International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

May 20, 2011

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0251, Food Safety Modernization Act: Focus on Preventive Controls for Facilities

Dear Sir/Madam:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies representing a $110-billion a year industry. IDFA is composed of three constituent organizations, the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members and their 175 divisions, subsidiaries, and joint ventures run nearly 575 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. In addition, 320 member companies provide processing equipment and supplies, packaging equipment and materials, ingredients and a wide variety of products and services to the dairy processing industry. More than 15 state and regional trade associations are also members of IDFA.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies.

IDFA and NMPF supported passage of the Food Safety Modernization Act (FSMA) and recognizes that a robust food safety system is crucial for both public health and the success of our member companies. We appreciate the need for enhanced preventive controls and support Food and Drug Administration's (FDA) efforts as it promulgates rules to implement the FSMA.

We commend FDA for the open and collaborative process it is using in advance of the promulgation of rules under FSMA. IDFA participated in the public meetings on Import Safety and Preventive Controls. We are extremely impressed with the value of these events and believe the effort will result in higher quality regulations. We look forward to continuing to work with FDA over the months and years ahead to enhance the safety of the US food supply.

I. Preventive Controls: General

IDFA and NMPF support FDA giving a high priority to the regulations for preventive controls under Section 103, as that provision is a major cornerstone of the FSMA with its focus on prevention. We urge FDA to take a general approach in the regulations, as dairy products will not necessarily have the same preventive controls as other food categories, and vice versa. Rather, it is the individual company's responsibility under the law to conduct a hazard analysis of each of its facilities and to develop a system of preventive controls tailored to address those hazards in those particular circumstances. We urge FDA to follow the statute's general framework in developing its regulations.

We also note the statute's instruction to FDA in Section 103(n)(5) to consider existing preventive controls programs, expressly including the Grade 'A' Pasteurized Milk Ordinance (PMO), in developing its own regulations and to seek consistency to the extent possible. The PMO has long been a lynchpin for assuring the safety of pasteurized milk and milk products, and a company's adherence to the PMO should go a long way towards achieving compliance with the new FDA regulations. Achieving harmony between these regulatory schemes is critical to the dairy industry.

II. Environmental and Product Testing

We were impressed with the meeting on Preventive Controls under FSMA and, in particular, appreciated the breakout discussion on Environmental Monitoring and Product Testing. However, we caution FDA to approach the subject of environmental and product testing within the context of its meaningful contribution to public health protection and not to mandate excessive testing regimes that would go beyond the structure and intent of the statutory provisions, or be contrary to Executive Order 13563. We are particularly concerned that FDA not seek to mandate a specific regime of finished product testing for dairy products that would impose enormous expense but provide no added public health benefit.

These comments in this section are intended to convey the following critical points:

1. It is common practice in the dairy industry to use environmental monitoring/testing in our plants, and we support its use in our industry.

2. The dairy industry also uses product testing on a regular basis, and we support its use in our industry. Specifically, the dairy industry conducts extensive testing on raw milk.

3. The dairy industry does not view product testing as being synonymous with finished product testing. "Product testing" would encompass both testing on raw milk (as well as

raw ingredients for other sectors) and testing on finished product. It is important to point out that Congress never used the term "finished" or "finished product" in the FSMA.

4. FDA has repeatedly rejected the notion that finished product testing is a means to establish that a product is pathogen-free, and we concur. Moreover, conducting finished product testing on a pasteurized dairy product, where the pasteurization process has been properly validated, provides no added public health benefit and would incur significant, unjustified costs.

5. Under FSMA, it is the dairy company's responsibility to incorporate environmental monitoring and product testing, as appropriate, to verify that its preventive controls are working. This is consistent with FSMA's overall approach to the food safety plan which places primary responsibility on the manufacturer to establish an appropriate food safety program, of which verification is a part.

As IDFA and NMPF support the appropriate use of environmental and product testing, the remainder of this section will address why we believe that the finished product testing of pasteurized dairy products should not be required under Section 103.

A. Finished Product Testing Cannot Establish Safety

FDA itself has long recognized there are important limitations to finished product testing, the most important of which is that finished product testing cannot establish safety. Both FDA and USDA spokespersons have stated on many occasions that "you cannot test your way to food safety." Indeed, FDA repeatedly stated during the Peanut Corporation of America (PCA) recall that pathogen testing of PCA ingredients or finished product made with PCA ingredients could not be used as means to verify the safety of a PCA ingredient or a product made with PCA ingredients. The reason FDA refused to accept or believe test results showing a food product was pathogen-free was that product testing can give misleading results. The attached Technical Bulletin from Silliker explains how discrepancies in testing can occur. To be certain of a product's status of being pathogen-free, one needs to test every particle of food. Thus, only an effective control step can assure safety, not testing.

This is a key point. It is the pasteurization step that is central to assuring the safety of pasteurized milk and other dairy products. And it is the validation of that pasteurization system that assures the system is working. For dairy products, that is where the attention needs to be focused, because that is where the public health benefit is. To add a regimen of finished product testing is simply not value added from a public health standpoint.

To be clear, IDFA and NMPF do not oppose the use of product testing--it has its place in food safety regimens. In fact, as FDA knows the fluid milk industry tests 100% of raw milk tankers for animal drug residues and for other adulterants. Literally millions of incoming product tests are done at our plants each and every year. We believe this is an excellent example of where product testing provides value as a verification step that dairy cows were not impermissibly treated with antibiotics, and the dairy industry has relied on it for many decades. We believe this practice would meet the expectations in Section 103 with regards to product testing for our product category. In addition, the dairy processing

industry makes extensive use of environmental testing, and we strongly believe that environmental testing programs are a critical part of our food safety verification programs.

B. Finished Product Testing is Extremely Costly, without Commensurate Public Health Benefit

Mandatory finished product testing is not only a flawed food safety enhancement strategy, it is extremely costly, and without commensurate public health benefit. The average food pathogen test costs about $15 to $20 per test and results will take about three days to acquire. A typical fluid milk plant has about six production lines; a food safety program that *attempts to rely on* finished product testing would need to sample from each and every line repeatedly throughout production runs. In order to be effective, a food safety plan that "relies" on finished product testing should also look for all pathogens that could be present. The fluid milk industry believes there could be as many as nine pathogens that could reasonably be considered. The higher the frequency of testing, the more robust the assurance of safety will be. But, as mentioned above, to have complete assurance, one would need to test every single particle of a food--but then there would be no food left, so a less robust strategy would need to be employed. To accomplish a lesser strategy but still have a fairly good assurance that the food was pathogen free, one could envision that each line would be sampled at least three times during each production run.

To gain an understanding of what this would mean to the fluid milk industry, please note the following facts. There are two production shifts at most milk plants. The plants operate six days a week. Given the above, each line will have six samples for nine pathogens each; 54 tests per day. If those tests are acquired at $15 per test it will cost $810 per line per day, or $4,860 for all six lines per day. The cost for a week at a milk plant will be $29,160. The cost per year is $1,516,320. There are about 400 fluid milk plants in the US. The annual cost of finished product pathogen testing for the fluid milk industry would be $606,528,000. That is a very high cost especially when the real verification step for a fluid milk plant should be the validation of the pasteurization process. Furthermore, this cost estimate does not take into account the cost of holding product – reducing the already limited shelf life of refrigerated dairy products – while waiting for the test results.

Those costs are just for fluid milk. Similar issues arise for finished product testing for our members who process cheese, ice cream, and yogurt products.

Moreover, the list of potential hazards could grow significantly. Section 103 includes all chemical, radiological and physical contaminants that could unintentionally or intentionally be added. Given the work that the dairy industry has done with FDA on food defense matters, we collectively know that there could be numerous ways to intentionally contaminate the food supply. The myriad of tests required to detect all the agents that could be used is overwhelming. In many cases, the tests simply do not exist.

We believe that if Congress intended to mandate finished product testing it would have done so in a clear and unambiguous manner as they did with the earlier House bill which

was contemplating pilots to evaluate the feasibility and benefits of collecting finished product testing results from certain facilities.

Finally, as noted earlier, Section 103(n)(5) specifically instructs FDA to review preventive control programs in existence on the date of enactment, including the Grade 'A" Pasteurized Milk Ordinance (PMO) and ensure that the regulations are consistent to the extent practicable. In this regard, it is important to note that the PMO does not mandate pathogen testing of finished product.

C. FSMA Does Not Mandate Finished Product Testing

As noted, FSMA does not mandate finished product testing. Indeed, FSMA does not even contain the term "finished product." Accordingly, FDA should approach the testing issue within the context and limitations of the statutory provision.

The key provision in FSMA on verification testing is Section 103(f)(4) which reads, in relevant part:

> **(f) VERIFICATION**.—The owner, operator, or agent in charge of a facility **shall verify that**—
>
> * * * *
>
> (4) **the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards,** including through the use of environmental and product testing programs and other appropriate means; (emphasis added)

The central statutory requirement is that that each facility "shall verify that" . . . "the preventive controls . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards, . . ." It should be up to each facility to determine how best to accomplish that verification. The statute does go on to state that environmental and product testing programs would be appropriate means to accomplish this objective, but we believe the statute can reasonably be interpreted to mean these are illustrative examples and not mandated steps.

This view is reinforced by the definition of preventive controls in Section 103(o)(3) which defines "preventive controls" (including environmental monitoring programs as a verification step) to mean:

> ". . . risk-based, **reasonably appropriate procedures, practices, and processes** that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified. . ." (emphasis added).

This view is further reinforced by the entire framework of the preventive controls section which places the responsibility squarely on each facility to assess the hazards in that facility and implement a system of preventive controls and

verification activities to significantly minimize or prevent those hazards. There is no reason why testing as a verification step should be singled out with more specific requirements than other provisions within Section 103.

Given this statutory framework, we believe that FDA should require facilities to conduct appropriate verification activities, and that those verification activities may reasonably include environmental and product testing of a type and extent appropriate for the product being manufactured, but that the precise extent and scope of such testing should be within the province of the manufacturer to decide, and that in no case should finished product testing of pasteurized dairy products be required.

III. Additional Comments

A. FDA Review of Food Safety Plans

A suggestion was made in FDA's public meeting that companies should be required to submit their food safety plans electronically to the FDA. We disagree. Food safety plans are of limited utility outside of the plant context, and FDA should not require companies to electronically submit their food safety plans to the agency for its review. The plans are best understood in the context of the plant, where inspectors can see the plan in operation, gain insight from discussions with plant employees, and examine related records. We also are concerned that it would be inefficient for FDA to require electronic submission of food safety plans because their remote review may raise unnecessary questions that could be readily resolved by a review of the plan in operation at the facility. Additionally, we question whether remote review of food safety plans is the best use of the agency's limited resources because of the overwhelming number of such plans. Because food safety plans are "living documents" that are regularly revised, FDA may be inundated by a constant stream of new versions of the plans. We note that the House version of the bill contained a provision on remote access to records, but that was not incorporated into the final legislation. In July 2012, FDA will have every right to review our members' food safety plans, but we believe the proper venue for that is during an on-site inspection.

B. Warehouses

Section 103 of FSMA provides FDA with the authority to exempt or modify preventive controls requirements for warehouses (i.e., "facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment"). FDA should limit the requirements for warehouses because many provisions in Section 103 do not make sense in this context. For example, although warehouses should apply general controls such as sanitation, pest control, and inventory management (e.g., segregation, security, recordkeeping), warehouses would not be expected to have any critical control points. No processing of food takes place in warehouses, so there is no reason to require a complete hazard analysis and a food safety plan for these facilities. Accordingly, FDA should exercise its authority to modify the requirements for warehouses in this way.

C. Use of Accredited Labs

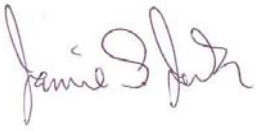
In Section 202 of FSMA, Congress provided that certain "food" testing is required to be conducted by accredited laboratories that must send the test results directly to FDA. This provision is expressly limited to testing for "identified or suspected food safety problems" or imports, which are both "for cause" situations. Congress did not elect to require broader use of accredited laboratories and did not grant FDA with the option to impose such requirements. Therefore, in developing agency thinking on how to create requirements around the use of accredited laboratories, we urge FDA to stay within this statutory scope. We believe it would be inconsistent with its statutory authority for FDA to require the use of accredited laboratories beyond these limited "for cause" circumstances.

* * *

We hope that FDA finds the foregoing information useful. IDFA and NMPF applaud the agency for its efforts to implement the FSMA and appreciate the hard work that is to come. The safety of the food supply is of utmost concern to IDFA, NMPF and our members, and we would be pleased to assist the agency further in this endeavor. Please do not hesitate to contact us if we can be of assistance.

Sincerely,

Clay Detlefsen
Vice President & Counsel
International Dairy Foods Association



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Qualitative Microbiological Testing:

Discrepancies Between Original and Retest Results

By Russell S. Flowers, Ph.D., and Michael S. Curiale, Ph.D.

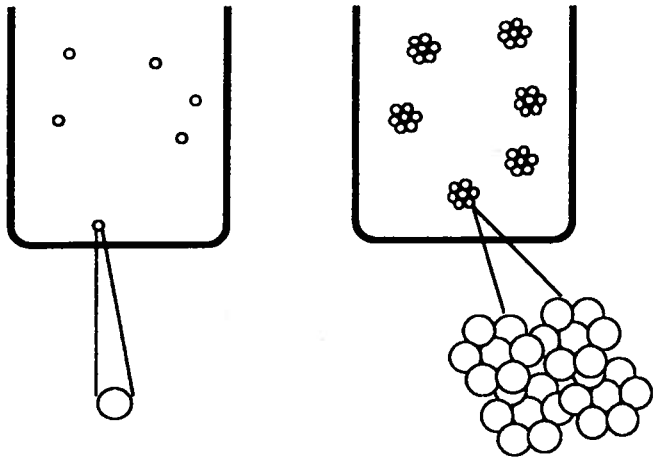
When microorganisms are detected in food products by enrichment techniques, there is often a desire to retest retained samples or resample the product in question, to verify the results. This is particularly true when there are economic and/or public health consequences associated with a positive result; such as when *Salmonella* spp. or *Listeria monocytogenes* are found.

Many times retest results do not confirm the original positive result, even when a much greater portion of product is analyzed in the retest. There may be a predilection to believe the original result to be in error, perhaps due to contamination during sampling or analysis. Certainly laboratory or sampling error are plausible explanations. However, there are several other explanations which should be considered such as: non-random or heterogeneous distribution, low incidence of contamination, and organism die-off between original and repeat tests.

A discussion of these other explanations for discrepancy between initial and retest data requires an understanding of how microorganisms may be distributed within a food product, and the difference between incidence and level of contamination. Incidence of contamination refers to the frequency at which multiple samples from a given product test positive. Level of contamination refers to the number of cells of a particular contaminant present in a given amount of product. Consider the examples in Figure 1. Both examples A and B have the same incidence of contamination per 100 lbs. If A and B were each divided into 100 - one pound samples and each sample tested individually with a method capable of detecting one cell per sample, both A and B would likely result in 6 positives per 100 samples tested. However, example B actually contains approximately 100 times the level of contamination, because each positive sample contains ca. 100 cells.

It is not uncommon in practice for microbial contamination to exist in clumps as represented in example B. The number of cells per clump will vary with the nature of the product, source of contamination, and stability of the microbial contaminant in the product.

Figure 1. Incidence vs. level



Example A

Incidence = 6 pos. per 100 x 1 lb samples
Level = 6 Salmonella per 100 lbs.

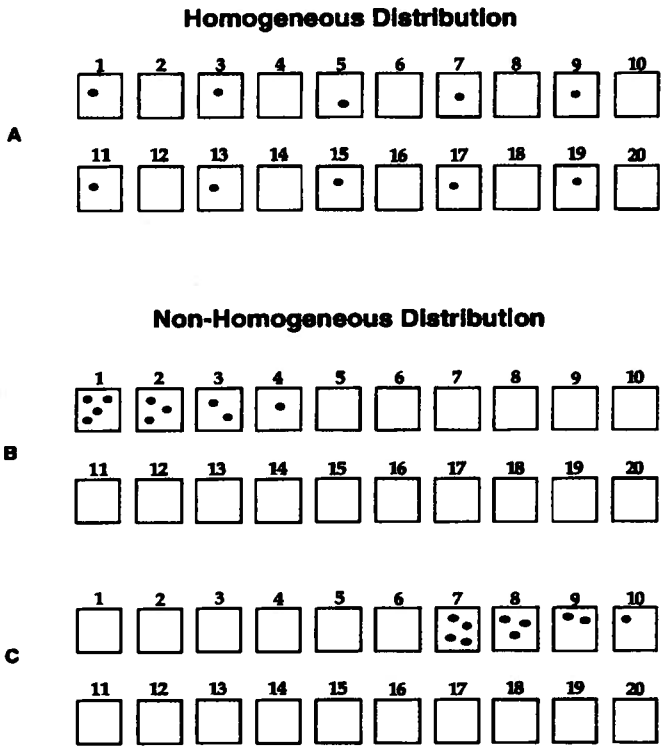
Example B

Incidence = 6 pos. per 100 x 1 lb samples
Level = 600 Salmonella per 100 lbs.

Secondly, the distribution of the microorganisms in the product must be considered. If distribution is random, i.e., it is not controlled by time, there is an equal opportunity for contamination to occur at any stage of the operation. If, on the other hand, contamination was limited to a certain segment of time during processing, then the defect would not be randomly distributed throughout the lot. If distribution is non-random, then regular random sampling procedures may not detect the organism. A random sample is one in which any individual aliquot tested is as likely to detect contamination as any other.

Microbiologists commonly refer to random distribution of microorganisms in a product as homogeneous and nonrandom distribution as heterogeneous. Figure 2 presents three examples of distribution of microorganisms in a lot of 20 consecutively produced boxes. In example A, the distribution is homogeneous; i.e., randomly distributed within the lot. Examples B and C represent non-random or heterogeneous distributions. In example B, contamination was greatest in the first

Figure 2. Distribution of microorganisms in a production lot of 20 boxes



sample followed by decreasing levels of contamination in boxes 2, 3, and 4. This type of distribution of organisms commonly occurs when product is produced on contaminated equipment. The product flushes contamination out of the system as production continues. Example C is similar to B, but results from introduction of microbial contamination into the system at some time during a production run. This type of contamination can come from a variety of sources and causes, e.g., equipment failure followed by substitution of an unclean unit, contamination from line workers or maintenance personnel, contamination introduced from the process environment via aerosol created by cleaning in an adjacent area, or contamination from outside the product stream falling into the product.

NON-HOMOGENEOUS DISTRIBUTION

Most sampling plans for microbiological analyses are based upon the assumption that the contaminant is homogeneously distributed within the product. In practice, microorganisms are rarely homogeneously distributed except in mixed liquid samples drawn from the same container. Depending on when and how the contamination has occurred, the distribution of contaminants will vary considerably as to the location and level of contamination within a batch. Consider the two examples below:

Example 1: Assume, due to a sanitation failure, there is *Salmonella* contamination within one of 10 filler heads of a particular liquid filler. At start-up the first product through this filler head will tend to flush out the contamination such that the first sample off that particular filler head will be more highly contaminated than the second, the second more contaminated than the third, and so forth until the samples coming off this filler head are no longer contaminated. This is similar to the example presented in Figure 2B.

Now consider, the laboratory testing the product obtains a positive result on a sample from the line. Unless the retest is performed on a sample from the same filler head very early in the run, there is little possibility that the initial positive result will be confirmed even if many samples from the run are analyzed.

Example 2 : Assume condensation exists at the top of a bucket conveyor handling dry product. Product dust collects in the condensation providing sufficient nutrient and moisture to allow growth of a potential contaminant. If an organism is introduced, a "microbial growth niche" is established. As dry product passes under this foci of contamination and the environment inside the bucket elevator becomes drier, the area dries up and a clump sluffs off into the product stream. At first, the contamination will be isolated to a particular bucket with product before or after the event being unaffected. However, as the product is further transported, perhaps by air or screw conveyor systems, the contamination clump breaks up and is diluted downstream. Thus, the organisms within the clump are distributed within the product much like a comet in space, with the highest level of contamination at the initial point where contamination was introduced followed by a dilution tail of decreasing level until the product coming off the line is again uncontaminated. This is similar to the example presented in Figure 2C.

In the above "comet-like" contamination example, the first product produced will be negative and the last bags produced will be negative, but somewhere within that day's production there exists a series of contaminated bags of product. Again, depending on the sampling plan, this contamination may or may not be detected, and extensive resampling and retesting may not confirm the positive result, unless these particular bags are analyzed.

A practical example of "comet-like" contamination was discovered by our laboratory involving a case in which a dry-blended product tested positive for *Salmo-*

nella. The product was sampled and tested at a Category II level according to FDA recommended sampling plans for *Salmonella* (BAM); i.e., 30 random 25 g samples were composited into two 375 g samples for analysis (750 g analyzed). All dry ingredients making up the product had been received with certificates indicating they had been sampled and tested negative for *Salmonella.* However, the blending operation was completely dry and there appeared to be little chance for contamination during mixing and packaging. Therefore, the ingredients were suspected as the source of contamination, and remaining material of the same lots were resampled extensively.

For one particular ingredient, 20 pallets of product had been received and eight remained. Every 50 lb. bag was sampled and analyzed at 375 g. Most bags from one pallet of this ingredient and a few bags from a different pallet tested positive for *Salmonella* with all other bags testing negative. Because the bags were sequentially numbered by the supplier as they were filled, it was possible to determine that the initial contamination occurred during the middle of the day and was diluted to below detection limits within a couple of hours. Further, one of the pallets that had been used as an ingredient in the blended product contained bag numbers within the range of those found positive, and the *Salmonella* isolated from the blended product had the same serotype as that isolated from the ingredient. These data clearly indicated the ingredient as the source of contamination in the finished product. Obviously, had all three contaminated pallets been used, extensive resampling of the remaining pallets would not have allowed the source of contamination to have been determined.

Over many years of providing the food industry with *Salmonella* and *Listeria* testing services, we have observed many other examples clearly demonstrating that non-homogeneous distribution of contamination may result in discrepancies between initial test results and extensive retest results.

LOW INCIDENCE OF CONTAMINATION IN A LOT OR BATCH

Sampling plans and microbial assays specify the quantity of product to be analyzed. Whether the microorganisms, such as *Salmonella* are detected will depend on whether or not they are present in a given test portion, the number of organisms present in the test portion and the sensitivity of the test method. When the microorganism is present in every portion at a high incidence and a level sufficient for detection by the test method, the initial analysis and subse-quent retests will be positive. When the microorganism is present at a lower incidence, not every test portion will con-tain the organism. Detection now depends upon the probability of selecting a contaminated portion. To confirm the initial positive result, a second positive sample must be selected. The probability of selecting two positive samples in a row is much lower than the probability of selecting the first positive portion. Difficulties associated with the detection and confirmation of positive results for microorganisms at low levels may be illustrated by the following example.

Envision a thoroughly blended product in a 100 gallon kettle. This product contains one *Salmonella* cell per 3750 grams. With a 375 gram sampling plan, there is one chance in 10 that each 375 gram test sample will contain one *Salmonella* cell. If the first sample tested positive, then the second 375 gram test sample obtained to confirm the positive result will likely test negative since there is only one chance in 10 that it will contain *Salmonella.* The probability of two positive test portions in a row is the probability that the first test is positive times the probability that the second test is positive. Thus, there is only one chance in 100 for two positive tests in a row for these examples. Given this situation, a retest used to confirm an initial positive will almost always result in a greater risk of passing a contaminated product.

Both the initial and retest portions have an equal probability of being positive when contamination is homogeneous. The probability that both will be positive is the square of the probability of a single portion testing positive (Table 1). The lower the incidence of contamination, the more difficult it will be to confirm. Confirmation will depend upon luck, or testing until the incidence of contamination is established. Very low incidence of contamination are virtually impossible to confirm by resampling.

Table 1. Probability of detecting a confirming analyte at low contamination levels

Probability of positive test*	Probability of test and retest positive
1 in 2	1 in 4
1 in 5	1 in 25
1 in 10	1 in 100
1 in 20	1 in 400
1 in 50	1 in 2,500
1 in 100	1 in 10,000

* Probability of a positive = batch size in grams x no. cells/size of test sample in grams

LOW INCIDENCE OF CONTAMINATION ACROSS MANY BATCHES

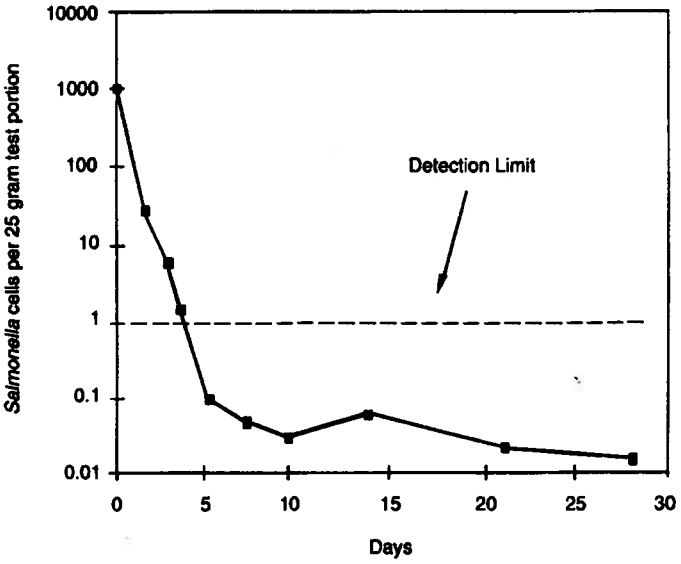
Occasional positive test results that are difficult or impossible to verify by retest may indicate that contamination is occurring frequently but at a very low level. Referring back to the 100 gallon kettle example of a homogeneous product contaminated with one *Salmonella* cell per 3750 gram, suppose 20 batches are prepared in a month. Using 375 gram test portions, only two will test positive. If sufficient retests are conducted to establish that the incidence of contamination in each of the two positive batches is one cell in 3750 grams, then one can conclude that there was one chance in 100 that two positive batches would have been found. Since this is a low probability event, one may suspect that the negative batches may also have been contaminated but at a low incidence. A thorough analysis of several negative batches will determine whether the contamination is widespread. In any event, product histories should be charted and inspected for "sporadic" instances of positive test results as an indication of low level widespread contamination.

CHANGE IN THE LEVEL OF CONTAMINATION

The number of viable microorganisms in a sample may increase, decrease, or remain the same with the passage of time. If the organism is growing, the level of contamination (cells/gram) will increase and it will be easier to detect. However, if the organism is dying, the number of viable cells in the product decreases and the probability of detection will also decrease. An example of a survival curve for *Salmonella* introduced into a dry product which does not support growth is shown in Figure 3. During the first few days the number of viable cells decreases rapidly. However, the organism is readily detected since its level is above the detection limit. A *Salmonella* test requires about five days for positive results. By this time, the level has dropped below the detection limit.

If a retest is requested at this time, there exists a high probability that the retest will not confirm the initial positive result. Actual rates of change for the initial rapid decrease and the later slow decrease shown in Figure 3 vary by product type, organism and storage condition. However, we know from many years of preparing inoculated samples for laboratory performance testing and evaluation of new methods, that transfer of organisms from a high moisture growth condition into dry product results in a survival curve

Figure 3. Typical survival curve for Salmonella in a dry product



similar to that shown in Figure 3. One would expect to see a very similar curve if an organism is growing in a plant environment and is then introduced into the product, such as in the condensation in the bucket elevator example described previously. If product is sampled and tested the first few days after production, the levels may be considerably higher than later when the survivors are more stable. Depending on the sensitivity of the method and the level of survivors after stabilization occurs, retests may or may not confirm the original result.

SUMMARY

There are many possible explanations for positive qualitative microbiological results not being confirmed by retesting. In practice, all of the phenomena described previously may come into play. Contamination may be non-homogeneously distributed at low incidence and be relatively unstable in the product. Therefore, initial positive data should not be negated because it is not confirmed by retests unless there is clear reason to suspect laboratory error or contamination during sampling. Since it is very often difficult or impossible to confirm laboratory or sampling error leading to erroneous results, it is extremely important that the laboratory performing qualitative tests have an extensive quality assurance program to prevent laboratory errors and to recognize contamination, if by chance, it does occur.