Comments on the Food and Drug Administration
Draft Risk Profile: Pathogens and Filth in Spices

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PURPOSE

I was asked to prepare a scientific review of the Food and Drug Administration's (FDA) Draft Risk Profile (DRP) on Spices, released October 30, 2013, with the express purpose of submitting my report to the FDA docket on this issue. In particular, I was asked to provide a scientific assessment whether FDA has appropriately characterized the risk that spices present regarding incidence of foodborne illness in the United States, whether there are any significant gaps in the FDA's DRP, whether or not FDA has appropriated characterized the industry's mitigation strategies, and any other scientific recommendations I may have as a result of my review. My scientific assessment is below. I am also attaching a copy of my CV so that FDA may have this information as part of the agency's official record of these proceedings.

EXECUTIVE SUMMARY

The Draft Risk Profile conducted by the FDA provides excellent data on the microbiological quality of spices, and fills a data gap within the public domain. However, the majority of the data represents spices before any mitigation treatments have been applied, either by the spice industry or by the food industry or both after incorporation into multi component foods. Because of this, it does not represent the actual consumer exposure to harmful microorganisms from spices. There are many foods which may be contaminated in their raw, unprocessed state which are then subjected to further processing to reduce human exposure, and spices fall in to this category. For this

reason, as well as others stated below, the risk of foodborne illness from consumption of spices would be much lower than that suggested by the FDA in the DRP.

Although they are widely used in foods, spices have been associated with very few foodborne disease outbreaks and FDA recalls. There have been three outbreaks associated with spices in the last 10 years, and one of those involved a product which may not meet the definition of a spice (broccoli powder). For comparative purposes, the Centers for Disease Control and Prevention (CDC) reported over 13,000 outbreaks of foodborne illnesses during a similar, but not identical, 10 year period. During the 4 year period when the three outbreaks actually occurred, the three outbreaks in total accounted for 0.33% of the total estimated foodborne salmonella cases during this time period.

The current laboratory methodology used to analyze spices for microbial contamination has inherent weaknesses, primarily because of the antimicrobial properties of some spices. It is appropriate to review these methods to assure that both the accuracy and precision as well as the results are the best achievable with the current state of the technology.

A quantitative risk assessment of the potential burden of foodborne illness from spices would provide additional information and perspective on the issue. Much of the data is already available, and additional data could be obtained relatively quickly, through a partnership of government, industry and academia. A similar approach was used in the development of the quantitative risk assessment for *Listeria monocytogenes* in deli meats.

Although only incomplete data is available, it would appear that there is essentially no difference in the risk of illness between a 3 $\log_{10}$ and a 5 $\log_{10}$ microbial mitigation process as applied to spices, based on the “worst case” data from the FDA Draft Risk Profile.

Comment by Sections

2. Foodborne Illness Outbreaks from Microbial Contaminants in Spices, 1973-2010

2.2 Outbreaks in the United States

The FDA identified three outbreaks attributable to spices in the United States during the 37 year period of 1973 to 2010, and an additional eleven outbreaks in other countries, for a total of 14 outbreaks attributable to spices in 37 years. It is acknowledged that food safety systems vary widely throughout the world, so direct comparisons of outbreaks in other countries, in comparison to the United States, may or may not be appropriate.

If we look just at outbreaks in the United States, it is difficult to ascertain the total number of foodborne outbreaks in the U.S. during this 37-year time period, although the Centers for Disease Control and Prevention (CDC) reported that there were 13,405 foodborne disease outbreaks during the ten year time period of 1998–2008 (Gould et al., 2013). Based on the available data, three outbreaks in the U.S. attributed to spices out of 13,405 total outbreaks would suggest that spices were responsible for only 0.02% of the total outbreaks ([3/13,405] * 100) in the U.S. during this ten year period, perhaps a more appropriate yardstick than the 37 year time period used for this risk profile. It certainly suggests that spices were not a leading cause of foodborne disease outbreaks in the United States.

Two of the three outbreaks occurred with a product that is known to be occasionally contaminated with salmonellae (pepper), while the third outbreak was attributed to broccoli powder, which may be more properly thought of as a seasoning, and may not meet the definition of spice as used in the FDA Risk Profile. That definition reads:

“any [dried] aromatic vegetable substances in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant

function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed".

Therefore, if the outbreak associated with broccoli powder is removed, the percentage of outbreaks associated with spices in the U.S. over the 10-year period is 0.015%. ([2/13,405] * 100)

The root cause failure of many foodborne disease outbreaks can be summarized as contaminated ingredients, improper process control, process failure or post-processing environmental contamination. For example, only one of the three outbreaks involved pepper that might (or might not have) have been treated with a mitigation process before use. The investigation was unable to confirm the details of the mitigation process. Since the details of the actual process the spices underwent prior to the outbreak are not fully understood, it is hard to ascribe a specific cause to these outbreaks. There have only been three outbreaks in the United States, these have occurred within in the last 10 years, and the root cause failures that resulted in the outbreaks are not fully understood.

2.4 Public Health Burden

The FDA Draft Risk Profile estimated the public health burden as 13,400 cases. The data presented in Table 2.1 indicates that there were 457 reported cases in the United States, based on a four year time period between the broccoli powder outbreak in 2007 and the two pepper outbreaks which began in 2008 and continued through 2010. The estimated cases are calculated by applying the underreporting factor of 29.3 (Scallan et al., 2011a). All of the outbreaks were caused by Salmonella spp.

The CDC estimates that there are approximately 1,027,561 cases of foodborne salmonellosis every year (Scallan et al., 2011a), or 4.1 million cases during the four year time period which includes 2007 and 2010. The percentage of these cases

attributable to spices during this time period would be 0.33% ([13,400/4,100,000]*100]. Given that spices and seasonings are included in a very wide variety of foods, the US population has a very great exposure to spices, albeit in low concentrations. This would suggest that if spices were a significant source of foodborne illness, reported illnesses attributable to spices would be much more frequent.

2.6 General Observations

There were fourteen outbreaks between 1973 and 2010, with only 3 in the United States. Six of the fourteen outbreaks occurred prior to 2000. It is difficult to determine the relevance of these earlier outbreaks, as the interest in food safety, especially in produce and field crops, has dramatically increased in the last decade. As a result, both the regulatory process and the industry evaluate risks in plant products much differently than they did twenty years ago. This again points to the ten year period as being the most appropriate for this risk assessment.

It is impossible to determine the total number of foodborne outbreaks in all of the countries which experienced outbreaks attributed to spices, but based on the U.S. data, spices would constitute a minor portion of the total number of outbreaks. The difficulties in determining the sources of foodborne outbreaks are well documented (Scallan et al., 2011b). However, the available data suggests that if spices were contributing to a larger portion of the overall burden of foodborne illnesses, more outbreaks would have been detected and reported during the time in question, whether it be 10 years or 37 years.

Attributing foodborne illnesses to a specific commodity is often difficult. However, a review of two attribution sources indicates that spices have a very low impact on the overall burden of foodborne illnesses. The Center for Science in the Public Interest has reported on the number and sources of outbreaks over a ten year period (CSPI, 2013). They reported a category of “nuts/dried spices”, without any further separation. However, between 2001 and 2010 the nuts/dried spices category were responsible for

14 of 2,874 reported outbreaks, or 0.49% [(14/2874)*100]. This category was responsible for 2.87% of the total cases [(2,039/70,989) *100]. Since the data set used to create the CSPI report is not readily available, it is difficult to confirm how many of the reported outbreaks were “nuts” compared to “dried spices”. However, this ten year period included the three outbreaks mentioned in the FDA’s Draft Risk Ranking report (2 pepper and 1 broccoli), so it is likely that the remaining 11 outbreaks would have been attributable to nuts. The attribution report published by the Center for Disease Control and Prevention (Painter et al., 2013) did not specifically mention spices, but did include a category of “fruits – nuts”. This report attributed 6.3% of the bacterial illnesses between 1998 and 2008 to “fruits – nuts”.

Direct comparisons between the CSPI report and the CDC report are not possible, because they cover different time periods and use different methods. However, if the “fruits” and “nuts/dried spices” categories in the CSPI report are combined, the number of cases attributable to this combined category would be approximately 7.98% [(5,688/70,989) * 100]. From a risk ranking perspective, spices would appear to be of less concern than other food products.

4. Prevalence and Concentration of *Salmonella* and Filth in Spices

4.1.3.1 Salmonella in shipments of spice offered for import into the United States

The FDA has done an impressive of surveying imported spices for the presence of salmonella. The concern is that most of the samples were collected at or near the port of entry, prior to any cleaning and/or mitigation strategies being applied. It is common practice in the industry to apply cleaning and or mitigation strategies to imported spices, as appropriate based on the past history of the spice and international source. Therefore, while the FDA survey does provide a snapshot of the status of imported spices, it is not likely representative of the actual spices as they are delivered for retail purchase.

The FDA Risk Profile states:

"The larger prevalence of *Salmonella* in imported shipments of spices as compared with other imported FDA-regulated foods can be surprising to some because the low water activity of spices does not support *Salmonella* growth, whereas the high water activity of some other imported FDA-regulated foods will support growth"
(Section 4.1.3.1 SALMONELLA IN SHIPMENTS OF IMPORTED SPICE OFFERED FOR ENTRY TO THE UNITED STATES, page 38)

Unlike many imported foods, such as seafood, fruits and vegetables, it is common industry practice to apply aggressive cleaning strategies to imported spices. In addition, there are effective mitigation strategies (steam, ethylene or propylene oxide gas or irradiation) which are routinely used by the spice industry to address microbial contamination in spices. While not applied to all imported spices, these mitigation strategies are generally effective in reducing potential microbial contamination, and are applied as necessary to achieve the desired technical effect. In addition, the majority of imported spices are incorporated into further processed multi-component foods, which undergo processing before reaching the consumer. Many of these processes are also effective in controlling microbial contamination. Comparing imported spices to all imported foods at the port of entry does not accurately reflect the additional processing that spices routinely undergo by both the spice industry and food processors in the United States before being delivered for retail purchase.

A second point of consideration is that the analytical methodology used for the detection of salmonella in the samples simply reports presence/absence, although the FDA did enumerate the salmonella populations in some samples. The low water activity would in fact limit the growth of Salmonella spp., which has a nominal a_w for growth of 0.94 (ICMSF, 1996). This would certainly support the contention that salmonella does not grow in spices, and that the presence of salmonella in spices at the port of entry is attributable to environmental contamination during the production and harvesting of the spices, and not attributable to growth. Therefore, the hazard at the port of entry is

stable, and will not increase unless the spices are mishandled during transportation and storage. It also means that effective treatments in the United States can provide adequate control for these hazards before the spices reach consumer shelves.

It is well known that the methodology of detecting and enumerating salmonellae in spices is challenging, as some spices naturally possess antimicrobial properties which may interfere with the assay methods. It would appear that there is a need for improved methodology for the microbiological analysis of spices, perhaps taking advantage of immuno-capture and PCR technologies, which may reduce the variability and increase the sensitivity of the assays. The development of improved methodologies could be undertaken by FDA alone, or in partnership with ASTA and academia.

Table 4.3

The data reported in Table 4.3 for specific spices ***may*** support a risk ranking system for which spices are treated and which are not. In addition, industry data which has already been provided by ASTA members to FDA for the purposes of the Draft Risk Profile provides an historical basis for the presence of Salmonella spp. could be used to add to this risk ranking system. The FDA data is from 2007-2009, while the industry data would provide a much greater time frame, and could be used to evaluate temporal trends.

Spices Subjected to a Pathogen Treatment

The FDA Draft Risk Profile states:

"Spice shipments which were classified as "commercially sterile", "heat treated", or "irradiated" or for which the industry supplied product description specified that a pathogen reduction process treatment had been applied to the spice (for example, "steam treated" or "treated with ethylene oxide") were grouped together in Table 4.3 as "Spices subjected to a Pathogen Reduction Treatment." Page 40

In section 2, the report suggests that not all steam treatments are equivalent, and that "steam washed" may be used to address filth and not microorganisms. It would be helpful if more information could be provided on the nature of the samples which tested positive, to determine if this was the result of an inadequate process, or the result of a process failure, as the answer to that question would help direct us to effective steps to address the issue.

Antimicrobial Resistance

Antimicrobial resistance is a growing issue in human and animal medicine. The FDA report follows standard accepted procedures for determining the antimicrobial resistance of the strains of salmonella isolated from the spics. However, the question that this information raises in the context of a Draft Risk Profile for spices is one of relevance. Of the strains showing resistance to various antimicrobials, how many of the antimicrobials would be used in human medicine to treat clinical salmonellosis? That is, the only way antimicrobial resistance can lead to a treatment failure is if the antimicrobial is used to treat the illness. If the antimicrobial that the salmonella strain is resistant to is not used, then resistance does not affect clinical outcome. While the antimicrobial resistance data is interesting, it should be provided in the context of clinical applications of antimicrobials to treat human salmonellosis.

Salmonella concentration in shipments of imported capsicum and sesame seed offered for entry to the United States, Aug-Dec 2010. Page 48

These data, combined with the historical data that the industry may be able to provide, may support a risk ranking system for imported spices, applying mitigations to selected spices known to have more frequent salmonella contamination. In practice, the industry appears to have an informal system already in place. This may provide an opportunity to formalize this ranking system across the industry.

Table 4.10 makes a compelling case for the current practices of the spices industry.

"**From 1969-2003, FDA identified 20 primary recalls of spices, all of which were because of *Salmonella* contamination** (Vij *et al*., 2006)." (page 57)
This is certainly true, but requires some additional context. Between 1 June and 2 Dec 2013, FDA (2013) reported approximately 130 recalls for human foods and dietary supplements, or approximately 21 recalls per month. If this were extrapolated over the 34 year period covered in the Draft Risk Profile, and there are obvious shortcomings with this extrapolation, that would be approximately 8,500 recalls in 34 years (34 years * 12 months * 21 recalls per month). Twenty recalls in 34 years is approximately 0.6 recalls per year, or 0.23% of the total ([20/8,500] * 100).

5. Characterization of Contaminants

5.1 Salmonella

Figure 5.6. WHO/FAO dose response curve.
The dose response curve supports the contention that very low levels of exposure are unlikely to result in illness, even in the upper 2.5% of the sensitive population. The FDA's survey of spices at or near the port of entry indicated very low populations, well under 1 cell per gram (Table 4.8, pages 49-50). The highest mean shipment concentration was found in sesame seeds, and the population was 0.042 MPN/gram, with a 95% confidence interval of 0.020 to 0.088 MPN/gram. Extrapolating these populations to the 350 gram composite samples which were analyzed, this would be 14.7 cells/350 grams, with a 95% confidence interval of 7 MPN/350 grams to 30.8 MPN/350 grams. The models shown in Figures 4.1 and 4.2 support the fact that *Salmonella* contamination, when it occurs in spices, occurs at very low populations; not cells per gram but grams per cell. Given the low populations enumerated in the samples, and the low risk of exposure (based on the small quantity of spices actually consumed), this data suggests that the consumer exposure even from untreated spices is very low. The subsequent processing which is commonly applied to spices, both by

the spice industry and the food industry in general, should also be factored in to this to determine the true consumer exposure.

6. Overview of Spice Farm-to-Table Continuum and Potential Sources of Pathogen and Filth Contamination

6.1 Primary Production

Many spices originate from economically under-developed parts of the world. Applying modern production standards and practices (GAP's) to some of these areas would be difficult if not impossible. Spice producers are unlikely to change existing practices to meet the expectations of a single consuming country. As an example, the data obtained by the American Spice Trade Association shows that more than 92% of India's red chile production is consumed domestically in India, with only 3% exported to the United States. The opportunities to make changes in the production practices are therefore extremely limited, given the relatively small percentage of the export market in the overall production.

6.3 Secondary Processing and Multi-Component Food Manufacturing

The FDA report states:

"Based on conversations with ASTA, we know that a majority of spices in U.S. commerce are used by food manufacturers as ingredients in the production of multi-component foods." Page 79

This statement is significant for several reasons. When spices are incorporated into multi-component foods, they are subject to buyer's specifications and inspection,

including analysis for salmonella. That is, in many cases spices are tested prior to incorporation into the multi-component foods. Secondly, “the majority of spices” may well be greater than 90% of the spices imported in to the United States, although the exact percentage is difficult to ascertain. This means that, in addition to the processing commonly performed by the spice industry, the majority of the spices will be subjected to secondary treatment before reaching the consumer.

Many multi-component foods undergo significant processing before being sold for consumer purchase. Many of these commercial processes are designed to control microbial pathogens which may occur in the raw materials, whether these raw materials are of animal or plant origins. As a result, the majority of spices, some of which may have already been subjected to mitigation strategies by the spice industry, are subject to a mitigation during incorporation into multi-component foods. Again, this greatly minimizes the risk from a public health perspective.

As an example, spices are used as a flavoring component in processed meats. Processed meats undergo a lethality (thermal) process sufficient to eliminate salmonella from the meat. The one outbreak associated with processed meat involved spices which were applied after the lethality process. Immediately after that outbreak, the USDA-FSIS issued a directive to its inspection staff requiring that any ingredients added after the lethality process be demonstrated to be free of pathogenic microorganisms, and especially salmonella. (Notice 01-11, reissued as Notice 08-12 and Notice 31-13; USDA-FSIS 2013). This Notice specifically requires that the Inspector verify:
“That the establishment is checking that its purchase specifications are met, for example, through certificates of analysis or other forms of documentation establishing the safety of the ingredients, spices, or sauces that it adds to the product, and that the establishment performs any verification testing it has identified as necessary”.
While no inspection system is flawless, USDA-FSIS is responsible (by many estimates) for approximately 20% of the US food supply, and this directive greatly minimizes any risk the public health risk of spices used in FSIS regulated foods..

Finally, many multi-component foods are not ready to eat, and are heated by the consumer prior to consumption. As an example, consider a frozen food which is heated by the consumer prior to consumption. While this does not make the consumer the critical control point in the process, it does further reduce the risk of exposure to salmonella from multi-component foods containing spices, by applying some form of thermal processing prior to consumption.

6.4 Retail/End User

Products (including spices) intended for direct sale to consumers are subject to product specifications, which do include the absence of pathogenic microorganisms. The FDA would in all probability consider the presence of salmonella in retail spices to be grounds for a Class 1 recall. Both the spice industry and retailers are motivated to assure that these retail spices are appropriately treated prior to retail sale to prevent consumers from getting sick and to prevent recalls.

7. Spice Production and Consumption

Table 7.4 Consumption in Grams per day.

The total estimated consumption from Table 7.4 is 6.65 g/person/day, or approximately 2.2 grams per person per meal (6.65 grams/3 meals per day). This data should be evaluated in the context of the populations of salmonella enumerated in the spices before treatment by the spice industry (Table 4.8), the WHO/FAO dose response curve for salmonella (Figure 5.6), and that the majority of spices are used in multi-component foods, which are subjected to processes which are lethal to microbial pathogens. Taken in that context, the consumption data supports the concept that very low populations of salmonella in spices, prior to subsequent treatment by the spice industry and the food industry, combined with the expected dose response curve, would result in a very low consumer exposure by spices. Even at the upper end of the confidence intervals (9

MPN/100g) for spices at or near the port of entry, the average consumer would be exposed to 0.59 cells per day. This does not consider the application of mitigation strategies applied directly to the spices, testing of the spices by the spice processors or purchasers, of further lethality processes which may be applied by either the food manufacturers or consumers prior to consumption. The exposure data, based on the expected processing which would subsequently occur after the point at which FDA sampled, would further reduce that risk. This data is consistent with the relatively low number of reported recalls, outbreaks and attribution of foodborne illness to spices. The data in total support the concept that spices represent a much lower risk of foodborne illness than suggested by FDA.

8. Current Mitigation and Control Options

8.2 Industry Programs

8.2.2 Industry Guidance from Trade Organizations on Practices Impacting Food Safety of Spices

The American Spice Trade Association has developed guidelines or best practices documents for spice processors. The industry has recognized the importance of these practices, and many have adopted or incorporated these into their standard practices. The declining trend in inspection citations would suggest that more processors are following the guidance documents.

9. General Conclusions and Potential Future Mitigation and Control Options

FDA states in its report:

“Most spices consumed in the United States are imported. The overall prevalence of Salmonella-contaminated shipments of imported spice offered for entry to the United States was 6.6% (750 g sample size; 95% CI 5.7-7.6%) for FY2007-FY2009. This value

is 1.9 times (95% CI 1.6-2.3) the prevalence found for other shipments of FDA-regulated foods examined during the same period. Salmonella was found in shipments of many different types of spices, in a variety of forms (whole, cracked, ground or blended) and from many different countries. As a result, we conclude that the presence of Salmonella is a general problem in the spice supply chain rather than a problem of a specific type/form of spice or source country." Page 126

It was noted previously that the majority of spices undergo vigorous cleaning and treatment steps after entry, and many, based on past history, are subject to mitigation strategies both by the spice industry and the food industry in general. Do the other imported foods that FDA is using for comparative purposes follow the same processes? If not, then the blanket statement that imported spices are "1.9 times" more likely to be contaminated with salmonella is an improper comparison. As stated previously, it is taking the data out of context.

A similar analogy might be to that of raw milk. Raw milk in bulk tanks on the farm will occasionally contain pathogens and filth. However, the risk to human health would not be adequately represented by using the incidence of pathogens in bulk tanks, as most milk undergoes substantial further processing. Mitigation strategies, in the form of pasteurization and subsequent processes, such as fermentation dramatically reduce the incidence of pathogens in dairy products. Perhaps a more appropriate point of reference for the risk of dairy products to human health would be at the point of human exposure (retail or food service), rather than at the bulk tank on the farm.

Imported spices, at the point of entry, will in most instances undergo further processing by the spice companies, much like raw milk. The majority of these spices will also undergo subsequent processes as a part of multi-component foods (e.g., a spice blend added to a sausage batter that will be fully cooked before distribution). Much like milk, perhaps a better point of reference in regard to the potential risk to human health would be at the point of human exposure (retail spices or multi-component foods) and not at the port of entry.

9.2.1. Primary Production

See comments from Section 6.1

10. Data Gaps and Research Needs

It may well be worthwhile to conduct a quantitative risk assessment, as a supplement to the Draft Risk Profile. This would estimate the risk of spices in the context of the overall burden of foodborne illnesses, and may also provide additional data on the attribution of foodborne illnesses to spices.

The basic steps in the framework for risk assessment are hazard characterization, release assessment, exposure assessment and consequence assessment, which are then used to estimate overall risk (Codex, 2001; USDA, 2013). In the case of spices, the existing draft risk profile provides an excellent hazard characterization, as well as some components of the release assessment. The additional data that would be needed to complete the release assessment would involve gathering data from some of the steps outlined in Figure 6.1 in the draft risk profile. The samples reported in the Draft Risk profile were collected at or near a point between “Arrive in U.S.A.” and the different “Transport” steps. Additional data would be needed on the volume and microbiological status of product tested and released without a microbial mitigation step, the volume and microbiological status of the products subjected to a microbiological reduction process, and the volume and microbiological status of the products which were neither tested nor subjected to a microbiological reduction process.

The most significant lack of information appears to be at the exposure assessment level. The exposure assessment is essentially captured in Figure 6.2. Again, the data which would need to be collected to complete this would include the volume and microbiological status of the spices moving through each pathway to the consumer. It

would also be important to understand what additional microbial reduction processes would be applied by the food manufacturers, and what buyer's specifications and testing protocols are commonly used for many of the groups listed in Figure 6.2.

A quantitative risk assessment would also allow a determination of recommended microbial reduction processes to achieve an appropriate $\log_{10}$ reduction in the population of salmonellae. It would also estimate the impact of various microbial reductions throughout the process, which would include mitigation steps applied by the spice industry, mitigations applied indirectly through further processing by the food manufacturing industry, and mitigations applied indirectly by the consumer (e.g., adding spices to soups or stew prepared and cooked at home).

As an example, if the worst case reported by FDA (0.042 MPN/gram) and the daily consumption data assumed to be 100% of the worst case (6.65 grams at 0.042 MPN/gram), what would be the $\log_{10}$ reduction needed to reduce this risk by 1000 fold? The following figures show a simplistic approach to illustrate the process which might be used to determine the necessary log reduction, which could be greatly refined with a quantitative risk assessment.

Figure 1 simply illustrates the worst case scenario, as reported in the draft risk assessment. In this case, no reduction was applied, although it is recognized that the majority of the spices are subjected to some form of microbial reduction process, either by the spice industry, further processors, or to a degree by the consumer. The salmonella population was modeled as a triangle distribution, using the mean and 95% confidence intervals reported in the draft risk profile (0.02, 0.042, 0.088 MPN/gram). The consumption was modeled using a triangle distribution with 50% variability in daily consumption (3.33, 6.65, 9.98 grams per day) over 1 year. 95% of the time, the total consumption over 1 year would be less than 200 cells. Assuming that an individual in the highest risk category (lower 2.5%) received the yearly exposure of all 200 cells in a single serving (and there are no data to support that assumption), the probability of

illnesses would be approximately 0.25 (1 in 4) based on the WHO/FAO dose response model shown in Figure 5.6.

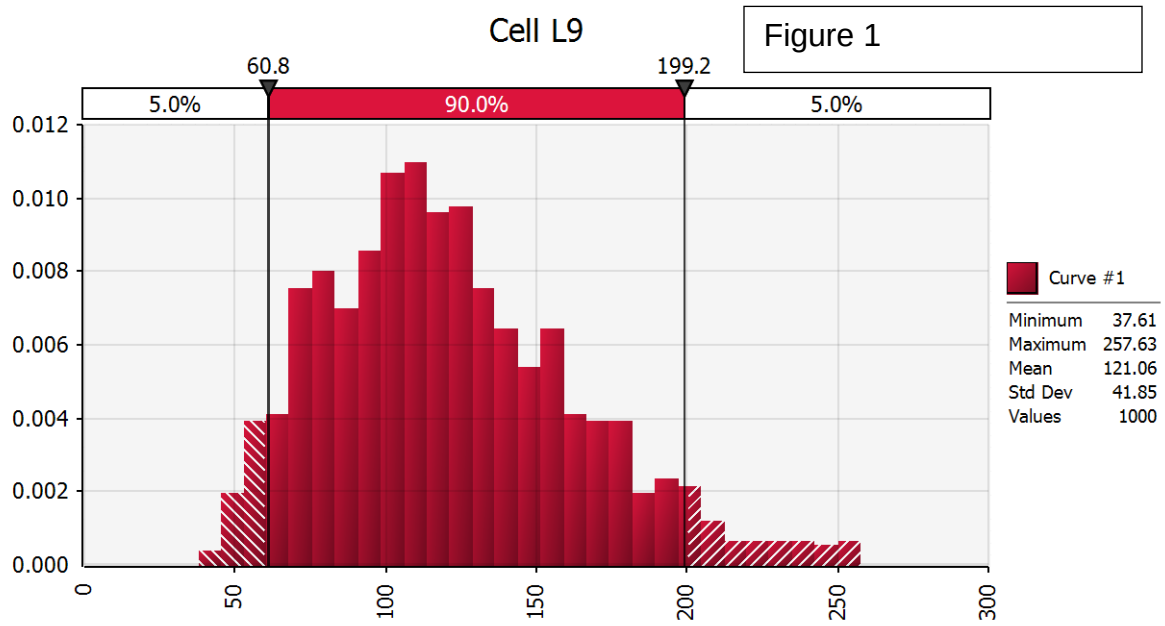

Figure 2 illustrates the same scenario as above, but with a 3 $\log_{10}$ reduction applied to the spices and 25% process variability (triangle distribution, 750, 1000, 1250 cell reduction, corresponding to a 2.87, 3.0 and 3.1 $\log_{10}$ reduction). The consumption was modeled using a triangle distribution with 50% variability in daily consumption (3.33, 6.65, 9.98 grams per day) over 365 days. 95% of the time, the total consumption over 1 year would be a negative 1.5 million cells. To place this in context, approximately 211 Americans (based on a population of 317 million) would be exposed to a single cell during the course of 1 year. Based on the WHO/FAO dose response model shown in Figure 5.6, the probability of illness if all 211 people were in the highest risk segment of the population (lower 2.5%) would be essentially zero.

Figure 2

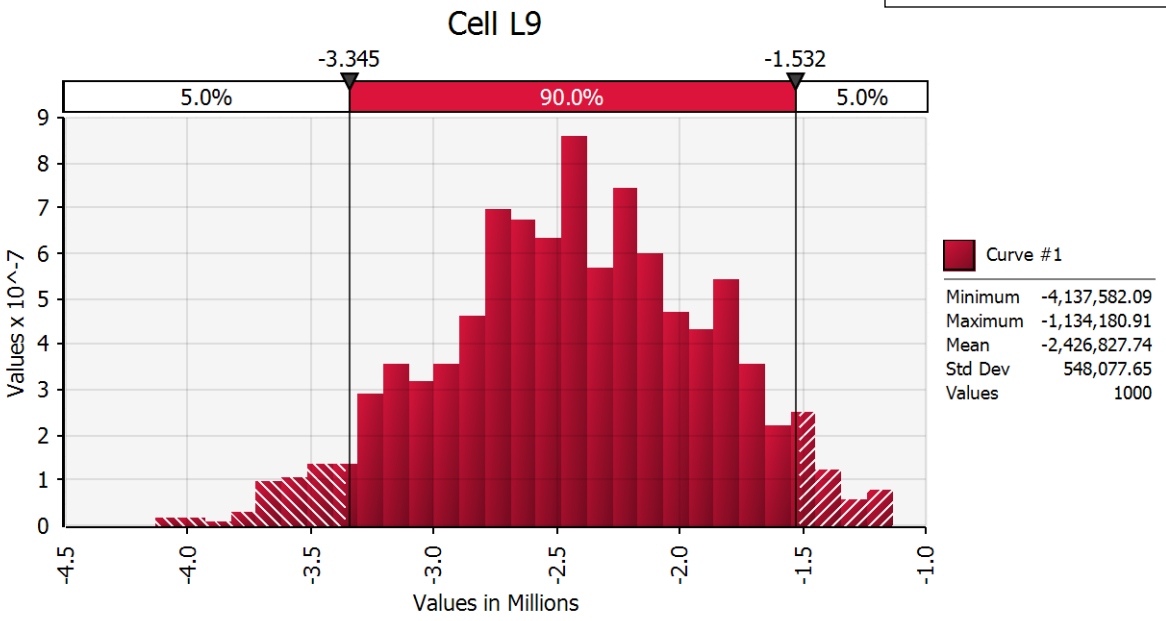

Figure 3 illustrates the same scenario as above, but with a 5 $\log_{10}$ reduction applied to the spices and 25% process variability (triangle distribution, 75,000, 100,000, 125,000 cell reduction, corresponding to a 4.87, 5.0 and 5.1 $\log_{10}$ reduction). The consumption was modeled using a triangle distribution with 50% variability in daily consumption (3.33, 6.65, 9.98 grams per day) over 365 days. 95% of the time, the total consumption over 1 year would be less than a negative 152 million cells. To place this in context, approximately 2 Americans (based on a population of 317 million) would be exposed to a single cell during the course of 1 year. Based on the WHO/FAO dose response model shown in Figure 5.6, the probability of illness if both people were in the highest risk segment of the population (lower 2.5%) would be essentially zero. From a practical standpoint, there is essentially no difference in the risk of illness between a 3 $\log_{10}$ and a 5 $\log_{10}$ microbial mitigation process as applied to spices.

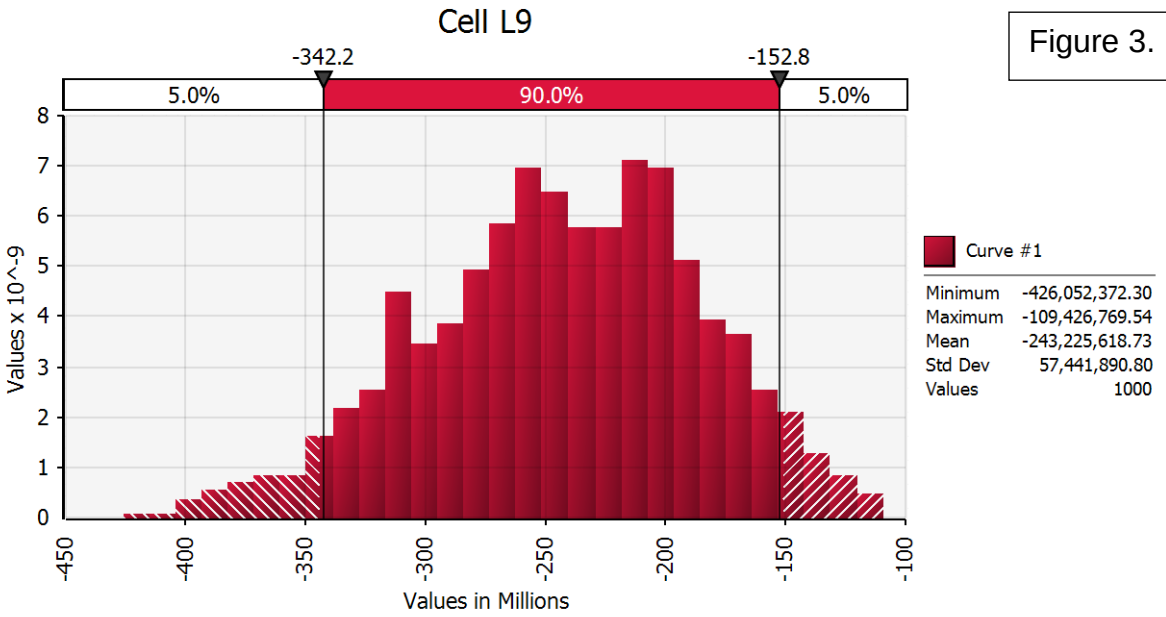

Figure 3.

Much of the data required for a quantitative risk assessment already exists, either from FDA's own data, or from industry data, which could be obtained for a project such as this. This would allow a more precise estimate of the risk posed by spices in the food chain, and would help in the decision-making process regarding the allocation of resources to addressing the overall burden of foodborne illness.

Additional Data Gaps:

The Draft Risk Profile raises a number of questions, which could be addressed by further data gathering. These include, in no particular order

1. What is the frequency of salmonella in spices presented at retail to consumers? That is, what is the direct human exposure to salmonella from spices? This is probably the single biggest gap in FDA's DRP which, as noted above, relies too heavily on testing of spices before, not after, treatment.
2. What is the frequency of salmonella in spices at the food processor level for multi-component foods? This data should already exist, as most food processors would have some testing data. The data might be accessible, if a

format was developed which would assure the anonymity of the submitting company. For example, various trade associations could try to obtain that information form their membership.

3. What is the frequency of salmonella after processing by the spice companies? ASTA has already provided some data, and there may be more available. This data might be useful if determining the relative risk of individual spices as they become available for consumer purchase in the United States.
4. Validation of mitigation processes. ASTA, along with the International Life Sciences Institute, have awarded research grants to develop surrogates and validation guidelines for microbial mitigation strategies in spices. The results should be available within the next 18 months.

CONCLUSIONS

A. The Draft Risk Profile conducted by the FDA provides excellent data on the microbiological quality of spices, and fills a data gap within the public domain. However, the majority of the data represents spices before any mitigation treatments have been applied, either by the spice industry or by the food industry after incorporation into multi component foods. Because of this, it does not adequately represent the actual consumer exposure to harmful microorganisms from spices, and the risk of foodborne illness from consumption of spices would be much lower than that suggested by the FDA in the DRP.

B. Although they are widely used in foods, spices have been associated with very few foodborne disease outbreaks and recalls.

C. The laboratory methodology to analyze spices for microbial contamination should be reviewed to assure that the accuracy and precision are the best available.

D. A quantitative risk assessment of the potential burden of foodborne illness from spices is needed to provide additional information and perspective on the issue.

E. There is essentially no difference in the risk of illness between a 3 $\log_{10}$ and a 5 $\log_{10}$ microbial mitigation process as applied to spices, based on the “worst case” data from the FDA Draft Risk Profile.

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