Journal of Food Protection, Vol. 76, No. 2, 2013, Pages 360–369
doi:10.4315/0362-028X.JFP-12-171

General Interest

Issues To Consider When Setting Intervention Targets with Limited Data for Low-Moisture Food Commodities: A Peanut Case Study

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MS 12-171: Received 14 April 2012/Accepted 30 August 2012

ABSTRACT

Peanuts and peanut-containing products have been linked to at least seven salmonellosis outbreaks worldwide in the past two decades. In response, the Technical Committee on Food Microbiology of the North American Branch of the International Life Sciences Institute collaborated with the American Peanut Council to convene a workshop to develop a framework for managing risk in low-moisture food commodities where large data sets are unavailable (using peanuts as the example). Workshop attendees were charged with answering questions regarding the appropriate statistical and scientific methods for setting log reduction targets with limited pathogen prevalence and concentration data, suitable quantities of data needed for determining appropriate log reduction targets, whether the requirement of a 5-log reduction in the absence of data to establish a target log reduction is appropriate, and what targeted log reduction would protect public health. This report concludes that the judgment about sufficient data is not solely scientific, but is instead a science-informed policy decision that must weigh additional societal issues. The participants noted that modeling efforts should proceed with sampling efforts, allowing one to compare various assumptions about prevalence and concentration and how they are combined. The discussions made clear that data and risk models developed for other low-moisture foods like almonds and pistachios may be applicable to peanuts. Workshop participants were comfortable with the use of a 5-log reduction for controlling risk in products like peanuts when the level of contamination of the raw ingredients is low (<1 CFU/g) and the process well controlled, even when limited data are available. The relevant stakeholders from the food safety community may eventually conclude that as additional data, assumptions, and models are developed, alternatives to a 5-log reduction might also result in the desired level of protection for peanuts and peanut products.

Peanuts (ground nuts) and peanut-containing products are produced and consumed extensively in most regions of the world. Historically, the primary food safety concern associated with peanuts has been aflatoxin production resulting from the growth of *Aspergillus flavus* during both primary production and subsequent storage. Recent outbreaks of salmonellosis have shifted focus from aflatoxins to the fact that peanuts and peanut-containing products can serve as a vehicle for *Salmonella* infections on rare occasions. Review of the international foodborne disease literature identified at least seven salmonellosis outbreaks associated with peanuts and peanut-containing products during the past two decades. One of the first outbreaks occurred in late 1994 and early 1995, when an increase in the number of *Salmonella* Agona cases was observed in England and Wales *(14).* This prompted a case-control study that showed a strong association between infection and consumption of a peanut-flavored ready-to-eat (RTE) snack imported from Israel. When samples of the implicated snack product were tested, the *Salmonella* concentration was estimated to range from 2 to 45 organisms per 25-g packet *(14).* A parallel investigation in Israel showed a similar number of cases, and the outbreak strain was eventually isolated from a reusable plastic bag used to store the snack product prior to packaging *(21).* After details about the outbreak in the United Kingdom were shared with other public health agencies, isolates of the outbreak strain

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were recovered from patients in the United States and France and from food samples in the United States and Canada *(22).* Subsequent outbreaks in Australia and the United States have further established peanuts and peanut-containing products as a potential vehicle for *Salmonella enterica (5, 6, 15, 17, 20).*

As a result of these outbreaks, the U.S. Food and Drug Administration (FDA) issued a guidance document in 2009 for managing the risk of *Salmonella* in foods that contain a peanut-derived product as an ingredient *(25).* The FDA recommends that manufacturers obtain peanut-derived products from suppliers with processes that ''adequately reduce the presence of *Salmonella* spp.'' or that they ensure that their manufacturing process would ''adequately reduce the presence of *Salmonella* spp.'' Although the FDA does not explicitly endorse a 5-log reduction as ''adequate,'' the 5-log example is given specifically in each of these two cases.

As noted by the International Commission on the Microbiological Criteria for Foods (ICMSF) in their definition of the Food Safety Objective (FSO) *(13, 27),* an appropriate log reduction can be determined once the initial level (H_0) is known and the FSO at time of consumption or the performance objective (PO) (at a specified point earlier in the food chain of the product) is specified. As in the case of products that do not support pathogen growth, this assumes that the total increase ΣI is zero, where the full ICMSF equations are $H_0 - \Sigma R + \Sigma I \leq FSO$ and $H_0 - \Sigma R + \Sigma I \leq PO$, and where terms are defined as above and ΣR is total reduction. This approach to establishing risk-based food safety metrics has been adopted by the Codex Alimentarius Commission.

Currently, there are very limited data available on the prevalence and concentration of *Salmonella* on raw shelled peanuts in the United States. The concentration data from two of the outbreaks listed above in which *Salmonella* was enumerated indicate a concentration of approximately 1 CFU/g *(14, 15).* The Technical Committee on Food Microbiology of the North American Branch of the International Life Sciences Institute (ILSI North America) partnered with the American Peanut Council (APC) to develop a detailed protocol for testing raw peanuts for *Salmonella*. Data were collected on 944 samples for the 2008 to 2010 crop years using this protocol. The *Salmonella* isolates were deposited in the ILSI North America Reference Strain Collection at Cornell University (http://foodscience.cornell.edu/cals/foodsci/research/labs/wiedmann/ilsi-na-strain.cfm), and an article on the survey is currently in press *(4).*

In preparation for publication of these data, the ILSI North America Technical Committee on Food Microbiology again collaborated with the APC to convene an expert workshop to discuss the data on the prevalence and concentration of *Salmonella* on raw shelled peanuts in the United States and to develop a framework for determining pathogen prevalence in low-moisture food commodities where large data sets are unavailable (using peanuts as the example). Workshop attendees were specifically charged with answering the following questions: (i) What are appropriate statistical and scientific methods for setting log reduction targets in the absence of pathogen prevalence and concentration data or with limited pathogen prevalence and concentration data? (ii) What constitutes ''enough'' data for determining appropriate log reduction targets for a given commodity? Would the ''raw peanuts'' model be applicable to other low-moisture food commodities? (iii) Is a 5-log reduction in the absence of any data to establish a target log reduction science-based and appropriate? (iv) What targeted log reduction would protect public health?

This document summarizes the findings of the workshop and presents recommendations on how to use these concepts to establish practical approaches for implementing food safety programs for dry foods and food ingredients.

QUESTION 1

What are appropriate statistical and scientific methods for setting log reduction targets in the absence of pathogen prevalence and concentration data or with limited pathogen prevalence and concentration data? A well-established food safety strategy for RTE foods is to employ an intervention technology to reduce the level of a hazard (i.e., pathogenic microorganism) to a sufficient degree such that the level remaining is not ''reasonably likely to cause harm.'' This is the food safety policy concept underlying treatments such as pasteurization, high-pressure treatments, and pulsed light technologies that reduce the levels of microbiological hazards but do not necessarily ensure complete elimination of the hazard. For example, the pasteurization requirements for fluid milk are based on a heat treatment that is sufficient to reduce the level of *Mycobacterium bovis* and *Coxiella burnetii* by 5- to 6-log cycles *(3).* Intervention treatments that are assumed to ensure the practical safety of a food or food ingredient have been articulated for a variety of RTE foods such as juices, post final packaging treatment of ground beef, and even drinking water. Establishing a suitable performance criterion *(13)* has long been an integral part of both purchase specifications and regulatory standards and guidelines for food worldwide.

Although it is relatively simple in concept, the implementation of a performance criterion requires reaching consensus on specific assumptions and protocols. For example, a statement about a specific log reduction might refer to the average log reduction of a process, the minimum log reduction achieved by a process, or some intermediate value such as the lower fifth percentile of a range of log reductions that are distributed normally. The average (or mean) log reduction may be most appropriate because many statistical analyses are developed around averages and standard deviations based on experimental data. However, since the variability of a process must often be considered, reporting a standard deviation or a 95% confidence interval will be essential in understanding the variation in a given data set and the overall risk reduction that can be achieved by an intervention step. Thus, the average log reduction will

TABLE 1. *A comparison of the difference between average log reduction and effective log reduction for two processes with different variability*

Initial concn (CFU/batch)	Initial concn (log CFU/batch)	Log reduction	Final concn (log CFU/batch)	Final concn (CFU/batch)
Process 1				
10,000,000	7	7	0	1
10,000,000	7	6	1	10
10,000,000	7	5	2	100
10,000,000	7	4	3	1,000
10,000,000	7	3	4	10,000
10,000,000	7	2	5	100,000
10,000,000	7	1	6	1,000,000
Sum CFU		Avg log reduction		Sum CFU
70,000,000		4		1,111,111
Sum log CFU		Effective log reduction		Sum log CFU
7.85		1.80		6.05
Process 2				
10,000,000	7	5	2	100
10,000,000	7	4.5	2.5	316
10,000,000	7	4	3	1,000
10,000,000	7	3.5	3.5	3,162
10,000,000	7	3	4	10,000
Sum CFU		Avg log reduction		Sum CFU
50,000,000		4		14,579
Sum log CFU		Effective log reduction		Sum log CFU
7.70		3.54		4.16

need to be designed so that a specified percentage of the process treatments exceed the designated reduction.

Understanding the implications of process variability is important. The importance of this variability can be demonstrated mathematically by considering a rather extreme case: a process that varies uniformly from a 1- to 7-log reduction. While such a process will show an average log reduction of 4, the effective log reduction of the entire population of product can considered to be approximately 1.8, as shown in Table 1. Effective log reduction is calculated by summing the effect of each log reduction over the entire number of log reductions. The consequences of lower log reductions tend to dominate the calculations so that the effective log reduction is less than the average log reduction. The consequences of this effective log reduction effect are less as the extremes of the process are reduced. For a process that varies uniformly from a 3- to 5-log reduction (instead of a 1- to 7-log reduction), the average log reduction is still 4, but the effective log reduction of the entire process is approximately 3.5 (Table 1). Alternative assumptions about the shape of the distribution will of course lead to different results.

The large variability in some industrial-scale processes *(28)* often means that, to achieve a high degree of control, the target degree of inactivation exceeds the target log reduction. For example, a thermal process that assures that a microbiological reduction of 5 log at the coldest point of a product means that the average log reduction for the entire food product will be substantially greater than the target reduction. This is characteristic of processes that are designed to ensure that all servings of a food receive at least that minimum process *(10)*. Because of the log-linear dependence of microbial inactivation kinetics on process conditions, a slight increase in process temperatures or related conditions can dramatically change the degree of inactivation.

Even given a specific log reduction, one needs to consider factors that obviate any log reduction that might be delivered. A common means by which a thermal process might be negated or reduced may be postprocess recontamination. Cross-contamination or recontamination that occurs after a thermal process with a given lethality reduces the effectiveness of the process, as shown in Table 2. For example, consider three scenarios: 1,000 kg of raw product containing 1 CFU/kg given a 3-log process, 10,000 kg of raw product containing 1 CFU/kg given a 4-log process, and 100,000 kg of raw product containing 1 CFU/kg given a 5-log process. If each of those products is subsequently subjected to postprocess recontamination with 0.1% raw product (i.e., 1 kg of product with 1 CFU/kg is mixed back into 1,000 kg, 10 kg containing 1 CGU/kg mixed back with 10,000 kg, etc.) the result will be product containing ~0.0010 to 0.0020 CFU/kg. This means that the overall process (i.e., treatment with an intervention technology plus subsequent handling) provides an overall 2.7- to 3.0-log reduction no matter the actual log reduction delivered in the initial process. This simple example emphasizes the need to consider the effectiveness of both the intervention step and subsequent good manufacturing practices (GMPs) when determining the number of log reductions needed to ensure safety *(7)*. It is also worth noting that this simple example ignores the complexity posed by the nonrandom distribution of contamination within a batch *(2)*. In at least some peanut butter outbreaks, the organism responsible for illnesses was

TABLE 2. *A demonstration of the effect of recontamination in producing an effective log reduction*

	3-log reduction			4-log reduction			5-log reduction		
Target log reduction	kg	CFU/kg	Total CFU	kg	CFU/kg	Total CFU	kg	CFU/kg	Total CFU
Initial unprocessed	1,000	1	1,000	10,000	1	10,000	100,000	1	100,000
Final decontaminated	999	0	0	9,999	0	0	99,999	0	0
Final contaminated	1	1	1	1	1	1	1	1	1
Recontamination	1 × 1 kg	1	1	10 × 1 kg	10	10	100 × 1 kg	100	100
Effective final	1,001	0.0020	2	10,010	0.0011	11	100,100	0.0010	101
Effective log reduction	−2.699 log reduction			−2.959 log reduction			−2.996 log reduction		

found in the environmental samples in processing facilities, giving credibility to the hypothesis that postprocess contamination (not process failure) was the root cause *(5)*.

Even after setting a target log reduction and developing GMPs, some degree of raw product sampling by the industry is needed to verify that the conditions have not changed, rendering the process insufficient to achieve the intended goals. For example, if a peanut butter process is based on the raw materials not exceeding 1 CFU/kg, a change in weather conditions that resulted in the raw peanut having up to 100 CFU/kg would likely lead to an increased incidence of process failures.

One of the approaches used to ensure that an intervention process is achieving the level of control desired is to combine that intervention with a raw ingredient testing program. The testing is used to confirm that the level of the microbiological hazard in the raw material is below the H_0 that was used to establish the required log reduction. However, the establishment of any testing program requires a clear understanding of the sampling plan that will be used. Key questions such as what is being sampled, the sampling protocol used (e.g., random, stratified random), the likely distribution of the contamination within the raw ingredient, and how the data will be expressed should be answered in advance *(2)*. Another key question is how to define individual lots. This can be a challenge with dry product processing, which may operate for extended periods between traditional wet cleaning, as opposed to dry cleaning, which is generally recommended for daily operations for dry products. Standard references on microbiological sampling *(13)* or expert advice should be consulted in establishing such programs. This should include consideration of moving to a statistical process control approach so that trends over time can be evaluated. Finally, the anticipated levels of the pathogen must be considered. *Salmonella* may be present at very low levels, ~1 CFU/g, but even elevated levels (e.g., 10 or 100 CFU/g) may not be detectable by standard enumeration methods. It is worth noting that the same questions must be addressed when establishing a testing program for finished products.

The experts participating in the workshop recommended that, prior to setting any target log reductions for any raw agricultural product, testing of several crop years should be conducted to assess prevalence and concentration. In statistical process control terms, this would be equivalent to a process capability study that is used to establish the baseline level of contamination that will have to be controlled by the hazard analysis and critical control point (HACCP) and GMPs. Once the baseline has been determined, the stringency of the log reduction step can then be established. In addition, this will also allow determination of the sampling plan for raw materials to ensure with a high degree of confidence that the H_0 is not being exceeded. There are potential benefits from doing this as part of an industry-wide collaboration, but such a program would likely require consideration of regional differences. Individual companies could do this as part of their HACCP validation and verification activities.

Because higher concentration levels can be very rare events, they may be hard to detect and measure *(8)*, although such events may still cause significant illness. Alternatively, epidemiology that involves many cases over a period of months suggests that this may not be the case, but instead suggests low-level, low-frequency contamination due to a systemic problem (e.g., contamination of equipment or facilities). Daily testing of a small number of products over the course of many months should give enough discriminatory power to find a significant difference compared with a well-established baseline. It was the opinion of the experts at the workshop that overengineering the food processing system to protect against these rare events may not be practical, and that understanding and preventing the conditions that lead to such events may be more effective.

Finally, the experts at the workshop noted that it might be possible to use data from other nut products (e.g., almonds, in which a substantial data set has been developed) *(1, 9, 16)* to guide the development of target log reductions. Workshop participants noted that the pistachio, pecan, and walnut industries are currently benchmarking against the almond industry as they develop their best practices. Although it might eventually be possible to combine data from across all nut types, it is not clear that this can be done at this time due to differences in many factors such as nut structure and harvest conditions. It is also not clear if all types of nuts can tolerate the same intervention treatments. A nut sensitive to quality loss during heating might require a substantially lower H_0 or an alternative nonthermal treatment if it cannot be subjected to the same log reduction as less heat sensitive nuts.

RECOMMENDATIONS AND ANSWERS TO QUESTION 1

Since the decision about a log reduction target is a risk management decision, a log reduction target is a policy

decision that requires a scientific/statistical basis to be scientifically defensible, but it must also take into account many societal considerations as well as the risk-averse nature of individual companies. Risk managers with limited access to data can still commission risk assessments to inform their decisions, but those risk assessments will be hampered by less data. In such instances, the uncertainty of the risks is greater. Under such circumstances, the general approach is to increase the target log reduction. The articulation of a required log reduction by the FDA has the benefit of clearly specifying the level of control required, thereby establishing a ''level playing field'' (as long as portions of the industry are not exempted). The typical response of the industry to such a situation is to further increase the log reduction by 1 to 3 log in order to have a high degree of confidence that companies are well below the residual risk associated with the regulatory requirement. As noted in the response to Question 2 below, there may be data and risk assessments developed from related commodities that would be useful for peanuts.

QUESTION 2

What constitutes ''enough'' data for determining appropriate log reduction targets for a given commodity? Would the ''raw peanuts'' model be applicable to other low-moisture food commodities? The answer to the first part of Question 2 regarding what constitutes ''enough'' data to set reduction targets depends in part upon how much data are available on the raw material (H_0). The importance of the raw material data in turn depends upon the severity of the lethal treatment that is feasible to give to the product (ΣR), and the degree to which postprocess recontamination (ΣI) plays a role in outbreaks. If postprocess recontamination is determined to be an important cause of outbreaks, the degree of raw material contamination is less important (see the discussion above demonstrating that a postprocess recontamination with 0.1% raw product is equivalent to a 3-log reduction).

A thorough investigation of outbreak events for root cause and likely contamination levels may be useful in determining the types of data most needed for setting appropriate log reduction targets. For example, are the reported foodborne illnesses coming from the tail of the ''typical'' contamination distribution, a very rare (e.g., <1 in 25,000) high contamination event, or the result of a low-frequency systemic process or GMP failure (e.g., a cold spot in a roaster, introduction of moisture in an otherwise dry product)? If the majority of the reported foodborne illnesses are coming from the tail of the ''typical'' contamination distribution, these can be considered sporadic, and illnesses will likely be improved with a modest reduction in contamination or a decrease in process variability. Based on our current understanding of dose-response relations, it is generally accepted that at the levels at which pathogens occur in these types of foods (i.e., raw foods that are contaminated at low levels and that do not support growth), a modest 1-log reduction in prevalence will give an approximately 1-log reduction in illness cases. If rare, high-concentration contamination events were to cause outbreaks that resulted in reportable cases, then a greater than 1-log reduction would be required to have a significant effect on reported illnesses. If rare, high-concentration contamination events are a primary concern, then prevention of those high contamination events through implementation of good agricultural practices or a HACCP program may be the best course of action. In either case, acceptance plan sampling of the raw material and/or finished product sampling may be useful. The efficacy of such plans increases when the contamination rate is high.

Following this point, if a food is ''marginally risky'' and there is no evidence of gross contamination, most food microbiologists are of the opinion that a 5-log reduction is likely a very adequate ''safe harbor'' standard. Again, based on our current understanding of dose-response relations, a 5-log reduction would decrease the risk of infection by 100,000-fold. Thus, if the risk of infection associated with a product contaminated at a level of 1 CFU/kg was one illness case per 100,000 servings, then a 5-log reduction would be expected to reduce that prevalence to approximately one illness case per 10 billion servings. If a food processor has sufficient data to demonstrate that a level of inactivation <5 log is appropriate for the process or that they are able to consistently reduce the H_0 by several orders of magnitude, this lower level of inactivation may also be acceptable.

When considering the second part of question 2 regarding the applicability of the ''raw peanuts'' model to other low-moisture food commodities, the workshop participants reframed the discussion to be about the use of known distributions for similar foods and bounding uncertainty for poorer-quality data sets. The workshop participants briefly discussed the use of index organisms *(12)* (as an alternative to *Salmonella*), but noted that a large database of test results would still be required to document the correlation between *Salmonella* and the specific index organism. Large data sets are currently available for *Salmonella* in other nut products such as almonds *(1, 9, 16)*. Because the pistachio and pecan industries are currently benchmarking against the almond industry as they develop their own best practices, there may be a need for a general model for all low-moisture raw agricultural food commodities, rather than a universally applicable ''raw peanut'' model.

Such a benchmarking approach would consider a variety of different data sets. The difficulty with this approach to circumventing a lack of specific data is the uncertainty associated with extrapolating these diverse data sets to another product (e.g., almond to peanut). As mentioned above, one of the normal responses of risk managers when facing such uncertainty would be to increase the required log reduction. This could result in an intervention step that adversely affects product quality. The way to offset this problem is to obtain sufficient data about the commodity in question to have confidence that the characteristics of the product (i.e., peanuts) are similar to those of the product for which there are sufficient data (i.e., almonds), such that the smaller data set is deemed ''good enough'' in light of its agreement with the larger one. If this

smaller data set does not give risk managers enough confidence in their decision, then more data would need to be collected.

The workshop participants outlined the minimum characteristics that a good quality data set would possess, including obtaining data that captures any year-to-year variability in pathogen prevalence; considering variation by region and season; and collecting data that focus on estimating prevalence at a specified detection limit first, and then estimating the concentration of more highly contaminated samples. Data collection should ideally proceed until positive samples have been detected so that an actual contamination baseline is available. Samples should be collected close to harvest time and stored refrigerated or frozen prior to testing to minimize the concentration declines typically observed during room temperature storage *(23)*. It may be feasible that, with sufficient data, the effect of longer storage times and conditions encountered during typical storage and handling could be factored into the determination of H_0 or log reduction values. However, until that relationship has been determined and validated, maximizing detection of *Salmonella* in the newly harvested peanuts helps to ensure that detection errors would be on the side of safety.

The workshop participants noted that modeling efforts should proceed in coordination with sampling efforts. For example, modeling could be used to compare various assumptions about prevalence and concentration and how they are ultimately combined. The ongoing collection of data can then be used with the model to disprove or confirm different assumptions and to validate and improve the model. For example, the ongoing addition of data would allow the model to show the differences between a prevalence estimated from 0 positives in 100 samples versus 1 positive in 1,000 samples. Modeling could also show the impact of using different sampling sizes (e.g., 25, 100, or 375 g). Modeling could be used to compare different assumptions about underlying prevalence and concentration. Contamination could be described as a single concentration distribution with most samples below detectable levels or as a small fraction of samples in which the pathogen is present at some concentration distribution. While the latter approach is more compatible with most currently available data sets, such databases are limited by the sensitivity of the sampling schemes used to collect the data. It is worth noting that many of the current exposure assessment models for foods are based on the former approach. Modeling before a sampling plan is conducted can be a very cost-effective way to ensure maximization of the usefulness of the generated data.

In any discussion about microbial risk that approaches the level of a quantitative microbial risk assessment, some mention of a dose-response model should be included. The canonical dose-response model for *Salmonella* is that used by the Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO) *(11)*. Although no model is ideal, the FAO/WHO method seems to be the most suitable for modeling *Salmonella* dose-response relationships in foods. This model assumes that there is no threshold (i.e., the ingestion of a single organism that has the potential to cause disease) even if that probability is extremely low. However, the workshop participants discussed the fact that while the FAO/WHO model is conservative (i.e., it potentially overestimates risk), it is virtually impossible to prove a threshold of infection when dealing with the large populations of highly diverse consumers that are often associated with foodborne disease outbreaks. Furthermore, with dry products such as peanuts, dose-response models may have to be adjusted for putative protective factors in foods such as fats. Any doubt about the reliability of the FAO/WHO *Salmonella* dose-response model can be addressed by including uncertainty in the dose-response model calculations. It should also be noted that dose-response models inherently have a large degree of uncertainty due to the highly diverse nature of consuming populations.

In many ways, what constitutes ''enough'' data will depend on the public health target desired by risk managers. For example, is more than one illness per year from the target food in the United States reasonable given the current consumption patterns, the technological capabilities of the industry to produce that product, and the nutritional or dietary impact if the product was not available or was altered drastically? An alternative approach that reflects that residual risk associated with the product when produced according to a specified log reduction requirement is to express the degree of control in relation to consumers' annual risk of foodborne disease if they eat the product every day. The 5-log reduction mandated in the juice HACCP regulations is estimated to result in the prevention of 160 *Escherichia coli* O157:H7 and 2,340 *Salmonella* cases per year, as well as the prevention of other illnesses due to *Bacillus cereus* and *Cryptosporidium parvum (26)*. The FDA's risk assessment determined that juice receiving a minimum 5-log inactivation (not limited to heat) could be labeled as receiving a pasteurization treatment and did not need a specific warning label. The FDA's juice HACCP rule also presumes that good process control eliminates potential high contamination by prohibiting the use of dropped fruit and culling unsound fruit before applying the 5-log reduction. This risk management action has proven to be effective, because no *E. coli* O157:H7 outbreaks associated with pasteurized juice have occurred since the rule was implemented. In arriving at their recommendation for the 5-log specification, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) *(18)* and the FDA *(26)* stated that ''a tolerable level of risk may be achieved by requiring an intervention(s) that has been validated to achieve a cumulative 5-log reduction in the target pathogen(s) or a reduction in yearly risk of illness to less than 10^{-5}, assuming consumption of 100 ml of juice daily.'' Given 365 servings per year, this risk is 3×10^{-8} illness per serving. This approach provided a means of ensuring improved food safety by minimizing unnecessary excess treatments, providing incentives for innovation, and avoiding the unprovable concept of ''zero tolerance.''

A similar situation exists for almonds, which must be treated by a process validated to achieve a minimum 4-log

TABLE 3. *The relationship between log reduction and number of contaminated servings per year and relative risk reduction*

Log reduction	Contaminated servings/yr (no.)	Contaminated servings (%)	Uncontaminated servings (%)	Relative risk reduction (%)
0	1,000,000,000	2.0000000000	98.0000000000	0.00000000
1	100,000,000	0.2000000000	99.8000000000	90.00000000
2	10,000,000	0.0200000000	99.9800000000	99.00000000
3	1,000,000	0.0020000000	99.9980000000	99.90000000
4	100,000	0.0002000000	99.9998000000	99.99000000
5	10,000	0.0000200000	99.9999800000	99.99900000
6	1,000	0.0000020000	99.9999980000	99.99990000
7	100	0.0000002000	99.9999998000	99.99999000
8	10	0.0000000200	99.9999999800	99.99999900
9	1	0.0000000020	99.9999999980	99.99999990
10	1 in 10 yr	0.0000000002	99.9999999998	99.99999999

reduction of *Salmonella*. The Almond Board of California administers the federal marketing order that regulates the handling of almonds grown in California. The board funded research with the University of California, Davis, in conjunction with Rutgers University, whereby a risk assessment model was developed *(8).* The model demonstrated that a minimum 4-log reduction provided a level of consumer protection that the board judged to be appropriate because less than one illness per year was predicted, assuming a 4-log reduction was applied *(24).*

RECOMMENDATIONS AND ANSWERS TO QUESTION 2

The judgment about enough data is not solely a scientific question, but is instead a science-informed policy decision that has to additionally weigh multiple societal issues. The workshop discussion concluded that the ability to use the raw peanut model as the direct basis for other low-moisture foods is limited considering both the technological and societal differences among the wide range of dry products. However, just as the data and risk models developed for other low-moisture foods like almonds and pistachios are helping to inform decisions related to peanut products, the risk framework, data, and intervention technologies implemented in establishing log reduction targets for peanuts would be expected to inform and facilitate the adoption of intervention targets for other dry products.

QUESTION 3

Is a 5-log reduction in the absence of any data to establish a target log reduction science-based and appropriate? The workshop participants support the use of the ICMSF conceptual equation to determine an appropriate log reduction, which was discussed previously and reviewed by van Schothorst *(27).* The workshop participants also support the consideration of the NACMCF definition of pasteurization *(19),* which states that pasteurization is ''any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.'' The NACMCF document further suggests the following steps in setting pasteurization conditions: (i) conduct a hazard analysis to identify the microorganism(s) of public health concern for the food; (ii) determine the most resistant pathogen of public health concern that is likely to survive the process; (iii) consider the level of inactivation needed, ideally determining the initial cell numbers and normal variation in concentration that occurs before pasteurization; (iv) assess the impact of the food matrix on pathogen survival; validate the efficacy of the pasteurization process; (v) define the critical limits needed during processing to meet the performance standard; and (vi) define the specific equipment and operating parameters for the proposed pasteurization process, including the developing GMPs and HACCP systems.

Risk manager decision-making may be aided by using a table similar to that shown in Table 3 as a means to illustrate the effect of different log reductions. Table 3 shows the effect of a progressively increasing log reduction on a very popular hypothetical food. It is clear from Table 3 that as the log reduction increases, the number of contaminated servings and the percent contaminated servings decrease in direct proportion. The relative risk reduction rises in direct proportion to the log reduction. The other key point to draw from Table 3 is that when a 1-log reduction is applied to one contaminated serving per year, the risk declines to one contaminated serving per 10 years (and not zero). Of course, tables such as this could also be expanded in the context of a more detailed quantitative microbial risk assessment, including many of the variables previously discussed.

As discussed above, the level of *Salmonella* per serving of raw peanuts is typically low and may be controlled through the implementation of good agricultural practices and with some microbiological testing. This ensures that H_0 is low and that a 5-log reduction in pathogen concentration in a food at consumption would result in a proportionate reduction in the risk of illness. The participants also noted that if one is in the linear portion of the dose-response curve, any 1-log reduction in the level of the pathogen (assuming no growth afterward) should yield a 10-fold reduction in risk. While this does not eliminate all residual risk, it should lead to a large reduction in predicted cases. With the Healthy People 2010 and 2020 goals set at 10 to 50% reductions in illness for most foodborne pathogens (which translates to a 0.05- to 0.3-log reduction in illnesses), a 5-log

reduction in pathogen levels would most likely exceed these public health goals by a substantial margin. It is important to emphasize that any approach to designing microbiological safety into the product through the use of intervention technologies is based on some key assumptions. One such assumption is that programs are in place to avoid problems that occur after the 5-log reduction step (e.g., avoidance of posttreatment cross-contamination, introduction of water into the product). The inclusion of such interventions is not a substitute for effective GMP and HACCP programs, but is instead the means for increasing the effectiveness of such programs to consistently deliver a safe product.

RECOMMENDATIONS AND ANSWERS TO QUESTION 3

The requirement for a specified log reduction step is dependent on having sufficient data to demonstrate that the incoming raw materials achieve a H_0 that is consistent with attaining the desired level of reduction, as well as sufficient GMP and HACCP programs to ensure prevention of the reintroduction of the microbiological hazard. While the selection of a specific log reduction is a scientifically informed societal decision, past history with other commodities has demonstrated that a 5-log reduction has enhanced public health and provided industry with opportunity for innovation that can lead to ''continuing improvement.'' The community of food microbiologists as represented by the workshop participants was generally comfortable with the use of a 5-log reduction for controlling risk in products like this, even with limited data. It is also worth noting that a risk management framework for food safety should include ongoing monitoring of efficacy and a log reduction policy that could be modified relatively easily if deemed appropriate.

QUESTION 4

What targeted log reduction would protect public health? The workshop participants noted that before this question can be answered, it must be known if the contamination is occurring before or after the log reduction step, a point also made in response to Question 2. This question also has an inherent assumption that the product remains in a condition such that pathogenic microorganisms are unable to grow. For example, the uncontrolled introduction of water into a peanut facility would likely overcome the inherent controls achieved by moisture control. Since recontamination after intervention will increase the chance of contaminated servings and microbial growth will amplify the risk, the actual degree to which postprocess recontamination occurs will be of critical importance in assessing and managing risk.

The workshop participants also noted that the targeted log reduction might vary for different peanut products or processes (e.g., dry roasting, oil roasting), due to differences in the processes and handling that those products might undergo. Participants noted that multiple treatments might be needed to achieve equivalent reductions in different products. Workshop participants also discussed the issue of combining multiple treatments to obtain the needed reduction, such as in the case for almonds that might be treated with polypropylene oxide prior to dry roasting or the role of GMPs or supplier controls to prevent recontamination.

Workshop participants underscored the importance of considering variability and uncertainty in any data used to set log reductions or assess risk. While the prevalence of *Salmonella* in the raw product will never be known with absolute certainty, even the current estimates of prevalence can be used to determine the suitability of current roasting practices. Finally, workshop participants noted that, irrespective of the final form of the quantitative microbial risk assessment used and log reduction proposed, some method to validate the predictions is needed to ensure their suitability and ongoing verification of the efficacy of the treatment should be an integral part of the food safety system.

RECOMMENDATIONS AND ANSWERS TO QUESTION 4

As with the other questions, what targeted log reduction would protect public health is a scientifically informed societal decision. As noted above, assuming that the H_0 for the raw peanuts can be maintained at a low level, food microbiologists and microbial risk managers are generally comfortable with a minimum 5-log reduction as sufficiently protective. As was evident in discussions following the publication of the first almond risk assessment *(8),* the relevant stakeholders from the food safety community eventually determined that, given the data, assumptions, and models at hand for almond risk, a minimum 4-log reduction resulted in an appropriate level of protection.

CONCLUSIONS

Peanuts and peanut-containing products have caused a number of salmonellosis outbreaks around the world in the past two decades and are an ongoing concern to the food industry, food safety microbiologists, and consumers. Despite this concern, little data on *Salmonella* prevalence and concentration in peanuts are currently available. While steps are under way to collect more data, a workshop was convened to discuss current options and strategies.

Workshop participants discussed appropriate statistical and scientific methods for setting log reduction targets in the absence of pathogen prevalence and concentration data or with limited pathogen prevalence and concentration data. Since the decision about a log reduction target is a risk management decision (i.e., a scientifically informed societal decision), workshop participants were unable to reach firm conclusions on this question. Risk managers with limited access to data can still commission risk assessments to inform their decisions, but those risk assessments will be hampered with less data, resulting in the need to offset the uncertainties. As discussed below, ongoing risk assessment and management activities related to other nut products may be helpful in informing decisions related to *Salmonella* in peanuts.

Workshop participants also discussed what would constitute sufficient data for determining appropriate log reduction targets for a given commodity and the suitability of an eventual ''raw peanuts'' model as applicable to other low-moisture food commodities. As noted above, the judgment about data sufficiency is a scientifically informed societal decision. The workshop discussion made clear that data and risk models developed for other low-moisture foods like almonds and pistachios would help inform decisions related to peanuts.

Participants were asked if a 5-log reduction in the absence of any data to establish a target log reduction would be science-based and appropriate. While again noting that establishing a required log reduction is a science-informed societal decision as well as the need to ensure adequate control of the incoming raw material and the posttreatment control of the product, the workshop participants were generally supportive of the effectiveness of a 5-log reduction, based on both a consideration of microbiological risk assessment concepts and the past use of such a requirement to protect public health.

ACKNOWLEDGMENTS

This work was supported (in part) by the Technical Committee on Food Microbiology of the North American Branch of the International Life Sciences Institute (ILSI North America). The Technical Committee on Food Microbiology received a grant from the ILSI Research Foundation to support this work. The American Peanut Council collaborated with ILSI North America on this project and provided blinded data for the workshop discussion and manuscript development. Dr. Schaffner received a grant for his work to review, analyze, and summarize information contained in this article. ILSI North America is a public, nonprofit foundation that provides a forum to advance understanding of scientific issues related to the nutritional quality and safety of the food supply by sponsoring research programs, educational seminars and workshops, and publications. ILSI North America receives support primarily from its industry membership. The opinions expressed herein are those of the authors and do not necessarily represent the views of the funding organization.

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