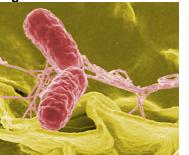
The possibility of *Salmonella* (Figure 1) contamination in pet foods presents two basic problems to the pet food manufacturers. Foremost is the potential of causing human illness by *Salmonella* infection, and second, the economic impact of a *Salmonella* based recall on the producer's business.

Disease caused by *Salmonella* infection is an important

public health issue, especially for susceptible persons whose immune system may be compromised. According to the Center for Disease Control (CDC) a total of 79 cases of *Salmonella* infection have been linked to





dry pet food in the period spanning 2006 through 2008¹. Among those infected for whom information is available, 40% of the cases were in infants less than 1 year old. While 79 cases is indicative of a significant public health problem, the CDC also estimates that only 3% of all *Salmonella* cases in the US are laboratory confirmed and reported. Therefore applying this reporting estimate to this situation, the 79 reported cases are indicative of 2,633 actual cases of *Salmonella* infection in the US population.

All of these cases have been linked to a specific strain of *Salmonella* and to a specific processing plant in Pennsylvania. Product produced during a 5 month period at this plant has been recalled and the plant was shut down for a period of about 5 months for intensive cleaning, sanitation, and disinfection.

The economic impact of a recall to a pet food producer is a significant risk for any producer, regardless of the reason for the recall. Based on Colgate-Palmolive Company's (the parent company of Hill's Pet Nutrition, Inc.) FY 2007 annual report², the accounting cost of their recall based on melamine contaminated wheat gluten was \$13.6 million. The report further states that this recall was limited to less than 0.5% of Hill's products, which based on their annual sales of \$1,859 million, would have had a value of around \$9.3 million. Therefore the accounting cost of this particular recall is approximately 1.5 times the value of the product being recalled. This accounting cost estimate does not, of course, enumerate the cost of collateral damage to the brand or lost sales due to the negative publicity encountered in a recall. As this information indicates, there is a very significant economic incentive for a petfood producer to take calculated steps to reduce their odds of a Salmonella-based recall.

There are a number of unique challenges associated with control of *Salmonella* contamination of product in the petfood industry. Of primary significance is that the ingredients used for producing petfood are highly suspect for contamination with *Salmonella* and other microbes as they arrive at the petfood manufacturing facility, supplying a steady stream of microbial inoculants to the petfood processing plant.

In the dry petfood processing plant *Salmonella* contamination has long been thought to be a limited risk because the preconditioning and extrusion process is widely recognized to be an effective kill step to eliminate microbes^{3,4}, particularly when certain minimum process temperatures are reached. However, once the product leaves the extruder die, it is subject to recontamination by microbes present in the air, lifted from the wet floor around the area of the extruder discharge, present in buildup in pneumatic transfer systems and in dryers, as well as in coating systems, and conveying systems. So although an effective kill step is in place, recontamination post kill appears as a significant issue.

Broadly speaking, there are two general approaches to addressing the issue of potential recontamination of product after the extrusion kill-step. The first, which is extensively employed, is to attempt to eliminate as much as possible the potential sources of *Salmonella* re-contamination. A second approach, which is under-utilized in the industry today, is to either decontaminate product that has been microbially contaminated after the extrusion kill step or utilize a secondary barrier to microbial contamination that is formulated into the product.

Eliminating sources of recontamination

The approach of eliminating potential sources of *Salmonella* re-contamination has been useful in significantly reducing the risk of *Salmonella* infection to the public. However, as evidenced by the recent problems, they are not completely effective. These approaches include intensive cleaning, equipment heat treatments, sanitizer applications, and focused attack of problem areas whenever they are revealed by environmental swabbing and testing procedures.

In addition, design for better sanitation of both the facilities and the equipment has been employed. For example, facilities can be designed to limit flow of personnel, materials, and air from areas containing raw, unprocessed ingredients to areas containing processed product. Equipment designs have been improved to increase access for cleaning, eliminate areas where product can build-up and act as a harborage and incubation of microbes, and in some cases, clean-in-place (CIP) systems have been utilized.

However, many manufacturers, as a final insurance step, are essentially holding finished product in quarantine and testing it for *Salmonella* before releasing it into the consumer supply chain. This approach is inventory intensive and expensive. When contaminated lots are discovered, the product may be re-worked back into the same product formulation. For some operations, however, re-work is not a viable option resulting in disposal of the product and the resultant irrecoverable loss of the ingredients, energy, and other resources employed in its production.

Decontamination of Microbial Populations in Recontaminated Product

In addition to the solutions already in use, there are additional approaches that pet food manufacturers can consider to mitigate the risks associated with *Salmonella* contamination in their products by reducing or eliminating microbial populations in product that has been recontaminated. These potential solutions include decontamination using irradiation, ultra-violet light, and ozone.

Irradiation briefly exposes products to a radiation energy source such as gamma rays or electron beams and is FDA-approved⁵ for use in petfoods. It is a proven means of eliminating harmful bacteria from foods.⁶ However, consumer resistance to the technology, potential chemical changes in the product, expensive equipment installations, and licensing issues are barriers to implementing this technology in the petfood industry.

Ultra-violet light radiation can be used to inactivate many types of microbes by injuring the cell's DNA and interrupting its reproductive systems. UV light works only on transparent materials or on the surfaces of opaque materials⁷. Thus to effectively apply UV light sterilization to petfoods, the system would need to expose all surfaces of potentially contaminated petfood to the UV light. While this may be possible, it will certainly involve some equipment and process design challenges. Another concern with UV light is the impact it will have on fat oxidation which could be very important to the shelf-life of petfood products.

Ozone is a FDA approved method for decontaminating certain food products⁸. It is reported to leave no taste, odor, or flavor on the product. Because ozone is an unstable molecule, on-site ozone generation equipment is required and seems to be readily available. Equipment to apply gaseous phase ozone to products may be available to petfood processors, but does not appear to be in significant use.

Secondary Barrier to Microbial Re-contamination

Building anti-microbial characteristics into products as a secondary barrier to microbial recontamination is another approach to preventing, reducing, or eliminating microbe populations in products after the extrusion kill step. Some petfoods, in particular soft-moist foods and treats already use parts of this approach by utilizing the addition of phosphoric acid, hydrochloric acid, or other acids to lower the pH. Generally, these acids are used in combination with other ingredients added to control water activity. However because the addition of most acids imparts a sour flavor to the product and results in the rapid hydrolysis of starchy materials in the extrusion cooking process, the pH is not typically lowered to less than about 5.5 for most products.

Acidic calcium sulfate (ACS) is a new ingredient available to the pet food industry under the trade name

pHresh® from pHresh Technologies, LLC, Sabetha, KS (www.phreshtechologies.com). ACS is produced by combining water, sulfuric acid, and lime in precisely controlled ratios and temperatures. Because all of the ingredients are GRAS (Generally Recognized As Safe) by the US Food and Drug Administration, the FDA has indicated that they have no objection to the use of ACS in foods. ACS has several characteristics that make it particularly useful to the petfood industry for control of *Salmonella* and other bacteria.

A very unique characteristic of ACS is that it does not have the strong sour flavor associated with other acids. Therefore addition levels required to reach a microbially stable or antimicrobial pH can be reached without negatively impacting the flavor of most foods. ACS has been documented to be effective at reducing bacterial loads and preventing bacterial growth in a number of platforms including very taste sensitive applications such as pumpkin pies⁹, cooked pasta, deli foods, and beverages. In addition, ACS is widely used in production agriculture in eliminating bacterial loads in the drinking water supplied to poultry. In this case, ACS is added to the poultry drinking water to eliminate one source of potential bacterial contamination of the poultry meat and eggs. There is no impact on the quantity of water that is consumed by the poultry, thereby reducing food safety risk in a very non-obtrusive manner.

In a recent study, ACS was added to both a commercial feline diet and a commercial canine diet, with

proximate analysis shown in Table 1, in both the extruded base product and the externally applied coating at the levels indicated in Table 2 to

Table 1.	Proximate Analysis			
of Control Diets				

	Canine	Feline
Protein (min)	23%	30%
Fat (min)	13%	15%
Fiber (max)	4%	4%

create both control and test diets.

Table 2. Summary of Test Petfood Diets

	Feline	Feline	Canine	Canine
	Control	Test	Control	Test
	(F-CK-C)	(F-AK-A)	(C-CK-C)	(C-AK-A)
ACS added				
to Extruded	0%	1.23%	0%	1.22%
Base				
ACS Added	0%	2.50%	0%	2.43%
to Coating	0%	2.50%	0 %	2.43%
Total ACS				
Content of	0%	1.35%	0%	1.30%
Diet				

These diets were used in feeding trials where they were fed to twenty animals (cats and beagles, respectively) where both the control and test diets were offered once daily for two days with the bowl placement reversed on the second day. Food consumption and first choice preferences were recorded for each animal with the average results¹⁰ shown in Table 3.

These results indicate that animals tend to choose the products containing ACS first, but then consume slightly more of the products without ACS. The results also tend to indicate that if the ACS-containing test products are fed alone, there would not be a reduction in consumption compared to the control products fed alone.

Table 5. Summary of Falatability Test Results				
	Feline		Canine	
	Control (F-CK-C)	Test (F-AK-A)	Control (C-CK-C)	Test (C-AK-A)
First Choice				
(Number of Times)	18	22	15	25
Average Consumption (grams)	49.8	38.6	299.1	176.8

Table 3. Summary of Palatability Test Results

Of further importance is that ACS does not hydrolyze starch in the manner that other acids do. If most acids, including phosphoric and hydrochloric acids are added to the extrusion process at levels sufficient to reach pH 5.2 or less, the process result is extreme stickiness of the product exiting the extruder die and dramatic alterations in product expansion and shaping. However, with ACS, it is generally impossible to tell from a processing standpoint if the ACS is being added or not. In other words, the addition of ACS to the kibble formulation will have no impact on the extrusion processing conditions required, the product's properties, or the kinds of extruded products that can be produced. For the same study mentioned in Table 2, there was less than 1% change in final dry bulk density for the canine diet and less than 3% change in final dry bulk density for the feline diet.

Another recent study using the canine products listed in Table 1 to determine the usefulness of adding ACS to both the extruded base and to the coatings in a petfood as a secondary barrier to protect against Salmonella contamination in pet foods, post extrusion. The study was conducted by microbiologists at Kansas State University and the results are slated to be formally presented at the annual meeting of the International Association for Food Protection in July 2009.

To simulate contamination with *Salmonella* in the processing plant after extrusion, drying and coating, products composed of control kibble (CK) and ACS containing kibble (AK) and then

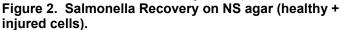
(AK) and then
coated with both
control coating
(C) and ACS
containing
coating (A) and
assigned product
codes as

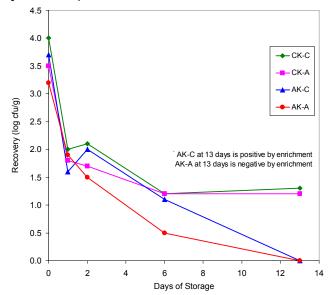
Table 4. Canine Products used in Salmonella Challenge Study

		Control	ACS	
		Coating	Coating	
	Control Kibble	CK-C	CK-A	
t	ACS Kibble	AK-C	AK-A	

indicated in Table 4. These coated kibbles were lightly misted with a 5-serovar mixture of *Salmonella*. The resulting total *Salmonella* population as measured by direct plating of the inoculated control kibbles with control coating (CK-C) on the kibbles was approximately 10,000 cfu per gram which can equivalently expressed as 10^4 cfu/g or 4 log cfu/g.

Salmonella populations in the inoculated products were enumerated on Day 0 (after storing for 1 hour), Day 1, Day 2, Day 6, and Day 13, being stored at ambient conditions. Salmonella populations were enumerated using both non-selective (NS) and selective (XLD) agars. Populations based on NS agar are generally higher than populations based on XLD agar and the difference between the NS and XLD populations can be regarded as the "injured" Salmonella population as injured cells will form colonies on NS agar, but not on XLD agar. If the direct plating results showed zero colonies, then the sample was analyzed using qualitative enrichment analysis (SDI RapidChek® immunoassay) to see if they were positive (contained at least one Salmonella cell) or negative (contained no live Salmonella organisms).

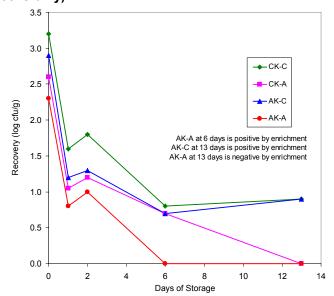




The recovery of Salmonella from each of the samples on NS agar over time is shown in Figure 2. The results indicate that having ACS in the product (either in the kibble, or in the coating, or in both kibble and coating) results in an immediately lower populations when measured one hour after inoculation, with a greater advantage at this point with coatings containing ACS, even if that coating is applied to a kibble that does not contain ACS. Also note that only the product with ACS in both the kibble and in the coating (AK-A) showed continuous and steady Salmonella population reductions during storage, ending with a negative via enrichment analysis on Day 13 – a total reduction exceeding 4 log cfu/g in the Salmonella population. In addition, the data indicate that including ACS in the kibble enhances the ability of subsequent ACS-containing coating materials to reduce post-enrobing surface contamination of Salmonella. For control kibbles (CK-C and CK-A) it appears that any Salmonella contamination remaining after several days will continue to be viable, and could even increase over time as indicated by the slight increase in Salmonella population which occurs in sample CK-C

between 6 and 13 days of storage. However, the product with ACS in only the kibble (AK-C) also results in zero *Salmonella* population after 13 days of storage. **Figure 3. Salmonella Recovery on XLD agar (healthy**

cells only).



Recovery of healthy *Salmonella* cells from each sample is shown in Figure 3. Note that there is greater initial reduction in healthy cells for samples containing ACS in the coating, but that the healthy cell population is reduced to zero by direct plating for the most highly treated sample (AK-A) after 6 days. It was still positive by enrichment at that point, but was reduced further to negative by enrichment after 13 days.

Based on the results of this study, the researchers conclude that using ACS in petfood formulations serves as an effective secondary anti-*Salmonella* barrier to help ensure that post-extrusion kibble and /or coating surface contamination would decline significantly during storage and distribution of commercial dry kibble petfoods.

Economic Impact Revisited – Secondary Barriers

Now the obvious question is if a formulated-in secondary barrier is an economically viable approach for petfood processors to implement. To address this question, consider the following scenario.

Suppose a petfood processor sells 500 million pounds (250,000 tons) of a product each year at an average price of \$1.00 per pound resulting in total yearly sales of \$500 million. Based on the Hill's recall cost presented earlier, this means that the cost of a recall of this product will be about \$750 million, not including the cost of lost sales and of damage to the brand. The cost of a formulated-in secondary barrier using ACS will vary depending on the product and volume purchases of ACS, but can often be accomplished at a cost of 2 cents per pound of product.

Given the present and anticipated future regulatory environment, it is reasonable to assume, based on the information presented here, that the ACS secondary barrier approach could prevent one recall of this product over the course of the next 10 years. The cost of adding ACS to the product over 10 years is just over \$10 million. However, the return on this investment is \$750 million – the cost of the averted recall. This means that the benefit/cost ratio of pursuing the secondary barrier approach is 7.4 – a good investment by any standards. If the assumptions are changed such that a recall is prevented in less time, then the benefit/cost ratio goes up considerably because the investment goes down. Going the other way, based on the cost and benefit assumptions presented here, *if the secondary barrier approach avoids only one recall over the course of the next 75 years, the processor will end up breaking even.*

Final Thoughts

At the end of the day, taking on the *Salmonella* issue within the petfood industry will continue to require a multi-faceted approach that includes all of the aspects discussed. Continuing work on good sanitation practices, better equipment design, better processing plant design will surely result in better control of the problem. However, some method of either eliminating possible secondary contamination or providing a formulated-in secondary barrier will likely be ultimately required to get a firm death-grip on the issue.

² Form 10-K (Annual Report) Colgate-Palmolive Company. Filed 02/28/08 for the period ending 12/31/07, pg 20.

 ³ C. M. Hoffmans and D. Y. Fung. Effective Method for Dry Inoculation of Bacterial Cultures, 1993. Journal of Rapid Methods and Automation in Microbiology 1:287-294.
⁴ Anonymous, (1965) Salmonella Contro, Feedstuffs, February 25.

⁵ Irradiation of Animal Feed, April 10, 2001. FDA Talk Paper T01-13

⁶ FDA Publication 00-2329, January 2000.

⁷ J. A. Guerro-Beltran an dG. V. Barbosa-Canovas. Review: Advantages and Limitations on Processing Foods by UV Light. Food Science and Technology International 2004, 10(3):137-147.

⁸ 21 CFR Part 174 Subpart D Section 173.368.

⁹ A. Tanus, R. K. Phebus, G. R. Huber,, A. Nutsh, and L. Franken. Validation of Adcidified Calcium Sulfate for control of Listeria monocytogenes, Staphlyococcus aureus, and Salmonella serotype Enteritidis in Shelf-Stalbe Pumpkin Pies. 2006.

¹⁰ Study Report #FPHT0109 and PHT0109, Summit Ridge Farms, Susquehanna, PA, 4/2009.

¹ CDC. Update: Recall of Dry Dog and Cat Food Products Associated with Human *Salmonella Schwarzengrund* Infections --- United States, 2008. MMR Weekly, 57(44):1200-1202.