The Extru-Technician

Art of validation

The challenge of correlating published validated science to a specific processing unit

In today's pet food industry, a simple word-association exercise would most likely link validation with *Salmonella*. Rightly so, as *Salmonella* has historically been the most prolific micro-organism in regard to public health (USDA, 2007). In the great words of Sun Tzu in regards to waging war … "Keep your friends close and your enemies closer."

In terms of battling *Salmonella*, the only trusted method of knowing our enemy is through proper scientific validation.

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Finding correlation through scientific validation

In this issue of *The Extru-Technician*, we discuss an enemy of the extrusion process – pathogens – and how to effectively prove your control of that enemy through correlation of appropriate scientific validation.

As has been seen with *Salmonella* throughout the years, pathogens evolve, adapting to preventive protocols, which requires us to keep a constant eye on how best to keep them at bay.

The correlation of published validated science to a specific processing unit or critical control point (CCP) is most definitely a challenge. As regulations begin to require more than stating the steps within a food safety program, you will need to prove, through scientific means, that the steps offer effective pathogen control. How does one do this? By relating portions of validation studies to your specific processing model.

This process of correlation is a journey, and *The Extru-Technician* aims to give you some insight on beginning that journey and making your way to the final destination. We welcome you to share with us your comments and thoughts on this, and all other, issues.

Sincerely,

R. Scott Krebs

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Executive V.P., C.O.O.
Extru-Tech, Inc.

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Extru-Tech events

You can find Extru-Tech Inc. experts and personnel at these upcoming events:

Practical Extrusion Work Shop, February 2-3, 2012, San Jose, Costa Rica. Contact: Osvaldo Munoz, director of Latin America sales, **osvaldom@extru-techinc.com**, +56.2.955.25.74.

Victam Asia 2012, February 15-17, 2012, Bangkok International Trade & Exhibition Centre, Bangkok, Thailand. Contact: Norm Schmitt, corporate sales manager, **norms@extru-techinc.com**, +1.785.284.2153.

Petfood Forum Asia 2012, February 16, 2012, Bangkok International Trade & Exhibition Centre, Bangkok, Thailand. Contact: Norm Schmitt, corporate sales manager, **norms@extru-techinc.com**, +1.785.284.2153.

Extru-Tech Extrusion Short Course: Pet Food & Aquatics, March 2012, Latin America. Contact: Osvaldo Munoz, director of Latin America sales, **osvaldom@extru-techinc.com**, +56.2.955.25.74.

AquaSur, October 24-27, 2012, Port Demontt, Chile. Contact: Osvaldo Munoz, director of Latin America sales, **osvaldom@extru-techinc.com**, +56.2.955.25.74.

On the cover:

Pathogens are constantly evolving, adapting to safety protocols.

Photo: Sven Hoppe. BigStockPhoto.com

continued from cover

The *Salmonella* group is comprised of roughly 2,500 strains of bacteria (Breslow, 2002) and supposedly dates as far back in history as 323 B.C. with the mysterious death of Alexander the Great. In terms of true classification, the discovery of *Salmonella* is attributed to Theobald Smith – lab assistant to Dr. Daniel E. Salmon whose namesake was taken for this microbe – while investigating the cause for hog cholera in 1885.

Photo: Eraxion. iStockPhoto.com

The *Salmonella* group is comprised of roughly 2,500 bacteria strains and thought to date back as far as 323 B.C.

Since the early 1990s, we have witnessed the discovery or emergence of various new antimicrobial resistance strains of *Salmonella* (CDC, 2005). Thankfully, the majority of *Salmonella*-based human infections are linked to only 10 common forms, mostly *S. Typhimurium* and *S. enteritidis* (Breslow, 2002). The 1950s saw the proliferation of one of the more temperature-resistant strains, *S. Senftenberg* (Ward, 1959). The primary point to take away is that our adversary is constantly evolving, adapting to our safety protocols.

The challenge is a journey

The most prominent challenge, in our experience, is the correlation of published validated science to a specific processing unit or critical control point (CCP). You see, in the near future, it will no longer be sufficient to state in a food safety program the steps you are taking to control pathogens. You must also prove, with scientific certainty, that the steps you are taking will control/eliminate pathogens. And, since your specific process/product has not been scientifically validated, you are left with the challenge of relating excerpts from these available validation studies to your processing model.

A cross-section of the extruder discharge (directly behind the die) that contains the temperature probe typically used to monitor and record the product temperature (see p. 7).

A cursory Google search will most likely result in hundreds of published and peer-reviewed challenge studies, of which none will have a direct relationship to your specific model, and some that will contain bits and pieces of information that can be used to justify your protocols. This is correlation.

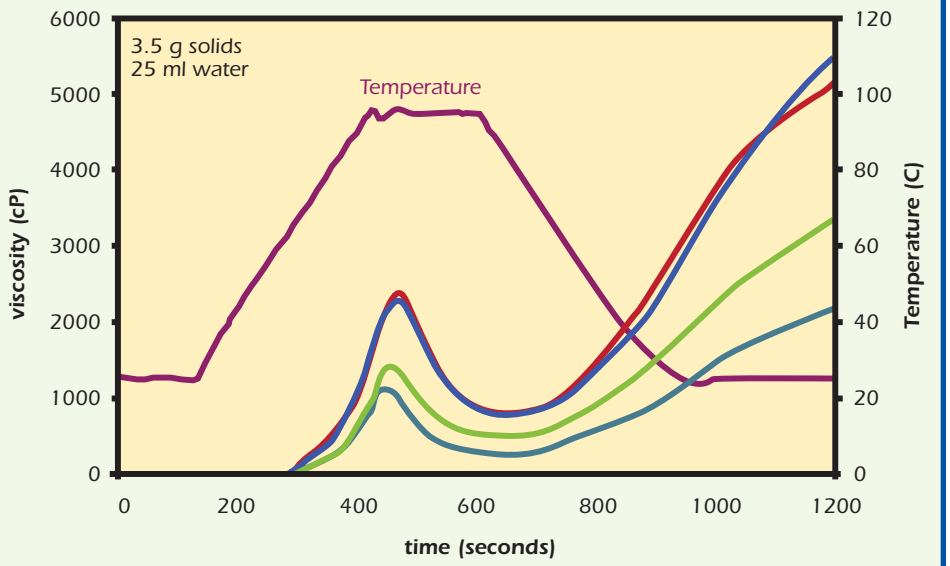
Think of this as a journey you need to map directions for so that someone can follow. The map is your food safety program, while the navigator is an auditor (internal, accreditation, etc.). The easier your map is to read, the less likely your navigator will get lost and determine the map is wrong.

The process of a scientific validation begins in a similar fashion to designing a food safety program:

1. Product description
2. Process definition
3. Risk analysis
4. Determine CCPs and critical limits (CLs)
5. Define monitoring controls
6. Develop corrective actions
7. Verify HACCP integrity
8. Documentation

A change in a product within any of these components, by definition, should require a separate food safety protocol.

Figure 1. Viscosity test of raw ground wheat



Though each sample plotted here is simply a different lot of the same species of wheat, we see a substantial difference in viscosity.

The first of many hurdles with correlation is the product description or formulation. Typical food safety programs require definitive product descriptions for each unique product. Unique product descriptions require, as a minimum (but are not limited to), the information shown below:

1. Formulation
2. Intended use
3. How it is manufactured (Process Flow Diagram)
4. Storage and handling recommendations
5. Feeding recommendations
6. Expiration guidelines

Learning through examples

Here are just a few examples. Figure 1 is the result of a viscosity test on multiple samples of raw ground wheat. Each sample is simply a different lot of the same species of wheat, and yet we see a substantial difference. If we see this type of variance in a single cereal grain, imagine the processing differences with more dramatic differences in raw material compositions.

To further shed light on the impact of ingredient composition, reference Figure 2, which depicts the variance of gelatinization of common starch sources. It shows the required energy (calories per gram) to cook the available starch components of these ingredients. It is not uncommon to use starch gelatinization

Figure 2. Heat gelatinization for various starches

	Heat of gelatinzation (cal/gram)	Amylose content (%)	Size (microns)
High amylose corn	7.6	55	5-25
Potato	6.6	20	15-121
Tapioca	5.5	22	5-35
Wheat	4.7	28	1-35
Waxy corn	4.7	0	5-25

Food safety managers and experts commonly use starch gelatinization as a reference target for thermal inactivation of some pathogens.

as a reference target for thermal inactivation of some pathogens. With this data, we can easily see that minute changes in component quantities or proportional changes of components will alter any relationship between starch gelatinization and thermal inactivation.

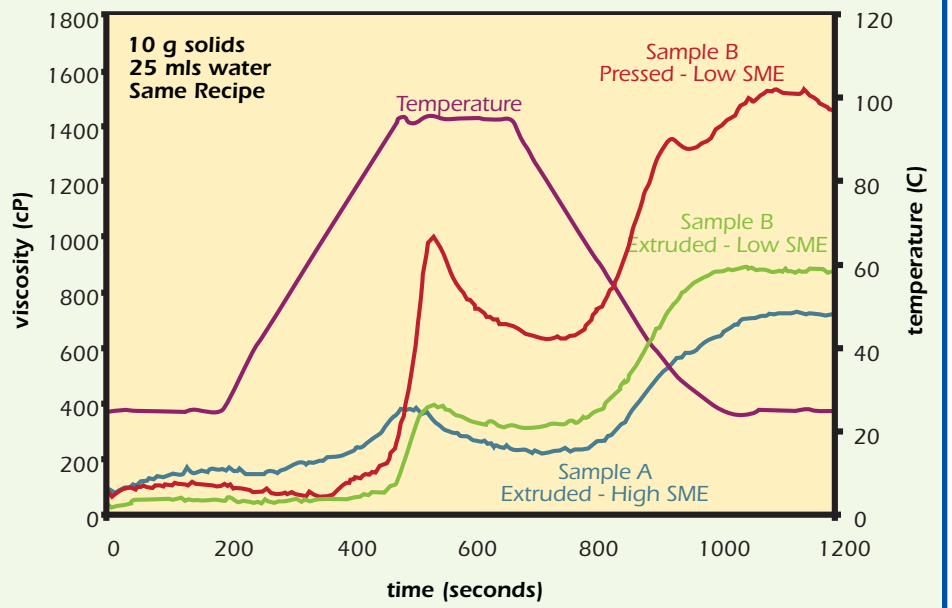
Another chart (Figure 3) is a viscosity comparison of similar products, processed under different mechanical configurations to vary the specific mechanical energy

(SME, kW Hrs per ton). It is extremely easy to see the impact these mechanical changes will have on the product and, hence, the control of pathogens within.

It is because of these critical relationships that careful attention should be focused on the raw materials and equipment configuration of the validation studies you are using to justify your food safety protocols.

One of the next major hurdles is the application of the validation study in regard to a specific CCP – see Figure 4 for an example (Fung, "Synopsis of Food Microbiology,"

Figure 3. Viscosity comparisons of SME levels

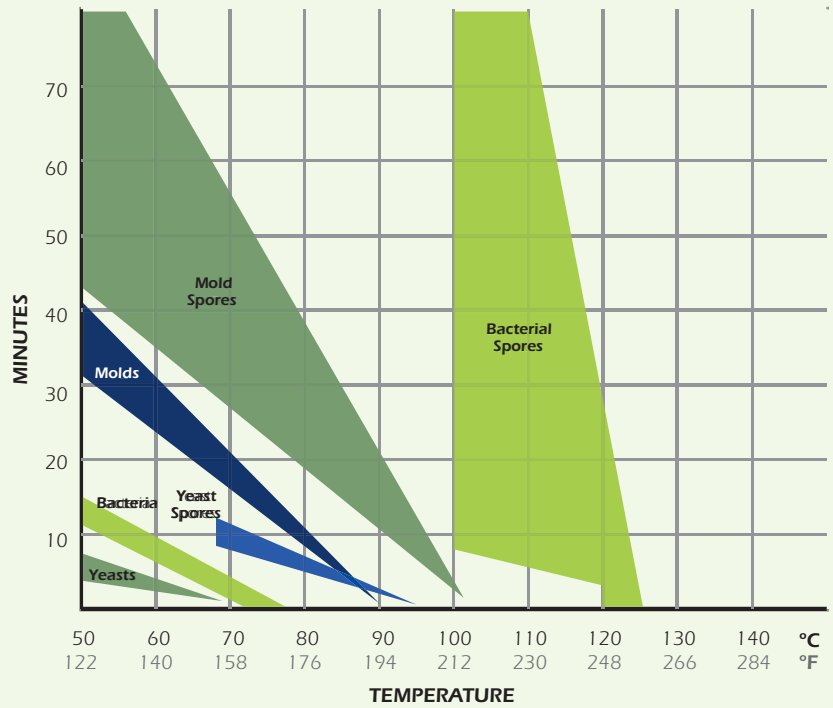


This test showed similar products processed under different mechanical configurations to vary the specific mechanical energy (SME, kW Hrs per ton).

2008). One may draw from this chart that at 80 degrees C or higher, the survival time of bacteria is negligible (under the basic assumptions of typical processing conditions, moisture and material matrix).

From this, a simple and common correlation for low moisture dry-expanded pet

Figure 4. Validating the study of a specific CCP



You might conclude from this chart that at 80 degrees C or higher, the survival time of bacteria is negligible.

food would be to assign a CCP at the discharge of the extruder with a CL set to 80 degrees C as the lower threshold. However, we must take care in the physical application of this science.

Take, for example, the photo (see p. 4) showing a cross-section of the extruder discharge (directly behind the die) that contains the temperature probe typically used to monitor and record the product temperature. Also, note Figure 5, which correlates installation position and recorded temperatures. For this data, 0% retracted relates to the end of the probe being located at the exact center of the product flow. Conversely, 100% retracted relates to the end of the probe being located flush to the inner diameter of the extruder barrel. By now, you have undoubtedly ascertained that the improper installation of this CCP probe could easily bias the target temperature by 30 to 40 degrees C.

Figure 5. Correlation of installation position and recorded temperatures

% retracted	Product temp (C)
0	140
33.3	139
50	138
66.7	135
83.3	122
100	104

For this data, 0% retracted relates to the end of the probe being located at the exact center of the product flow (see photo), while 100% retracted relates to the end of the probe being located flush to the inner diameter.

In summary, scientific validation studies for the extrusion process number in the hundreds, possibly more, depending on how thorough of a search you decide to embark on. The products and markets represented in this collection of challenge studies are extremely broad. A careful dissection of the objectives and constraints for these studies, not to mention mechanical configuration and application, is paramount.

Look for the next issue of *The Extru-Technician,* in which we will continue this conversation of validation correlation into the areas of surrogates and cocktail validations.

ARE YOU FOCUSED ON PETFOOD SAFETY?

Petfood safety has become the industry's key topic affecting producers, manufacturers and consumers. Moving forward, every company involved will have to be actively engaged in a food safety program that fulfills universal food safety schemes to ensure consumer safety.

At Extru-Tech, we maintain trained and certified consultants on-staff as well as within our network of partners to assist clients with process focused behavioral-based food safety management systems. Our team will assist in analyzing, monitoring, controlling, testing and validating every step in the petfood production process to create a food safety culture.

There is no better time than now to become skilled on food safety certification. It's just one more way the market's best manufacturers partner with Extru-Tech to optimize petfood safety.

Contact one of our professional consultants today at 785-284-2153.

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