To mimic how pet food is contaminated under real-world production facility conditions, Extru-Tech built a BSL (Bio-Safety Level) 2 Pilot Plant outfitted with a production scale Extru-Tech E525 Extrusion System. As a result, Extru-Tech now offers the industry's first scientific validation study of a pet food extrusion system that kills *Salmonella* at levels higher than normally found in most facilities.

"Extru-Tech is using actual equipment that you would find in most pet food plants in a bio-hazard laboratory or a pilot plant," says Dr. Jim Marsden, Regents Distinguished Professor

Extru-Tech, Inc. BSL-2 Pilot Plant
E525 Extrusion System

at Kansas State University. "Raw materials can be inoculated with *Salmonella* or other pathogens and the effect of the extrusion process can be exactly quantified. This process is a breakthrough for the pet food industry."

Production scale vs. traditional testing methods

Pet food manufacturers have been relying on traditional lab studies based on testing equipment ranging from beakers and pressure pots to table-top model extruders. Most testing has been completed on a lab table at very low production rates of 30 grams to 1 kg per hour — not exactly real-world conditions.

Typically for a pilot scale extrusion lab, the Extru-Tech Model E325 would be used. However, the smallest change, from the lab E325 (3.25in. bore) to a production E525 (5.25in. bore), translates to a production rate of 200 to 600 pounds per hour for the E325 and upwards of 8,000 pounds per hour for the E525 (in terms of typical pet food). The process data translation from the lab to the plant is cumbersome at best and filled with non-linearity.

With all this in consideration the BSL-2 pilot plant was outfitted with an E525 production scale extruder system and the equipment was configured for the production of an industry generic low-moisture dry-expanded pet food.

Conditioning Cylinder Inlet: Inoculation Port with AVT (Advanced Venting Technology)

Creating a dry inoculant test

A significant point of discovery is how a raw material is contaminated or inoculated in a factory. Through various preemptive trials, we learned that many of the readily available and scientific methods of inoculation are not truly representative of a typical contamination event that our clients deal with on a daily basis.

For example, some studies have developed thermal survivability profiles (charts that show death of various microbes against time or temperature). However, these data sets were created with the microbes suspended in a largely aqueous solution. If *Salmonella* is in a liquid, heat will transfer quickly and kill it quickly. However, this is not a representation of what happens in a pet food plant and creates a false set of operational parameters that do not control *Salmonella*.

For pet food manufacturers, *Salmonella* is usually introduced through dry ingredients. For this reason, we developed a dry inoculant. A dry inoculant introduced into the ingredient stream better represents how the pathogens are usually present within contaminated raw ingredients.

The obvious pathogen choice was a 3 serotype cocktail of *Salmonella* as it is the most opportunistic organism that is prevalent in the pet food industry and the media. The selected industry generic pet food formula was charged with a tailored inoculant that represents typical contamination events in the manufacturing process.

Ultimately all three replications of the challenge study resulted in a log reduction of *Salmonella* that exceeded the 5-log reduction requirement of a CCP allocation.

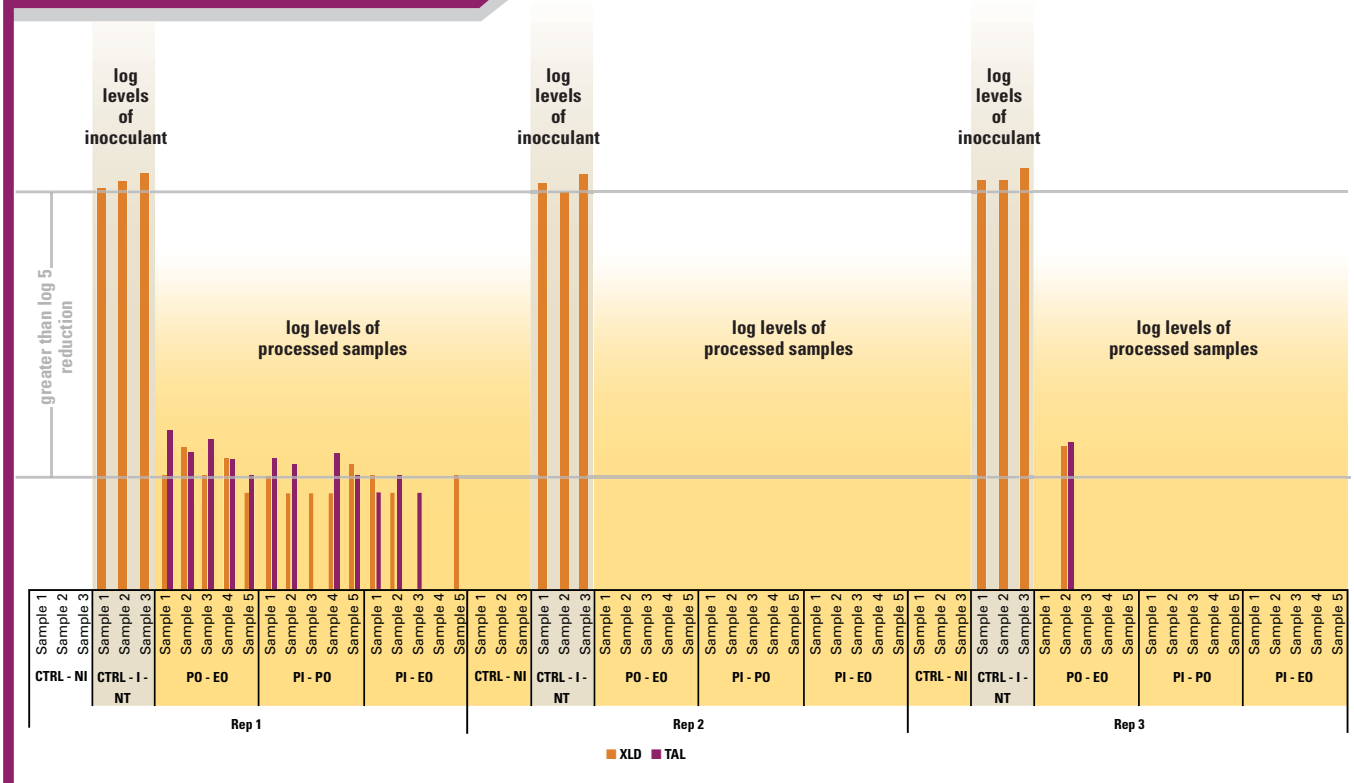
Study parameters

Possible paths for validation of a typical pet food process were reviewed in order of preference and viability:

Pilot Plant – Most Accepted and Least Risk

- Configure a pilot plant with representative production-scale equipment models and perform a tailored challenge study with specific formulations, equipment configuration, product specifications and targeted pathogens.
- Pros – Correlation becomes moot, no risk.
- Cons – None

Figure 1.



KEY CONSIDERATIONS USED IN THE STUDY

For the development stage of this process, key operational parameters were analyzed to scientifically validate a typical extruded pet food process.

- **Equipment Scale – Production Rates**

  Impartial and internal studies have proven the agnostic relationship between laboratory scale equipment and production scale equipment.

- **Equipment Configuration – Barrel Screw Stack-up, Preconditioner Paddle Configuration**

  Impartial and internal studies have shown that even the slightest change in equipment setup will impact the process's pathogenic efficacy.

- **Formulation**

  Impartial and internal studies provide excellent insight into the variations inherent within individual ingredient components and how they interact differently within a processing environment (i.e. thermal energy efficiency, water absorption, energy of gelatinization).

- **Product Specification**

  Parameters such as: size, shape, density, cell structure, moisture and water activity.

  Impartial and internal studies reflect that specific changes in product characteristics via process management, equipment configuration or formulation, will directly affect the efficiency of microbiological control.

In-Plant Surrogate

- Select non-pathogenic surrogate and inoculate actual production process flow.
- Pros – Matched equipment and process model.
- Cons – Lack of applicable (correlation) challenge study data.

In-Plant Pathogenic

- Inoculate actual production process flow with pathogenic microbe.
- Pros – Correlation becomes moot.
- Cons – Risk of future events and liability thereof.

Laboratory Validation

- Secure a BSL-2 Laboratory to perform "bench-top" validation.
- Pros – Specific pathogen, surrogate correlation, tailored formulation.
- Cons – Does not replicate equipment scale, configuration or the manufacturing process.

Scientific Literature – Least Accepted and Most Risk

- Search for existing scientific data that best represents your manufacturing model.
- Pros – Least cost
- Cons – Difficult to find a single study that will be even minimally representative of a pet food extrusion process.

Validation 101

As any Food Safety Auditor may tell you, the ability to correlate the assignment of critical control points to scientifically validated proof of their effectiveness in the control of targeted pathogens is the ultimate confirmation of effectiveness.

All pet food manufactures are required under the Food Safety Modernization Act to develop written food safety plans," says Dr. Marsden. "For example, if *Salmonella* is a hazard that is reasonably likely to occur in the process or product, then a series of interventions are required and they must be scientifically proven."

Validation is the process of demonstrating that a food safety system (HACCP, CCPs, CLs) as designed can adequately control (5-log reduction) the identified hazards to produce a safe product. As the United States Department of Agriculture indicates there are two distinct elements of validation:

- The scientific justification or documented basis for the system

design requires scientific and technical documentation that demonstrates the designed process can control the identified hazard. The practical and scientific demonstration must prove the system can perform as expected. This consists of keeping records to demonstrate the plan in operation and that the HACCP plan achieves expectations.

a real-world food plant to measure the reductions associated with that treatment. As a result, we know exactly how effective an intervention is in controlling specific pathogens."

Basing a pet food safety system on impractical data is not safe. By selecting a sub-standard pet food safety model, you forfeit all leverage to mitigate the risk of a food safety event.

"This process is a breakthrough for the pet food industry."

— Dr. Jim Marsden, Kansas State University

- Conducting multiple repetitions in a real-time processing environment using full- scale production equipment and actual production formulations that have been inoculated with designated high levels of specific (non-man made) microorganisms. The process also must prove that high levels of microorganisms are reduced or killed through the lethality conditions of the CCP.

"The best way to see how effective an intervention is against certain pathogens is to actually inoculate a food product with *Salmonella*," says Dr. Marsden. "We then apply that intervention under conditions that ideally replicate

Validating your pet food safety system

Until now, kill step validation has not been available in the pet food industry. Extru-Tech now offers scientific validation focused on the extrusion of low-moisture dry-expanded pet food that exceeds FSMA requirements.

"Extru-Tech is documenting the parameters that are required to deactivate *Salmonella* in the extrusion process," says Dr. Marsden. "There are other production steps that follow where *Salmonella* could re-contaminate the product. Extru-Tech is looking at those additional steps to identify interventions that could be applied downstream to prevent recontamination."

To find out how Extru-Tech's team of experts can validate that your pet food safety system is effective and complies with regulatory requirements, contact:

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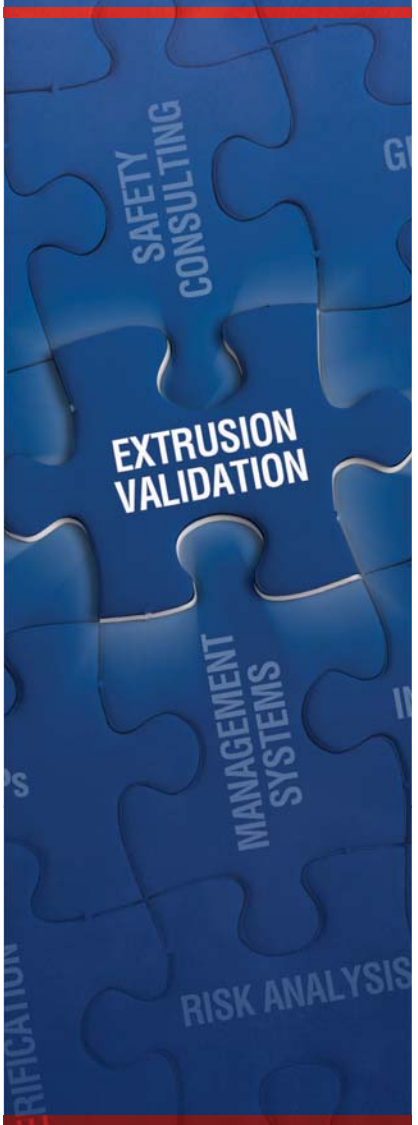

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The Extru-Tech Team includes personnel with expertise in: Quality Assurance, Facility and Process Engineering, Extrusion Manufacturing, Microbiology, Material Handling, Technical Services, Research & Development and Regulatory Affairs. Contact us today for details.

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