A Note to Review Information for the Risk Management of *Salmonella* on Raw Peanuts

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ABSTRACT

A *Salmonella* outbreak in 2007 affected at least 625 people in 47 states. As a result of this outbreak a number of initiatives were undertaken by the peanut industry. Review of scientific literature found very little data on the prevalence or thermal inactivation of *Salmonella*. Additional outbreaks reinforced the need for more data. Research was commissioned by the American Peanut Council (APC) to provide processors information needed in mitigating the risk of *Salmonella* in raw peanuts. Studies were completed to provide prevalence, concentration, and time/temperature conditions to thermally inactivate *Salmonella* present. Subsequently, a quantitative microbiological risk assessment (QMRA) was performed and published. These studies and QMRA were reviewed with their results used to suggest potential risk management practices.

When considering risk management both actual baseline results and what-if data for factors were explored. Prevalence and concentration of *Salmonella* is best controlled with established Good Agricultural Practices that can be recommended by processors to suppliers. Storage was shown to significantly reduce *Salmonella* levels, however there is limited opportunity for control due to quality requirements that are dependent on shelf-life. Blanching was shown to only minimally reduce *Salmonella* levels. Lower consumption of raw peanuts reduced risk moderately. Higher log reductions through roasting was shown to effectively reduce risk, potentially more so for split peanuts. This article reviews the research studies commissioned by the American Peanut Council and related quantitative microbiological risk assessments and factors for decision making that risk managers at peanut and peanut product processing facilities should consider for hazard control measures.

Key Words: Prevalence, QMRA, inactivation, assessment, validation

Recalls and outbreaks associated with *Salmonella* contamination in peanut-containing products have been reported (CDC, 2007; CDC, 2009; CDC, 2012; Christian *et al.*, 2007; Kirk *et al.*, 2004). The peanut industry became very concerned after the initial outbreak and took steps to improve food safety for peanuts and peanut products. These steps included assigning individuals to review the current state of knowledge regarding potential pathogen contamination. Additionally, Good Manufacturing Practices for all segments of the industry were revised (American Peanut Council, 2016) and literature searches were initiated to identify where knowledge and training were needed. It was discovered that very little published information was available on the prevalence of *Salmonella* on peanuts as well as the times and temperatures needed to adequately inactivate the bacterium during roasting. This led to the approval and funding of two research studies.

Food and Drug Administration rules under the Food Safety Modernization Act (FSMA) require raw peanut handling facilities to report identified hazards, such as *Salmonella*, to their customers. Facilities that only store or handle peanuts are not required to apply preventive controls for *Salmonella*. However, notifications must be made up the supply chain until a customer with control capability, such as roasting, is reached. This facility would then be expected to include the control step in their food safety plan. A FSMA requirement, currently on hold, would require the controlling facility to communicate control actions taken back down the supply chain.

This article reviews the research studies commissioned by the American Peanut Council (APC) and related quantitative microbiological risk assessments and factors for decision making that risk managers at peanut and peanut product processing facilities should consider for hazard control measures. Factors considered include not only prevalence and concentration of *Salmonella*, but also inactivation treatment (roasting), product storage conditions and times, blanching, and amount of peanuts consumed raw. Additionally, what-if scenarios were explored to investigate the impact of varying levels of prevalence, concentration, and percent consumed raw.

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Review of Salmonella Research Studies and QMRAs

The first study reviewed in this paper was designed to establish various times and temperatures needed to reduce *Salmonella*. The inactivation study entitled "Effect of Oil and Dry Roasting Peanuts at Various Temperatures and Times on Survival of *Salmonella* and *Enterococcus faecium*" was conducted and published in *Peanut Science* (Sanders *et al*., 2014). FDA's guidance document entitled "Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient" states that "manufacturers of foods containing a peanut-derived product as an ingredient obtain peanut-derived product only from suppliers with validated processes in place to adequately reduce the presence of *Salmonella* spp. (e.g. by 5 logs)" (FDA, 2009).

A set of tables from the roasting inactivation study was made available to the peanut industry summarizing times and temperatures for various log reductions of *Salmonella* (Sanders *et al*., 2014) . These tables included data for both small and large runner and Virginia type peanuts, both oil and dry roasted. An example is shown in Table 1. Processors were urged to use the tables as guidance to set up validation studies on their own specific processes for approximating the time and temperature conditions preferable for their desired log reduction (for example, from Table 1, 146°C for 15 minutes for a 5.1 log reduction).

A second research study reviewed was performed to determine the prevalence and concentration of *Salmonella* on raw shelled runner and Virginia variety peanuts in the United States (Calhoun *et al.,* 2018). A total of 2,506 samples were analyzed over 7 crop years. The prevalence study resulted in 41 positives (1.63%) with concentration levels ranging from below the lower detection limit of 0.003 MPN/g to 2.4 MPN/g. Most samples with detectable *Salmonella* measured <0.03 MPN/g. The MPN method may underestimate the true numbers of microorganisms present in food due to clumping of cells, especially when the numbers are very low as in this case (Danyluk *et al*., 2006; Matner *et al*., 1990). In attempt to obtain enumerative data as close to the true level present as possible, the sample homogenate in this study was blended to promote the breakup of clumped cells (Calhoun *et al*., 2018). Regardless, the prevalence of *Salmonella* in raw peanuts is likely of greater significance than the low numbers present. There was a single result of 2.4 MPN/g that was significantly higher than any other result.

Table 1. Time and temperature, Salmonella log reduction on dry roasted small unblanched runner peanuts[a]

Oven temp		Roast time - minutes	Avg. log reduction
Deg-C	Deg-F		
129	264	30	3.5
		45	4.6
		60	6.5
138	280	15	3.7
		25	4.8
		35	6.9
146	295	10	3.7
		15	5.1
		20	6.0
154	309	10	4.7
		15	3.9
		20	3.9
163	325	10	6.0
		15	6.9
		20	6.9

[a]Data presented is an excerpt of data previously published in: Sanders, T.H., R.S. Calhoun. 2014. Effect of oil and dry roasting of peanuts at various temperatures and times on survival of *Salmonella* and Enterococcus faecium. Peanut Science. 41:65-71. Printed with permission.

Another key finding from this study was that the difference between the number of positive whole peanuts and positive split peanuts was statistically significant with splits having greater prevalence (Calhoun *et al*., 2018). Another study on raw peanut prevalence published in 2013, although confined to the runner variety only, yielded similar results for prevalence and counts (Miksch *et al*., 2013).

Using data from the American Peanut Council prevalence study, as well as collecting and providing data on other necessary variables, a quantitative microbiological risk assessment (QMRA) was performed (Casulli *et al*., 2019). Other necessary variables for a QMRA include factors that may contribute to the reduction of the pathogen, in this case, *Salmonella*. Factors in this QMRA included peanut storage times and treatments (blanching and roasting). Potential raw consumption was also included. Another important variable is the dose-response, the relationship of the amount of *Salmonella* consumed to illness produced (Casulli *et al*., 2019). QMRA uses statistics, mathematical models, and information about pathogen prevalence and concentration to simulate the probability of foodborne illness for a given food, hazard, and population of interest.

Although there is no established standard risk measurement, the chance of greater than one illness per year is often referenced. Key results from the QMRA statistical models included that under the

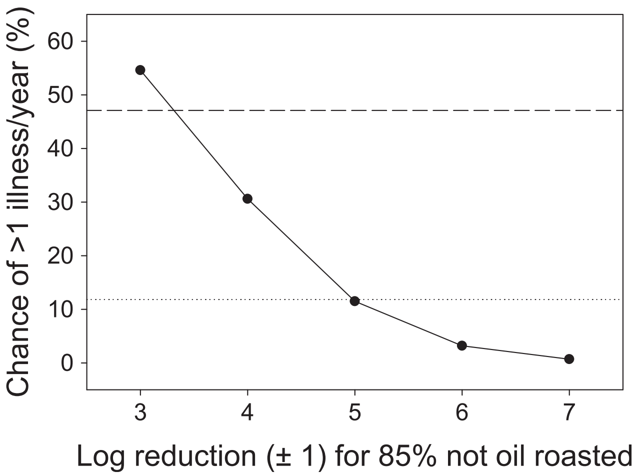

Fig. 1. Probability of more than 1 Salmonellosis illness per year as a function of the log reduction of the presence of *Salmonella*. Data previously published in: Casulli, K.E., S. Calhoun, and D.W. Schaffner. 2019. Modeling the risk of Salmonellosis from consumption of peanuts in the United States. J. Food Prot. 82:579-588. Printed with permission.

current baseline conditions that include the current assumptions of storage conditions, peanut processing conditions, and consumption patterns in the United States, as well as the measured *Salmonella* prevalence and concentration, the model predicts an 11.9% chance of greater than 1 illness per year from all U.S. peanuts. Statistical modeling showed that if the industry applied conditions for a uniform 4 ± 1 log reduction for dry roasting runner and Virginia peanuts the chance of greater than one illness per year from all U.S. peanuts would increase to approximately 30% (Figure 1) (Casulli *et al*., 2019). It should be noted that there is some degree of uncertainty associated with any QMRA. This is due to the potential variability in assumptions made for contributing factors as well as variability in measured data. Quantitative microbiological risk assessments are still a valuable tool for identifying and comparing risk management practices.

Risk Management Considerations

Now that risk assessment data is available, the challenge is to use this information to make valid risk management decisions regarding treatment conditions or other controllable factors. It is important to keep in mind that the risk assessment consolidates data from a wide variety of sources to make an estimate of the risks that apply to the entire industry. For example, the model uses variables such as the percentage of facilities applying 5 log reduction roasting, the percentage of facilities oil roasting for 7 log reduction, and an estimate of the number of facilities using unvalidated processes with less than 5 logs reduction (Casulli *et al*., 2019). Therefore, the baseline results are the calculations based on the proportional combination of these treatments. Similarly, applying the variable of storage times (another factor in the assessment), a range of times were possible based on surveys of storage facilities, so the model used a triangular distribution based on the range, not just one storage time value (Casulli *et al*., 2019). In this way all the possible variable values were integrated into the calculation. Blanching conditions were also included as a potential reduction factor for the estimated percentage of processors that incorporate this step (Casulli *et al*., 2019). Although peanuts are rarely consumed raw, the risk due to this consumption was also included in the calculations using an estimate of the percent of peanuts consumed raw (Casulli *et al*., 2019). So, the statistical modeling software uses the prevalence and concentration data, data from the above described variables, and total consumption data to calculate the estimated illness per year due to consumption of contaminated servings (Casulli *et al*., 2019).

One should keep in mind that the QMRA consolidates data from a number of processors and storage facilities to gauge the overall risk to the industry. Even though the results of the QMRA do not apply directly to any one specific facility, managers can make logical risk management decisions based on the indications in the data.

Generally, *Salmonella* reduction occurs during storage. (Casulli *et al*., 2019). Obviously, longer storage times would be beneficial in reducing the risk from *Salmonella*. However, processors and warehouse manager's incentives are to maintain inventory levels for "just-in-time" logistics practices in order to deliver fresh product. Consumer storage times simply vary depending on individual need with the freshness dates of consumer retail units dictating the maximum storage time. One can predict the range of storage times and associated reductions but control measures that increase storage would be counter-productive to the quality of peanut products.

Log reduction achieved from blanching was calculated using previously reported thermal inactivation data (Sanders *et al*., 2014) and common blanching time and temperature (Casulli *et al*., 2019). Varying these conditions significantly for risk management purposes would be counterproductive in achieving the function of skin removal. Products using blanched peanuts do so to meet product design requirements for quality.

Table 2. Scenario exploration results for no storage reduction, changed prevalence (prev), changed concentration (conc) and raw consumption patterns.[a]

Scenario variation	Details	Mean illnesses per year	Geometric Mean		Chance of greater than		
			log illness per year	illness per year	1 illness per year	10 illnesses per year	100 illnesses per year
					%		
Baseline	With storage	14.2	-1.91	0.012	11.9	3.3	0.7
	Without storage	153	-0.22	0.598	47.0	21.3	6.3
Prev[b]	All low, no high	5.5	-2.11	0.008	8.8	2.3	0.4
	Half low, half high	10.2	-1.80	0.016	13.3	3.9	0.9
	No low, all high	18.6	-1.51	0.031	17.1	5.4	1.2
Conc[c]	All low, no high	3.2	-2.01	0.010	10.5	2.5	0.4
	Half low, half high	85.5	-0.98	0.105	32.2	16.0	5.6
	No low, all high	260.0	0.05	1.120	55.0	30.3	10.5
Prev and conc[b,c]	Prev low conc low	2.9	-2.15	0.007	8.0	1.8	0.3
	Prev high conc low	9.2	-1.57	0.027	16.0	4.1	0.9
	Prev low conc high	115.0	0.12	0.767	51.1	25.9	8.0
	Prev high conc high	350.0	0.48	3.010	65.5	40.8	16.6
Raw Consumption	0% raw	5.4	-1.95	0.011	11.2	3.2	0.7
	0.5% raw	6.9	-1.94	0.012	11.7	3.4	0.6
	1% raw	11.0	-1.90	0.013	12.4	4.0	0.9
	5% raw	5.9	-1.95	0.011	11.4	3.0	0.6

[a]Data previously published in: Casulli, K.E., S. Calhoun, and D.W. Schaffner. 2019. Modeling the risk of Salmonellosis from consumption of peanuts in the United States. J. Food Prot. 82:579-588. Printed with permission.

[b]Means prevalence is defined as low ($\mu = 0.789\%$, $\sigma = 0.56\%$) or high ($\mu = 3.96\%$, $\sigma = 0.205\%$)

[c]Means concentration is defined as low (triangular: 0.0012, 0.0219 and 0.0708 MPN/g) or high (triangular: 0.42, 2.4 and 10 MPN/g).

What-if scenarios were modeled to estimate probability of illness if some of the variables were different than actually measured. This allows risk managers to assess the impact for conditions that they may be able to control or change as well as natural variables (such as prevalence) that may vary from year to year. Table 2 summarizes the results of the what if scenarios (Casulli *et al.*, 2019).

Looking at the table we can make some interesting observations. First, if there happens to be a period of time where prevalence is low, as you would expect, there is a significant reduction in predicted illnesses (Casulli *et al.*, 2019). However, prevalence is not routinely measured and there are limited actions product processors can take to reduce raw peanut prevalence. Good agricultural practices such as use of pathogen free seeds, exclusion of animals from crop fields, sanitary agricultural water, and proper storage and transportation are used to reduce field and harvesting contamination. Chapter 1 of the American Peanut Council Good Management Practices reinforces these practices and can be recommended by processors to their suppliers (American Peanut Council, 2016).

Looking back at the prevalence study it was found that shelled split peanuts had a higher prevalence than whole peanuts (Calhoun *et al.*, 2018). This may be due to the fact that splits are the result of kernels that separate during harvest or processing, or result from damaged kernels, exposing more surface area to the environment for a longer period of time. A potential risk management decision may be to treat production lots of split peanuts at a higher level than production lots of whole peanuts. Removal of damaged kernels using high efficiency sorting equipment could also be an effective measure.

Similar to prevalence, there are few practical controls that peanut product processors can apply to control incoming raw peanut *Salmonella* concentration. Important to note here, though, is that the result of 2.4 MPN/g is rare. It only happened once in 2506 samples over 7 years of representative sampling (Calhoun *et al.*, 2018). Without that high lot, the predicted risk would be lower. When determining treatment levels risk managers may want to take into consideration that the predicted arithmetic mean number of illnesses per year drops from 14.2 to 3.2 if the rare concentration level does not occur (Casulli *et al.*, 2019), still recognizing that rare spikes in the level of contamination may occur. Their decisions can be based on product design criteria, relative confidence in the supplier, crop year quality, and risk tolerance.

Looking at another important result as indicated in figure 1, the predicted chance of >1 illness per year increases from 11.9% to 30% if the industry were to change from a 5-log reduction to a 4-log reduction for all dry roasted peanuts (Casulli *et al.*, 2019). Risk managers should take note that this is an indicator of significantly higher risk and certainly should be taken into consideration. For example, if there are no compelling product design requirements, a minimum validated 5-log reduction, currently used by most processors, would be lower risk than a 4-log reduction. Of course, product design and additional processing may play an important role in these decisions. An example is found in peanut brittle. Many peanut brittle producers favor a light roast peanut that would likely require less than 5-log roasting conditions for the peanuts. However, the temperature of the caramel matrix used in the process of making brittle would likely be high enough to result in additional log reduction conditions to the surface of the peanuts, the likely location of *Salmonella* contamination. A process validation study could confirm this.

Processors that have not performed a validation study should consider that by not having data regarding their log reduction they are running with the potential risk of not adequately reducing the presence of *Salmonella* spp. as recommended in the aforementioned FDA guidance (FDA, 2009).

Another factor to consider is the variability of a process. Log reduction calculations in the APC risk assessment all assumed variability of ± 1 log (there was no published data found on log reduction variability for roasted peanuts) (Casulli *et al.*, 2019). If a processor were to measure and reduce the log reduction variability, the result may be a lower risk level. It is important to note that the measured log reduction is an average. Some nuts in a process will receive a higher log reduction than the average. Other peanuts that receive a lower reduction than the average will be at the highest risk of *Salmonella* survival. Processors can use oven profile studies to establish variability related to oven performance and relative location of peanuts during conveyance through the roaster. Efforts can be made using this data to reduce the magnitude of the variability as well as apply the greatest possible log reduction cycle consistent with color and flavor objectives.

Looking at raw peanut consumption patterns in Table 2 we see a reduction in the arithmetic mean illnesses per year from consumption of 1% to 0.5% to 0% of 11.0 to 6.9 to 5.4 respectively. It would therefore make logical sense to keep raw consumption as low as possible. Larger shellers are now limiting sales of raw peanuts to retail to help manage this risk. Proper cautionary labeling on retail packages of raw peanuts can also help manage this risk.

Other quantitative microbiological risk assessments that may be of interest to peanut risk managers have been performed on almonds. An almond assessment published in 2006 suggested that treatment with polypropylene oxide (PPO) as well as other treatments were promising toward controlling the disease risk associated with consumption of raw almonds (Danyluk *et al.*, 2006). United States regulations implemented in 2007 require all California-grown almonds sold in North America to be processed with a treatment capable of achieving a minimum 4-log reduction in *Salmonella* (Almonds grown in California: outgoing quality control requirements, 2007). An assessment published in 2012 established that the regulation is effective in maintaining the risk of salmonellosis from consumption of raw almonds below an arithmetic mean of 1 case/year (Lambertini *et. al.*, 2012). These studies show that treatments other than roasting, such as PPO, can be effective in controlling salmonellosis risk in almonds. However, there is little incentive for application of these treatments to peanuts as peanuts are rarely consumed raw. Processors that wish to sell raw peanuts directly to consumers or at retail stores may want to consider investigating non-roasting treatment methods to reduce the risk to consumers who may buy raw peanuts to cook at home.

Summary and Conclusions

No product is risk free. Even though suggestions have been made in this article regarding risk management decisions, only the managers of a specific facility can make these decisions, taking into consideration data from the studies and QMRA, the type of products made, and the company's risk tolerance. A company may consider performing a customized risk assessment based on their specific business to make more focused decisions. However, these assessments can be very expensive and time consuming.

One should also always keep in mind the FDA regulation on adulteration (Adulterated Food, 2011). If a product at retail is discovered to be positive for *Salmonella*, it is considered adulterated and is subject to enforcement actions including recall. A deliberate, well thought-out food safety plan and risk analysis can go a long way to protecting consumers from illness and protecting a company from regulatory action.

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