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

November 14, 2013

Submitted Electronically Via Regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Docket No. FDA-2011-N-0920; RIN 0910-AG36); Food and Drug Administration

Dear Sir or 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 within a $125-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 180 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The National Milk Producers Federation, 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 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

IDFA and NMPF supported passage of the Food Safety Modernization Act (FSMA) and recognize 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 the Food and Drug Administration's (FDA) efforts as it promulgates rules to implement the FSMA.

To that end, we are jointly submitting the following comments on the proposed rule on current good manufacturing practice (CGMP) and preventive controls.

IDFA and NMPF also support the extensive comments being submitted by the Grocery Manufacturers Association (GMA), and many of our members are also GMA members. Our comments are intended to reinforce important common themes highlighted by GMA, as well as to address areas of specific application to the dairy industry that are not addressed by GMA or other trade organizations.

General Principles

There are several main principles that cut across all of our comments on the FSMA preventive controls proposed rule:

1. **Requirements/standards should be risk-based and promote food safety**

   It is essential that all of FDA's preventive controls requirements be risk-based and truly promote food safety. The scope of products affected by this regulation is so broad that a prescriptive "one-size fits all" approach will not be effective. We recognize that FDA has moved in this direction in much of its proposal, but in moving to a final regulation extra attention needs to be placed on allowing food companies to adapt general requirements to the needs of their own products and manufacturing circumstances. Companies should be able to customize the regulatory requirements to their own systems in a risk-based fashion that advances food safety. Asking the two simple questions, (a) is the requirement risk-based? and (b) does the requirement promote food safety?, should be cornerstones to FDA's analysis. There is simply no place for prescriptive requirements in this rulemaking.

2. **Rulemaking should stay within FSMA's framework that protects public health**

   It is equally essential that FDA's proposal stay within the legislative framework prescribed by FSMA and that FDA implement that framework in a manner that protects public health. FSMA received broad public support for Congressional passage largely due to the manner in which it was drafted. In particular, FSMA incorporates well-accepted principles of food safety but does so in a way that facilitates the risk-based, food safety outcomes referenced above. Any significant deviation from the FSMA legislative framework should be questioned and reexamined. FDA should not finalize any rules that do not have a solid legislative footing in the statute itself. FSMA was designed to protect public health and it is important that FDA remain true to the statutory framework.

3. **Consistent and appropriate enforcement of FSMA is required to promote food safety**

   Even with a rational set of risk-based rules that are consistent with the FSMA statutory framework, FSMA's implementation will not be successful unless FDA can ensure that

its inspection and enforcement program is applied consistently across the country and effectuated in a way that promotes food safety. This means that extensive attention will need to be given to training inspectors. Similarly, FDA must provide food companies with a ready mechanism to appeal inspectional findings that are felt to be inappropriate, not required by the statute or regulations, and/or not consistent with promoting food safety and protecting public health. We support the Food Safety Preventive Controls Alliance (FSPCA) as one means of facilitating a common understanding of how FSMA is to be interpreted and applied in the real world setting. We urge FDA to continue its high level of transparency and collaboration with stakeholders during this transition process.

Specific Comments

Specific comments are organized below according to the Subpart of FDA's proposed rule. Any comments for Subpart A (e.g., definitions) will be incorporated into comments on the corresponding substantive section of the proposed rule.

Subpart B: Good Manufacturing Practices (GMPs)

Main Messages:

There is general support within our memberships for FDA's proposed revisions to the food GMPs. We appreciate FDA's incorporation of comments submitted by the industry GMP Coalition, led by the American Frozen Foods Institute (AFFI), to FDA's GMP Modernization docket and cite that collaborative success as a model for FDA rulemaking throughout FSMA. We do request clarification on certain allergen-related issues, as explained below. We support making training a requirement, as recommended by the GMP Coalition, provided the regulatory requirement is general so company training programs can be tailored to meet individual company needs.

Additional details:

We are pleased to support the general approach taken by FDA in its revisions to 21 CFR Part 110 and, in particular, appreciate the agency's incorporation of a number of prior industry comments.

Allergens. We agree that added attention needs to be given to food allergen/cross-contact issues and support this provision of the proposed rule. To improve the rule further, we ask that FDA clarify that: (a) allergen cross-contact is not a form of contamination (proposed section 117.3), (b) the agency is not imposing a zero-tolerance standard for allergen management; and (c) necessary allergen controls are driven by the hazard analysis.

- Food-contact terminology: this is an example of where nomenclature matters. Food allergens are regular food and not "contaminants" in the sense that biological, chemical, or physical contaminants would be. Food allergens are not harmful to the general population, just to those individuals with particular allergies. Therefore, it is important to characterize necessary separation between food allergens and other food ingredients as avoiding "allergen cross-contact" and not "cross contamination." This terminology is already used and accepted through much of the food industry.

- Not a zero-tolerance standard: we agree that food companies should strive to minimize allergen cross-contact and that adherence to GMPs should significantly enhance control of food allergens. But allergen cross-contact cannot be assured in the absolute sense. In some situations, even application of the most robust GMPs cannot prevent all allergen cross-contact. We ask that FDA clarify in the final rule and preamble that the goal is to *minimize* cross contact as much as is reasonably feasible, but that the agency is not imposing a zero-tolerance requirement. We strongly support continued efforts to establish science-based allergen thresholds that would complement these GMP regulations.

- Tying controls to hazard analysis: Although FDA has divided allergen control between Subpart B (GMPs) and Subpart C (Preventive Controls) in the proposed rule, we believe the two are linked for purposes of allergen control. We ask that FDA clarify that the specific types of allergen controls needed should be tied to the hazard analysis, as different types of degrees of allergen vigilance will be needed in different settings. That would further the goal that the regulations be risk-based.

Training. FDA solicited comment on how best to address training in the final rule – specifically whether training should be a required or recommended activity. We do support training as a mandatory element of the regulations, as well-trained employees are an essential element of a strong food safety program. But with one important caveat: any requirements for education and training must provide flexibility for companies to determine the scope and frequency of such training, depending on the facility, the types of products, and the job responsibilities of the employee. This too would further the goal that the regulations under FSMA be risk-based.

Additional Comments. We offer two additional points on GMPs. First, FDA should clarify that food packaging material refers to the food-contact portion of the packaging material (proposed section 117.3), and not materials that do not come into contact with food (e.g., secondary packaging like cases that contain finished product for shipping purposes). This is common sense as packaging that does not come into contact with food is not a food safety risk. Second, rather than using the broad term "cross-

contact," FDA should use the more specific description "allergen cross-contact." This would be consistent with the intention indicated by the term's proposed definition.

Subpart C: Preventive Controls

Main Messages:

We support the preventive controls provision of FSMA (§ 103), but seek significant modifications to the proposed rule to be consistent with the FSMA legal framework and facilitate implementation. Rather than trying to retro-fit FSMA preventive controls into a regimented seafood/juice HACCP model, the regulations should follow the FSMA statutory language to provide for: (a) consideration of "known or reasonably foreseeable" hazards (as opposed to hazards that are "reasonably likely to occur"), (b) implementation of a range of preventive controls (not just at critical control points (CCPs)) as needed to control those hazards, and (c) gradations in the level of rigor used to manage this range of preventive controls should be commensurate with the nature of the risk and the type of controls being used, with only CCPs receiving the most rigorous management oversight. In conducting a hazard analysis, consideration should be given to the benefits derived from existing prerequisite programs, such as GMPs. Industry supports FDA's on-site access to records for all preventive controls, including prerequisite programs that provide the foundational support for other preventive controls.

Additional details:

The preventive controls provision of FSMA forms the cornerstone of the statute's guiding principle that food companies should direct more food safety resources to preventing foodborne illness outbreaks rather than reacting to them. Therefore, it is essential that FDA "get it right" in implementing the regulation.

In reviewing FDA's proposed rule, it certainly appears that the agency has sought to transform FSMA into a traditional HACCP program in the image of the agency's seafood and juice HACCP regulations. This is apparent not just from FDA's preamble but, even more importantly, from the agency's choice to use traditional HACCP terms such as hazards "reasonably likely to occur." We believe this is the wrong approach, and contrary to the legal framework of FSMA. In drafting this central FSMA provision, Congress specifically decided not to require HACCP. Although Congress did rely on general HACCP principles (i.e., hazard analysis and adoption of control measures, with application of an oversight system of monitoring, corrective actions, and verification), the drafters took great care to avoid directing the agency to adopt HACCP per se. This is illustrated by Congress's avoidance of many HACCP technical terms in the statute (e.g., "reasonably likely to occur," "critical limits" and "validation"), which was intended to

preclude the very type of outcome FDA has proposed. We urge FDA in the strongest terms to take a step back and revise the proposal to apply the FSMA statutory framework adopted by Congress—not to retro-fit the FSMA regulation into the agency's pre-existing HACCP regime.

To be consistent with the plain language and direction of the statute, FDA should revise the final rule in two very significant ways. First, as FSMA prescribes, FDA should base the hazard analysis on a review and evaluation of "known or reasonably foreseeable hazards." [1/] As under Codex Alimentarius international food standards, this hazard analysis should take into account both the severity of the hazard and the probability of the hazard. See Codex General Principles of Food Hygiene, *CAC/RCP 1-1969, Rev. 4-2003 – Annex, p.25.* A hazard should only warrant adoption of control measures if it has both sufficient severity and probability of known or reasonably foreseeable hazards. A facility also should consider the benefits that derive from prerequisite programs as part of the hazard analysis, which may assess whether any further preventive controls are needed and the appropriate rigor to apply in the management of a preventive control.

Second, also as FSMA prescribes, FDA should treat the facility's management of these hazards through a range of preventive controls – not just at "critical control points" – and the degree of a facility's management over those controls should be commensurate with the nature of the hazard and the type of preventive control(s) used. FSMA clearly defines "preventive controls" as being much broader than just CCPs, through examples of programs such as GMPs, sanitation, and employee training. (In fact, by referencing "critical control points, *if any*" (emphasis added), FSMA §103 (a), FSMA does not even require CCPs.) Because there is a wide range of preventive controls, from basic programs like GMPs and training through possible CCPs like pasteurization, the range of preventive controls should be managed with varying degrees of rigor, based on risk.

As with traditional HACCP, we agree that any CCP would need to have the same high level of management oversight rigor in terms of monitoring, verification, and corrective actions as would be the case for a CCP in one of FDA's HACCP regulatory programs. But other preventive controls that are not CCPs should have a lesser degree of rigor in their management, tailored to the needs of each case. This approach is necessary because FSMA so clearly defines preventive controls as being a much broader range of food safety programs than CCPs. In the proposed rule FDA implicitly acknowledges this principle (i.e., not all preventive controls can be applied the same way), by exempting recall plans, a preventive control under FSMA, from the requirements of monitoring, verification, and corrective actions. To treat all preventive controls in the same way as CCPs would not only be wrong, but doing so would divert attention and resources away from other activities important to food safety. Clearly, FSMA should be implemented in a way that will enhance food safety, not dilute its effectiveness.

[1/] FFDCA § 418(b)(1).

In sum, the three critical changes we urge FDA to make are:

> (a) designate the hazard analysis as being based on "known or reasonably foreseeable hazards" (not on hazards "reasonably likely to occur"), including an evaluation of probability and severity;
> (b) recognize the wide-range of preventive controls needed to control hazards, which are not just applied at critical control points (CCPs); and
> (c) specify that the degree or rigor for managing implementation of preventive controls be applied on a sliding scale, commensurate with the nature of the risk and preventive controls used, commensurate with the nature of the hazard, including its probability and severity, and of the preventive controls applied for its control.

We recognize the importance of FDA having the ability to enforce the regulations against companies that are not employing sufficiently strong preventive controls programs. The FSMA statutory framework should once again serve as the agency's guidepost. FSMA provides that during an on-site inspection FDA has access to records not just for CCPs, but rather for the full range of preventive controls, including sanitation and good manufacturing practices (which are specifically listed in FSMA as preventive controls). This is much broader than the records access authority underpinning the agency's mandatory HACCP programs, which is limited to CCPs. With this scope of records access during an on-site inspection, FDA will be able to conduct a full and fair evaluation of each facility's food safety program and take enforcement action as appropriate. Unlike with seafood and juice HACCP, the agency does not need to make every control point into a CCP in order to gain access to company records during an on-site inspection.

Additional points of note regarding preventive controls in Subpart C include the following:

- In the hazard analysis, radiological hazards should be a subset of chemical hazards. This would be consistent with Codex and would obviate the need for food companies to revise all their food safety plans just to add a new category of hazard. Clearly, doing so would add significant cost without any food safety benefit. FDA has the legal authority to take this approach, as FSMA identifies several other hazards that must be considered that are not specifically itemized in the proposed rule (e.g., drug residues, decomposition).[2/]

- Parameters should not be required for <u>all</u> preventive controls. The term "parameters" does not appear in FSMA (nor does its HACCP counterpart

[2/] FFDCA § 418(b)(1)(A).

"critical limits"). Some preventive controls, such as GMPs, are simply not amenable to quantifiable parameters. FDA's proposal here is another carryover from HACCP and FSMA provides a much broader degree of flexibility.

- Validation (proposed § 117.150(a)) should be addressed separately from verification because the two are different. We view "validation" as meaning the system has the capacity to work effectively, which is a process that is conducted up-front. In contrast, "verification" means that the system is being executed as intended, and is a process that is conducted after-the-fact. FDA has ample legal flexibility to make this change as the term "validation" is not even listed in the statutory language.

  In addition:
  1. Validation should not be required for each individual control, but rather it should be permissible to validate combinations of controls or the overall food safety system; and
  2. 90 days should be provided to conduct validation, which is consistent with the Food Safety Inspection Services' (FSIS's) draft guidance on this issue.

- In response to FDA's request for comments on this issue, we encourage the agency not to require review of consumer complaints as a verification activity. Food companies may choose to evaluate consumer complaints as a potential signal about the general operation of their preventive controls system, but review of complaints should not be regarded as a mandatory verification step under the food safety plan. Consumer complaints are highly variable and range widely in their content, so they are not always a strong indicator of whether a system or program has problems. Requiring review of consumer complaints could result in unnecessary time and effort being spent on an activity with a limited correlation to food safety.

- IDFA has worked closely with FDA, the United States Department of Agriculture (USDA), the Department of Homeland Security (DHS) and other federal and state agencies since shortly after 911 on food defense issues. IDFA has played a leadership role in the Food and Agriculture Sector Coordinating Council since shortly after its inception which continues to this day. We have participated in numerous vulnerability assessments that were conducted with the Federal Bureau of Investigation (FBI), USDA, FDA, DHS, state and local officials under the Strategic Partnership Program on Agroterrorism (SPPA) as well as other vulnerability assessments. We worked with FDA in the development of many food defense tools including but not limited to FREE-B and the Food Defense Plan Builder Tool. IDFA is extremely well informed on food defense matters and fully supports FDA's decision to address food defense in a separate rulemaking. We look forward to

working through the food defense regulatory promulgation process in the months ahead.

- Food companies should not be required to develop a food safety plan for pilot plants and test kitchens where the resulting food is not sold to consumers. These are limited settings that should not be lumped together with full-scale manufacturing plants. FDA should either:
  - (a) exempt pilot plants and test kitchens from registration under the Bioterrorism Act, or
  - (b) exempt these facilities from the preventive controls rule, or
  - (c) formally exercise enforcement discretion on this issue, or
  - (d) designate these facilities as very low enforcement priorities for the agency

- FDA should provide greater clarification on the needed credentials for a "qualified individual." The agency's interpretation of this phrase should be consistent with precedent for the agency's HACCP programs.

- We support the Food Safety Preventive Controls Alliance and the importance of education, but FDA should also expressly allow for trade associations, in specialty areas, to provide their own training as, in many cases, such specialized industry-specific training may be of even greater value than the more general FSPCA training.

Exemption for Pasteurized Milk Ordinance (PMO) Regulated Facilities

At the March 1, 2013 public meeting on preventive controls, in response to a question from the audience regarding whether FDA would consider exempting PMO-regulated facilities from the preventive controls rule for food, FDA stated that a two-fold test would need to be met in order to create an exemption. First, a request for an exemption would need to show that the food would be as safe as if regulated under the preventive controls rule. Second, the request would need to explain where in the Act an exemption would be permitted. We address both these points below.

As discussed in greater detail in separate comments IDFA and NMPF filed to the preventive controls docket, IDFA and NMPF believe the PMO already achieves the same, if not a higher, standard of food safety as the preventive controls rule would when it is finalized. FDA certainly appears to have shared this view when the agency stated the following in its Memorandum of Understanding (MOU) with the National Conference of Interstate Milk Shippers (NCIMS), "FDA considers these standards, requirements and procedures to be adequate for the protection of the health and safety of the consumer" in reference to the PMO and the NCIMS process and concept. A copy of the MOU is attached here. See also: Federal Register 77-37071, Filed 9/19/77.

With respect to whether an exemption is permitted under the precise language of the FSMA, IDFA and NMPF have identified two areas in Section 103 which we believe establishes Congress's willingness for FDA to use its judgment to create exemptions where warranted, especially for foods subject to the PMO.

First, FSMA Section 103(n)(3) states that "[t]he regulations promulgated under paragraph (1)(A) shall . . . (C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods." In essence, Congress has instructed FDA to acknowledge that multiple sets of regulations do not necessarily enhance food safety and that, indeed, FDA should minimize redundant sets of standards. This is particularly appropriate where there is already an existing set of state food standards that are directed to a particular set of products. Indeed, Grade "A" dairy products are already regulated under the PMO. Subjecting them to the Preventive Controls rule would apply two separate standards, doubling rather than minimizing "the number of separate standards that apply to separate foods." Instead, FDA should acknowledge the reduced risk profile of foods produced in accordance with the PMO and allow dairy products to continue to be regulated under one standard, the PMO. Moreover, removing PMO-regulated facilities from the Preventive Controls rule would allow FDA to better tailor its requirements to those foods without such regulatory programs, which would also minimize the need to develop separate guidance and standards for this segment of the dairy industry.

Congress, in fact, specifically endorsed the PMO and instructed FDA to ensure the Preventive Controls rules are consistent with it and other domestic and international preventive control programs:

> "In promulgating the regulations under paragraph (1)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the FDA Food Safety Modernization Act, including the Grade "A" Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date." FSMA § 103(n)(5).

Congress thus specifically recognized the PMO as an appropriate—indeed a model--preventive controls program for addressing the food safety hazards being addressed by FSMA. The most effective way to ensure the Preventive Controls requirements for dairy facilities are "consistent, to the extent practicable, with" the PMO is to exempt dairy processors regulated by the PMO from the Preventive Controls requirements, or otherwise deem dairy facilities that are compliant with the PMO to also be in compliance with FSMA's preventive controls provision.

To the extent needed, FDA should work with the NCIMS to make such minor adjustments to the PMO as FDA may deem necessary to sustain the exemption requested. We

believe that, if challenged, an exemption granted by FDA from the Preventive Controls regulation for dairy facilities under the PMO would withstand judicial scrutiny. The federal courts give great deference to an agency's interpretation of its statutory authority and to an agency's factual determinations, such as a determination that the PMO achieves the food safety results called for by FSMA without subjecting the dairy industry to duplicative regulatory programs.

Taken together, we believe that: (a) Congress's instructions in FSMA; (b) the fact that FSMA itself cites the PMO as a model for food safety regulation, and (c) FDA's longstanding authority under the FFDCA to efficiently enforce the Act, make it clear that FDA has ample legal authority to exempt PMO-regulated facilities from the Preventive Controls rule.

As noted above, IDFA and NMPF are filling separate comments which go into more detail on this particular issue. Please consider that submission.

Preamble to Subpart C: Testing

Main Messages:

We support testing as a "verification" activity (not a "control" step), but the nature and extent of testing needs to be adapted to the particular circumstances of each facility and product. In general, each kind of testing has its own role and purpose. Environmental testing is usually the most beneficial type of testing to verify if sanitation and other preventive controls are working effectively. Testing of raw materials also has a role, such as the testing of raw milk for drug residues by milk producers. Finished product testing is only a beneficial verification activity in very limited circumstances. FDA should require each company to build into its food safety plan a program for appropriate testing, to explain the basis for such testing, and to implement its food safety plan accordingly. Inasmuch as FDA did not propose specific codified language on testing in the proposed rule, should the agency do so for the first time in a final rule, the agency should provide an additional opportunity for public comment, either as a re-proposal or as an interim or tentative final rule that would not be enforced until after an opportunity for public comment and publication of a final rule.

Additional details:

IDFA previously commented extensively that a broad based mandate to conduct finished product pathogen testing is unsound. We have attached those comments to this document. The key points we made in those comments which bear repeating here are:

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 raw materials (or incoming ingredient) 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 pathogen testing. "Product testing" for us is very broad and includes many types of tests. We test incoming raw milk for a number of substances and parameters and we conduct in-process tests as well. In-process testing can be used to look for chemical, physical and microbial contaminants. Indicator tests like coliform testing can be used for determining proper sanitation. Finally, alkaline phosphatase testing is a check for proper pasteurization. These tests are done in many of our plants on a daily basis and will continue to be performed to assure our systems are operating properly. It is important to point out that Congress never used the term "finished" or "finished product" in 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.

In addition, we presented information about how costly finished product pathogen testing could be for the fluid milk industry alone – over $600 million per year. Besides factoring in the high cost of testing, FDA should consider what additional information, if any, such testing would reveal. Take for example the fact that in 2006, a prison dairy in California was implicated in an illness outbreak that involved 11 different prisons and sickened as many as 1,300 inmates. Yet, investigators never found any pathogens in the milk samples that were collected. This is an excellent example of where finished product testing has a high false negative rate, thereby significantly diminishing its value. It obviously would be a wrong conclusion to say that these samples verified that there was nothing wrong with the milk when, according to all regulatory authorities involved, that was clearly not the case.

Outside of prison dairies, illness outbreaks associated with pasteurized fluid milk are rare. There was one in 2009 which was ultimately found to have occurred due to external contamination of the product packaging. Had the fluid milk been tested, the tests

would have come back negative. In another outbreak involving fluid milk, the Whittier Farms outbreak in 2007, it was ultimately determined that Whittier Farms did not have any environmental monitoring program whatsoever. If that dairy had had a robust environmental testing as is the standard in our industry, that outbreak in all likelihood would not have occurred. This example underscores the point that environmental monitoring is precisely where resources and efforts should be directed.

Yogurt is another product where it makes very little sense to employ finished product pathogen testing. As presented in a journal article prepared by Dr. Kathleen Glass and Dr. Russell Bishop, it was determined that yogurt with active cultures, at a pH of 4.6 or below before storage, which was processed in compliance with the GMPs prescribed by the Pasteurized Milk Ordinance (PMO), is inherently safe and does not support the growth of pathogenic organisms. See Glass KA, Bishop JR, *Food Protection Trends*. [2007, 27(6):380-388]. IDFA is attaching the journal article to these comments. Yogurt is yet another example of a food where finished product pathogen testing would produce absolutely no benefit, though it certainly would come with a cost.

IDFA and NMPF are not opposed to all finished product pathogen testing. There are clearly situations where finished product testing is beneficial, in particular for products that have not been subjected to a kill step. For example, while FDA, IDFA and NMPF all strongly oppose the direct sale and consumption by consumers of raw milk on public health grounds, that type of product would be an excellent candidate for broad and robust pathogen testing. But in any FDA regulations implementing FSMA, the needs for finished product testing must be the exception and not the general rule. As described above, there is no scientific basis for requiring routine finished product testing for pasteurized milk or yogurt products.

In 2010, *Food Safety Magazine* published a very insightful article "Shifting Emphasis from Product Testing to Process Testing," by William H. Sperber, Ph.D. Dr. Sperber posits that "HACCP is a preventive system designed to control significant identified hazards by means of validated process control measures. It does not depend on product testing to assure food safety. In fact, HACCP was developed precisely because product testing cannot reliably detect low-level defects such as low-incidence pathogen contamination in foods." He also states that "Pathogen testing in pasteurized dairy products is not required or necessary." Dr. Sperber points out the numerous shortcomings of product testing and advocates testing the process as is done under the PMO. In his conclusion, Dr. Sperber states, "To more effectively assure the safety of all foods, I believe that we must spend more effort on validating and implementing process controls and process testing measures while eliminating unnecessary product testing. Dr. Sperber is a former chair of the IFT Division of Food Microbiology and was appointed five times by the U.S. Secretary of Agriculture to the National Advisory Committee on Microbiological Criteria for Foods.

We concur with Dr. Sperber's views on product testing and have included the article as an attachment to these comments. We support an integrated approach to testing as a verification activity (not as a "control" step), applied as appropriate and necessary depending on the risk and value of test results to improve food safety. FSMA itself is very general as to the role of testing, and FDA should take a risk-based approach and allow each facility to customize its testing program to take into account the unique circumstances within that facility. This is particularly important given the significantly different benefits and costs for different types of testing. Specifically, environmental testing is often the most beneficial type of testing in terms of verifying the effectiveness of sanitation and other preventive controls and is also cost-effective. There are also important roles for the testing of incoming raw materials/ingredients, particularly where the manufacturing process does not apply a "kill step" to prevent the presence of pathogens in finished product (e.g., raw milk sold intrastate). Finally, finished product testing has very severe statistical limitations as a testing program, as acknowledged by the agency in the Appendix to the proposed rule. In most cases, lot-by-lot testing of finished products does not help improve food safety. Facilities should be given the flexibility to determine whether finished product testing will improve food safety for their products and apply it only in those circumstances.

Preamble to Subpart C: Supplier Verification

Main Messages:

We support including a supplier verification provision in the regulations on preventive controls, but urge FDA to direct its focus to require each manufacturer to develop a risk-based supplier verification plan that takes into account the risks presented by the ingredient (e.g., inherent risks) and the supplier (e.g., performance history). In particular, FDA should: (a) expand the scope of supplier verification to most types of ingredients – so as to cover the full range of microbiological, chemical, and physical hazards – but allow the specific types of verification activities applied for a given supplier to be determined by the manufacturer based on an evaluation of risk; and (b) make on-site audits more risk-based, so that audit frequency would be based on risk and not necessarily conducted on an annual basis. FDA should have access to records demonstrating the manufacturer is conducting the needed verification activities, but should not have access to the underlying records of the verification activities themselves (e.g., supplier audit reports).

Additional details:

We support a requirement in the final regulations for supplier verification, but believe that FDA's approach should be revised to reflect the following principles:

- Supplier verification functions as a prerequisite program and does not itself make food safe. Thus, the scope and extent of the supplier verification requirements should be commensurate with its benefit and not divert company resources away from other programs that directly enhance food safety.

- Each manufacturer should be required to develop a risk-based supplier verification plan, taking into account supplier and ingredient risks. (This is similar to Option 2 in FDA's proposed rule for the Foreign Supplier Verification Program.) Indeed, the manufacturer's risk assessment is a critical feature of an effective program. The history of the supplier, the nature of risks presented by the supplier and ingredient, and whether such risks are adequately controlled by the manufacturer, should all be taken into account and incorporated into an integrated supplier verification plan with regulatory flexibility for the verification activities applied. However, we do not support a specific requirement to conduct a review of regulatory compliance status because this focuses too narrowly on just regulatory compliance—which is only one issue that should be considered when assessing supplier risk.

- The supplier verification plan should apply to all suppliers—not just those with ingredients that present hazards not controlled by the manufacturer.

- Supplier verification should apply to the immediate supplier (one-step back) and not the supplier's supplier. This is where the manufacturer has the greatest leverage and ability to conduct meaningful oversight.

In particular, the role of on-site audits needs to be recalibrated. We believe that FDA's proposed FSVP Option 1 requirement for an annual, on-site audit for all suppliers controlling Class I hazards overstates the role of such audits at the expense of other verification steps. The manufacturer should have a broad tool kit, in which on-site audits are an important tool, but not the only tool. We do agree with FDA that on-site audits are an important tool, and typically should be conducted as part of initial qualification or within a reasonable time within beginning use of a supplier that controls a Class I hazard. But after that, the frequency and intensity of the audit should be an outgrowth of the manufacturer's overall evaluation of risk.

We are pleased that FDA recognized the value and contribution of leading third party audit systems, and manufacturers should be able to consider such audits/certifications as another tool in the supplier verification tool kit – but such voluntary audits must be outside the scope of the agency's proposed regulatory framework for third party accreditation – which should only apply, as prescribed by FSMA, to the mandatory import certification (MIC) program and the voluntary qualified importer program (VQIP). Such audits can add efficiency and reduce "audit fatigue" on

the part of suppliers. However, we do not support extension of FDA's third-party accreditation program to domestic supplier verification under preventive controls.

We support FDA access to the manufacturer's supplier verification plan and basic documents to demonstrate that the plan is being carried out. However, we strongly oppose FDA access to the underlying audit reports. Such information needs to be confidential between the manufacturer and the supplier if the supplier is to be open and transparent during the audit process.[3] Thus, this is a case where more limited records access by the FDA will actually enhance food safety by creating an incentive for openness. An overly intrusive rule would likely have the unintended effect of chilling the ability to conduct thorough audits. FDA would still have full records access for its own inspections of suppliers.

We support exceptions to the supplier verification requirements for small quantities of food intended for research and evaluation purposes (as is the approach under the Foreign Supplier Verification Program (FSVP) section of FSMA).

Finally, as FDA has recognized, any supplier verification requirements under the preventive controls rule—as this rule imposes supplier obligations domestically—must be consistent with any FSVP requirements in order to fulfill international trade obligations.

Subpart D: Modified Requirements for Warehouses

Main Messages:

We strongly support the proposed exemption for warehouses where the food is not subject to Time/Temperature Control for Safety (TCS). We request expansion of the exemption to cover all frozen foods, which FDA acknowledges are not typically subject to TCS. For those refrigerated facilities that are TCS facilities, FDA should recognize that GMPs already provide for adequate controls and so specific modified requirements are not necessary. This approach follows the principle described above that the nature and extent of the controls employed, and the management of those controls, should be risk-based, commensurate with the nature and degree of the hazards/risks being controlled.

Additional details:

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[3]/ Current agency programs recognize the importance of maintaining this confidentiality. 21 C.F.R. § 106.100(j) (infant formula); 61 Fed. Reg. 52602, 52613 (Oct. 7, 1996) (medical devices).

We strongly support FDA's proposal to exempt from Subpart C (preventive controls) warehouses where the food is not exposed to the environment and not subject to time/temperature control for safety (TCS). We agree with FDA that the statutory criteria for such exemption have been met, and that adherence to Subpart B (GMPs) is adequate to assure food safety.

Frozen dairy foods: With respect to frozen dairy foods, we believe this category of products should be expressly exempt because freezing is generally performed for quality reasons rather than food safety reasons – e.g., ice cream is not ice cream if it is not frozen and even short temperature deviations will make the product unappealing and unsalable, though not necessarily unsafe. Thus, we believe the presumption for warehouses storing frozen products should be that they also are exempt from Subject C (preventive controls) and only are subject to Subpart B (GMPs).

Refrigerated Foods: With respect to warehouses storing refrigerated products which are TCS, FDA should recognize that the current and proposed revised GMP's adequately address refrigeration and warehousing which requires the warehouse to be under conditions that will protect against cross-contact and biological, chemical, physical and radiological contamination of food as well as against deterioration of the food and the container. In essence, the GMP's obviate the need for any further regulation. FDA should therefore expand the warehouse exemption to include TCS foods without any further obligations.

Finally, FDA proposed to limit the warehouse exemption where the facility is *solely* in engaged in storing a particular type of product. We believe that is too restrictive. Where portions of a warehouse in the same registered facility are dedicated to the storage of an exempted type of product – and that section of the facility is sufficiently segregated so that a separate regulatory regime can be effectively implemented – that section of the registered facility should qualify for the exemption. So, for example, if a warehouse had two rooms – one with only non-refrigerated food and one with only refrigerated TCS food – the former should qualify for the exemption from Subpart C.

Subpart F: Records

Main Messages:

We strongly oppose both (a) the concept of requiring submission of facility profiles with hazards and controls information as well as (b) any requirement to provide FDA with remote access to company manufacturing and related records. Both concepts are clearly outside FDA's statutory authority under FSMA. We believe that FDA's access to and review of company records must be done on-site in the course of an authorized inspection, so that FDA may understand the full context of what the records show. We also urge FDA not to apply Part 11 to food company

electronic records because such regulation is disproportionate to the regulatory oversight needed. Instead, FDA should establish a simplified set of modified controls that are feasible to apply and adequate to assure authenticity of electronic records. Finally, FDA should provide a more practical framework for the storage and retrieval of records as needed for an FDA inspection.

Additional details:

- Facility profiles: We strongly oppose the imposition of a requirement on facilities to submit to FDA facility profiles that contain the hazards and controls from the facility's food safety plan. Such a requirement is completely outside of the FSMA legislative framework and is not needed to promote food safety. If Congress had wanted to give FDA this legal authority, Congress could have done so through FSMA. In addition to being outside FDA's legal authority, we believe that the submission of this information would be extremely time consuming for food companies without a commensurate benefit to food safety – in fact, it would divert a facility's food safety staff away from higher priority activities that do enhance food safety. FDA's examination of a facility's hazards and controls needs to be conducted within the context of an on-site inspection, so that agency officials can understand how the particular hazards and controls apply in that particular facility. Moreover, FDA has access to this same information during on-site inspections, which is currently captured in Establishment Inspection Reports, and can use that vehicle to collect and assemble any desired FDA database.

- Remote access to records: For similar reasons, we also strongly oppose any requirement for food companies to have to submit records to FDA remotely. There is no basis in FSMA to authorize this type of requirement. In fact, the House version of the legislation did contain such a provision, but the fact that it was not included in the final law clearly demonstrates that Congress chose not to give this authority to FDA. That decision was well-founded. As noted for facility profiles, an evaluation of a facility's records needs to be conducted within the context of an on-site inspection so that FDA officials can see first-hand how the food safety plan operates and can ask important clarifying questions to company experts on hand. We oppose the concept of a "desk audit" whereby FDA investigators could conduct their inspections from a remote office without actually visiting the facility. Such an approach is not authorized by FSMA and would not enhance food safety. Recent high-profile outbreaks have illustrated why facilities need to be visited in person rather than just assessed through their paperwork. Accordingly, remote records access must not be included in the final rule.

- Electronic records: FDA should exempt Part 117 records from compliance with Part 11 and instead require a simplified, practical set of requirements to ensure authenticity of electronic records. As FDA itself noted in

implementing the Bioterrorism Act of 2002, it would be extremely burdensome for the food industry to have to comply with Part 11. We commend the agency for exempting the food industry from compliance with Part 11 in the Bioterrorism Act context. As FDA acknowledged that subjecting the very limited set of records required under the Bioterrorism Act (essentially, the one up/one back traceability records) to Part 11 would be too burdensome, it also should understand how and why the burden under FSMA would be many times greater and therefore even less justifiable. FDA recognizes this in the preamble to the proposed rules and suggests that Part 11 may be a more extensive level of regulation than needed. We completely agree. What matters is authenticity of the records, which can be assured with a more simplified approach that places the burden on each facility to develop and implement its own controls that work with existing systems. We urge FDA to follow its own lead and exempt records under Part 117 from compliance with Part 11.

- Storage and maintenance of records: We understand and accept that a facility's records documenting its adherence to its food safety plan need to be maintained and made available for FDA inspection. But more flexibility is needed as to where the records are stored. It is simply not feasible – or appropriate – to store all relevant records on-site at each facility for 6 months after they are produced. Many types of records – such as supplier verification, testing analyses, or scientific validation – are often maintained at corporate headquarters or at another centralized facility, and are not specific to each manufacturing facility. The agency's focus through the regulations should not be where the records are kept, but rather that the records must be made available for FDA inspection with a reasonable amount of time (e.g., 24-48 hours). Records should be allowed to be maintained in the same facility where they are created, at a corporate office, or in an off-site storage facility. A 6-month requirement to keep records on-site – as proposed by FDA – is arbitrary and not even helpful as most FDA inspections will not occur during that 6-month period. It will result in unnecessary costs and reorganization that will not improve food safety or the agency's ability to address food safety problems. Again, the guiding principle should be not on where the records are kept, but that records should be accessible to an FDA inspector within a reasonable amount of time.

Economic Analysis

Main Messages:

FDA's economic analysis greatly understates the expected costs from the preventive controls rule, as proposed. Substantial changes to the proposed rule are needed to meet FDA's vision of this rule being largely cost-neutral for food companies with advanced food safety systems, as well as for medium and smaller food companies. Such changes also are needed to comply with the Paperwork Reduction Act. If the

proposed rule is revised in the manner we suggest in these comments, it will be more consistent with the agency's economic analysis.

Additional details:

We strongly disagree with FDA's general conclusion that large facilities will not have any significant added costs as a result of complying with these new regulations. As has been pointed out repeatedly in these comments, if FDA does not change these proposed regulations in the final rule in rather significant ways, the requirements would impose very substantial costs without any commensurate benefit to food safety. If FDA's intent was to be cost-neutral, then the agency should respond favorably to the many comments submitted above and by others in the food industry to make the final regulations less prescriptive and more risk-based so that each company can customize its food safety plan to what is truly needed to assure the safety of its food products. The disparity between cost and need is even greater with medium and smaller companies, who have to carefully target and focus their food safety resources where they are most needed. We also question the accuracy of many of FDA's time estimates under Paperwork Reduction Act and believe that the agency greatly underestimates the time needed to create and maintain the wide array of records required under FSMA. FDA should seek to minimize such costs and not divert precious company resources away from the central task of assuring food safety.

* * *

If we may provide any further information to assist the agency, please do not hesitate to contact us.

Respectfully submitted,

Clay Detlefsen
Vice President & Counsel
International Dairy Foods Association

Beth Panko Briczinski

Beth Briczinski, Ph.D.
Senior Director, Regulatory Affairs
National Milk Producers Federation

Attachments:
IDFA August 22, 2011, Comments
FDA MOU with NCIMS (1977)
Factors That Contribute to the Microbial Safety of Commercial Yogurt
Shifting the Emphasis from Product Testing to Process Testing

Attachment 1

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

August 22, 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-0238, Food Safety Modernization Act: Preventive Controls for Registered Human Food and Animal Food/Feed 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.

Introduction

IDFA 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 the Food and Drug Administration's (FDA) efforts as it promulgates rules to implement the FSMA. In these comments, we respond to FDA's request for information on current industry practices and views that will inform the agency's development of guidance on preventive controls for food facilities. In particular, we respond to FDA's

request for input on microbiological and other testing used to help ensure the safety of food.

In May of this year, IDFA and the National Milk Producers Federation jointly filed comments on preventive controls with considerable discussion about environmental and product testing, the associated costs, and the efficacy of finished product testing for pathogens. We are attaching those comments as an appendix to these comments for your convenience. We offer the following comments as a supplement to the information we previously supplied. As explained in our previous comments, we are concerned that FDA may be considering requirements that would broadly mandate finished product pathogen testing for dairy and other products. Such an approach would present significant concerns:

- The FSMA does not mandate finished product testing for pathogens;
- Finished product testing is not a control measure and does not make food safe;
- Public health is best protected when food facilities implement the verification activities best suited to their particular circumstances, taking into account the specific product, process, historical information, science and other relevant factors (e.g. for pasteurization, finished product testing is not usually the most effective verification tool); and
- A broad requirement for finished product pathogen testing would be extremely costly without a commensurate public health benefit.

We discussed the first two points at length in our previous comments and will not repeat our arguments here. Instead, we want to share our views regarding the product testing that is commonly conducted in the fluid milk industry and the potential impact that a mandatory finished product pathogen testing regime would have.

Product Testing in the Fluid Milk Industry

When product testing is used to help ensure food safety, it is used as a verification activity. That is, it is used to verify whether the preventive controls are working effectively. In the dairy industry, one of the most effective preventive controls is pasteurization. The effectiveness of pasteurization at controlling food safety hazards – including many pathogens -- has been well validated. However, the appropriate verification tool for pasteurization is not finished product testing for pathogens. Instead, other verification activities are commonly used. These include alkaline phosphatase testing and time and temperature checks.

Alkaline Phosphatase Testing

We mentioned alkaline phosphatase testing in our previous comments briefly, but feel that we did not give this important tool its proper emphasis. Alkaline phosphatase is an enzyme that is naturally found in milk. Although the alkaline phosphatase in milk is more thermal resistant than nonsporeforming microorganisms, it is denatured by pasteurization temperatures. Therefore, the presence of alkaline phosphatase can indicate the milk was not properly pasteurized. The alkaline phosphatase level should generally be negligible in

dairy products, other than certain cheese and cheese products. It is important to note that an alkaline phosphatase test is not a pathogen test; it is a chemical test which indicates whether proper pasteurization was achieved. Alkaline phosphatase testing was recognized in the 1930's and has been in extensive use over the decades since. FDA clearly recognizes its value; in fact the Pasteurized Milk Ordinance (PMO) states that "Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk products involved shall not be offered for sale."

While phosphatase testing is extremely valuable, there are a few caveats that must be noted. First, for some dairy products such as certain cheeses, microorganisms used during production produce alkaline phosphatase. In some cases, the maximum level of alkaline is established in the standard of identity for the cheese (21 CFR part 133). For other cheese and related cheese products required to be made from pasteurized milk, the alkaline phosphatase level should not be greater than 3 μg/0.25 g. Therefore in these cases relying on alkaline phosphatase testing as a verification of adequate pasteurization is not an option. Secondly, there appears to be a growing body of evidence that in some cases, phosphatase can be reactivated over time and a product that tested phosphatase free immediately after pasteurization may in fact test positive after a short period of storage.

Despite the limitations, alkaline phosphatase testing is an extremely valuable verification tool that is used in the dairy industry. It is inexpensive, provides rapid results and has been shown effective since the 1930's. Unlike finished product pathogen testing where bacteria are frequently not evenly distributed and results can be hit or miss, phosphatase results are more robust because the presence or absence of phosphatase is homogeneous throughout the product. It is also a superior strategy because it verifies that the pasteurization process is working properly versus looking at the presence or absence of bacteria that may be intermittently present and which could be easily missed. Further, it is one test that verifies that the system is working overall. If the dairy industry were to pursue verification by using finished product pathogen testing, numerous different tests would need to be performed and the costs and time delays would be substantial. We shared some good information on the costs in our earlier comments.

Time and Temperature Charts

In addition to alkaline phosphatase testing, the dairy processing industry makes extensive use of temperature recording devices on pasteurization equipment as well as storage tanks and cleaning systems as another verification tool. Appendix H of the PMO has extensive prescriptive requirements on how the recording devices are constructed and how they are to be operated, maintained and periodically tested. For example, a recorder for continuous pasteurizers must have an accuracy of +/- 0.5° C, the pen line must be no wider than 0.07 millimeters, and the circular recording chart must make one revolution in not more than 12 hours. Numerous other parameters are also prescribed. The PMO itself states that all pasteurization recording charts shall be preserved for a period of three months for traditional pasteurization, three years for aseptic milk. Further, Table 4 of the PMO lists 15 different equipment tests that must be performed on pasteurization equipment to ensure it is operating properly. These tests include time and temperature accuracy, calibration, pressure tests and tests to make sure electro-magnetic interference

is not occurring. The well thought out strategy in the PMO recognizes the importance of pasteurization, the need for it to be properly conducted and importantly the need for it to be verifiable. The time-temperature charts are an excellent means to verify that proper pasteurization has been conducted. The PMO does not mandate or suggest pathogen testing as a means to verify proper pasteurization.

Additional Concerns

Food industry personnel have for some time held food product production runs that have been subjected to testing until the test results are available. In many cases, tests results can take 3 or 4 days and frequently longer to acquire. FDA is well aware of the hold policy and the time it takes to get test results. The private sector is not alone in advocating a test-and-hold policy, earlier this year, USDA's Food Safety and Inspection Service announced a test and hold rule for meat which mandates holding tested food until test results for harmful substances are received. While that strategy makes sense and may work well for the meat industry and others, it does not work well for the fluid milk industry.

In most cases fluid milk is packaged and placed into commerce within 24 hours. If the fluid milk industry were to conduct pathogen testing on finished product, we would have to hold the product for three to four days while the test results were pending. At best, most fluid milk processing plants have on site storage for a little over one day's production. Holding milk for three or four days would require the expansion of storage capabilities by a factor of three or four. Cost aside, which would be enormous, most plants simply do not have the space to add that kind of storage capacity on site. As a result processors would need to acquire land and build new storage facilities or rely on third party warehouses, which in all likelihood do not have the capacity to accommodate our production at this point in time, so they too would need to acquire and build new facilities.

Finally, fluid milk products have a short sell-by shelf life, typically around 14 days. Holding product for test results on a short coded product runs contrary to good dairy practices of providing consumers with fresh and wholesome milk and retailers and consumers would not accept a three or four day reduction in that shelf life. As it is, many see the 14-day period as being too short and the industry is always trying to increase it where state law does not prescribe a maximum sell-by date. The bottom line is the fluid milk industry cannot test and hold at this time, nor will we be able to any time in the near future.

Conclusion

The dairy industry has extensive testing programs. As specified in the PMO, these include coliform testing on private water supplies, pesticide testing, and testing for the detection of drug residues in raw milk. In addition to those tests, some segments within the dairy industry use metal detection tests to ensure that no foreign metals have become incorporated into the products. And as discussed above, the dairy industry extensively uses alkaline phosphatase testing. It is the dairy product manufacturer's responsibility, however, to determine and implement the appropriate verification activities for its preventive controls, which are in turn specific to its facility, products, and processes. A

one-size-fits-all requirement for finished product testing for pathogens is not appropriate in the dairy industry and should not be required.

* * *

We hope that FDA finds the foregoing information useful. 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, Preventive Controls, Compliance and Enforcement and in the recent trade association meeting with Mike Taylor and senior FDA officials. We are extremely impressed with the value of all 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.

Please do not hesitate to contact us if we can be of further assistance.

Sincerely,

Clay Detlefsen
Vice President & Counsel
International Dairy Foods Association

APPENDIX

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

NATIONAL MILK
PRODUCERS FEDERATION

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" for us is very broad and includes many types of tests such as raw milk testing for a number of substances and parameters as well as in-process testing for chemical, physical and microbial contaminants as well as the use of indicator tests like coliform testing which is an indicator of proper sanitation and alkaline phosphatase testing which is an indicator of proper pasteurization. Many of these tests are done in our plants on a daily basis and will continue to be performed to assure our systems are operating properly. 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. 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.

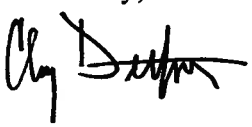
C. Use of Accredited Labs

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.

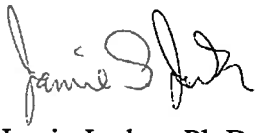
* * *

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



Jamie Jonker, Ph.D.
Vice President
National Milk Producers Federation

Attachment 2

MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

BACKGROUND

The Food and Drug Administration (FDA) is the federal agency responsible for enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. Included within the FDA's responsibilities under the Act is the responsibility for regulation of foods shipped in interstate commerce including milk and milk products.

The National Conference on Interstate Milk Shipments (NCIMS) is a voluntary organization directed and controlled by the member States and open to all persons interested in its objective of promoting the availability of a high quality milk supply. It is governed by an Executive Board whose members include representatives from state departments of health and agriculture, the FDA, the U.S. Department of Agriculture and industry.

Through their collaborative efforts, the FDA and the NCIMS have developed a cooperative, federal-state program (the Interstate Milk Shipper Program) to ensure the sanitary quality of milk and milk products shipped interstate. The Program is operated primarily by the States, with FDA providing varying degrees of scientific, technical and inspection assistance as provided by FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers ("Procedures Manual")*. The result has been the establishment of a viable and effective certification and enforcement program which has been of significant benefit to consumers.

The Interstate Milk Shippers Program relies upon the Grade "A" Pasteurized Milk Ordinance and related technical documents referred to in the Procedures Manual for the sanitary standards, requirements and procedures it follows to ensure the safety and wholesomeness of Grade "A" milk and milk products. FDA considers these standards, requirements and procedures to be adequate for the protection of the health and safety of the consumer. Sources of Grade "A" milk and milk products intended for use on interstate conveyances and subject to the Interstate Conveyance Sanitation Regulations (21 CFR 1250 et seq.) promulgated pursuant to the Public Health Service Act (42 U.S.C. 264) are considered approved sources for purposes of 21 CFR 1250.26 if they have a State or local permit, are under the routine inspection of a State or local regulatory agency and meet the provisions of the Procedures Manual.

PURPOSE

The purpose of this Memorandum is to strengthen the Interstate Milk Shippers Program by stating the responsibilities of the FDA and the NCIMS for execution of the Program, the means for resolving questions of interpretation that may arise in the execution of the Program, and the means for making modifications in the Program.

AGREEMENT

The FDA and NCIMS have agreed upon the following principles:

A. The Interstate Milk Shippers Program shall be governed by the provisions of the current FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers*, and by the documents referenced therein. Copies of all governing documents are available for review in the office of the Food and Drug Administration, Hearing Clerk.

B. The responsibilities of the NCIMS, the participating States, and FDA for execution of the Interstate Milk Shippers Program shall be as stated in the above referenced Procedures Manual.

C. Failure on the part of any certified state milk sanitation rating officer, state milk laboratory survey officer, or state sampling surveillance officer to comply with the provisions of this Memorandum or the Procedures Manual shall be sufficient cause for FDA to proceed to a hearing to provide said rating officer, laboratory survey officer, or sampling surveillance officer an opportunity to show cause why his/her certification or approval should not be revoked.

D. It shall be the right of the NCIMS and each participating State to request and receive consultation with the appropriate representative of the FDA to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The initial contact office at FDA for all inquiries pertaining to the Program is Bureau of Foods (HFF-415)**, FDA, 200 C Street, S.W., Washington, D.C. 20204.

E. It shall be the right of the FDA to request and receive consultation with appropriate officials of the NCIMS or any of its member States to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The Executive Board of NCIMS can be contacted by FDA personnel through the Bureau of Foods (HFF-415)** at the address indicated in paragraph D, above.

F. Problems of interpretation regarding provisions of the Procedures Manual and the documents referenced therein, or their application, shall be subject to resolution by mutual agreement of the parties.

G. Changes in the provisions of the Procedures Manual and the documents referred to therein shall be mutually concurred in by NCIMS and FDA.

H. This Memorandum of Understanding may be modified by mutual consent of the parties and may be terminated by either party upon a thirty (30) day advance written notice to the other. Any modification or notice of termination will be published in the Federal

Register.

For the FDA.

Dated: August 5, 1977.

Donald Kennedy,
Commissioner of
Food and Drugs.

For the NCIMS.

Dated: June 28, 1977.

H. H. Vaux
Chairman, NCIMS.

Effective date: This Memorandum of Understanding became effective August 5, 1977.

Dated: September 12, 1977.

Joseph P. Hile
Associate Commissioner
for Compliance

(FR Doc. 77-37071 Filed 9/19/77; 8:45 a.m.)

* Current document is titled: Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.

**Note: HFF-415 mail symbol for Dairy and Lipid Technology Branch, DFT, Bureau of Foods is now HFS-316, Center for Food Safety and Applied Nutrition, Milk Safety Team, 5100 Paint Branch Parkway, College Park, MD 20740.

Attachment 3

Factors that Contribute to the Microbial Safety of Commercial Yogurt

Kathleen A. Glass, Ph.D[1]. and J. Russell Bishop, Ph.D[2].

University of Wisconsin-Madison
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Executive Summary:
Yogurt with active cultures, at the pH of 4.6 or below before storage, that is processed in compliance with GMPs currently prescribed by the PMO, is inherently safe and does not support the growth of pathogenic organisms. More specifically, the safety of commercial yogurt in the United States is primarily dependent on the use of pasteurized milk to eliminate vegetative bacterial pathogens and spoilage microorganisms, good manufacturing practices and sanitary operating procedures to reduce the potential for recontamination, and a robust fermentation to produce sufficient acid and other antimicrobial metabolites to prevent growth of pathogens, should recontamination occur. In the case of commercial yogurt, high numbers of live and active *S. thermophilus* and *L. bulgaricus* assure safety by generation of acid and other antimicrobial metabolites (acetaldehyde hydrogen peroxide, acetic acid, formic acid, diacetyl, and bacteriocins) during a short (3 to 6 hours) fermentation at 42 to 45°C (107 to 113°F), preventing growth or causing death of pathogens. Chilling of the acid food to <7°C (<45°F) within four hours after coagulating of the milk (pH ~4.6) serves to reduce additional acid production to prevent adverse flavor defects. However, rapid cooling does not appear to provide any safety advantage over extended cooling to <7°C (<45°F) in 72 hours because the high levels of lactic acid will provide a barrier to microbial growth.

Research also demonstrates even in the absence of starter cultures or competitive microflora that a low pH (≤4.6) will prevent growth of pathogens during extended cooling if recontamination should occur, and will prevent growth and toxin production by spores (such as *Bacillus cereus* and *Clostridium botulinum)* that survive pasteurization. These same factors will also serve to inhibit enterotoxin production by *S. aureus* if the product were recontaminated after processing. The pH range for enterotoxin production is 5.2-9.0. Based on pH requirements for enterotoxin production identified in the published literature and predictive models, as well as challenge study data for yogurt, no growth or enterotoxin would be observed during the proposed extended cooling period.

Data described in this paper for microbial challenge studies of yogurt, as well as modeling information for the inhibition of various pathogens in laboratory media, support the safety implications of the 2005 NCIMS Proposal 130, especially at typical pH values (≤4.6) found in commercial yogurt today. The practice of cooling yogurt from 24°C to <7°C (75°F to <45°F) within 72 hours is safe provided the manufacturer complies with the described processing parameters (rapid and extended generation of acid by the yogurt starter cultures). Environmental controls are necessary to prevent recontamination with acid-tolerant microorganisms that may have long survival times.

Manufacturing Practices Ensuring the Safety of Yogurt:
Yogurt is inherently safe due to a number of contributing factors. In addition to core good manufacturing practices, which are cornerstones to the safety of all food products produced in the United States, yogurt has additional manufacturing safeguards to further guarantee food safety. U.S. regulations require use of pasteurized milk in yogurt production. Current industry practices typically exceed minimum thermal requirements by pasteurizing to 91°C (195°F) for 40 to 60 seconds (HTST) or to 85°C (185°F) for 30 minutes (vat) to ensure destruction of indigenous thermotolerant microflora that may interfere with the rapid growth and acid development of the starter bacteria (Kosikowski and Mistry, 1997; Vedamuthu, 1991). Pasteurized homogenized milk or milk mix, and any stabilizers or sweeteners are then cooled in closed vats to 42 to 45°C (107 to 113°F) before concentrated starter culture is added to yield approximately 6 to 7-log cfu/ml or greater of each *S. thermophilus* (ST) and *L. bulgaricus* (LB). Product mixture may then be filled immediately for cup-set yogurt or vat-fermented before filling for blended-style. During the fermentation, regardless of product type, lactic acid is produced from lactose by the yogurt starter culture, whose population increases 100- to 10000- fold to a final concentration of approximately 10^9/ml. The reduction in pH, due to the production of lactic acid, causes a destabilization of the micellar casein at a pH of 5.1 - 5.2 and with a complete coagulation occurring around 4.6. At the desired final pH, the coagulated milk is cooled quickly to 4-10°C (40 to 50°F) to slow down the fermentation to retard further acid development. Cultures will continue to metabolize and produce acid after yogurt is chilled to 7°C (45°F) or less, although at a slower rate than when held at elevated temperatures (Matalon and Sandine, 1986).

Effect of Synergistic Growth of Active Starters:
Lactic acid bacteria starter cultures have long been used to ensure the safety of fermented foods because of their ability to compete with pathogens for nutrients, rapidly produce lactic and other acids to reduce pH, as well as generate other antimicrobial compounds such as acetaldehyde, diacetyl, hydrogen peroxide, and bacteriocins. Even if a food substrate is contaminated with high levels of pathogenic bacteria prior to fermentation, such as through cross-contamination with raw milk, certain pathogens may initially be able to compete with the starter and grow but will die or be inhibited when the level of lactic acid is sufficient to achieve pH 4.8 or less (Attaie et a., 1987; Bodnurak et al., 1988; Schaack and Marth, 1988b).

On the other hand, factors such as antibiotics, bacteriophage, or high salt content which prevent starter culture activity essential for production of yogurt will also interfere with the overall safety system. If starter culture metabolism and the rate of lactic acid production is eliminated or significantly reduced, the resulting environment could permit pathogen growth and toxin production in recontaminated, unfermented milk stored at ambient temperatures for extended periods (see reviews by Minor and Marth, 1972; Tatani, 1973). Therefore, starter activity is an important consideration to prevent pathogen growth of yogurt if recontaminated and stored at ambient temperatures.

In the case of commercial yogurt, high numbers of live and active *S. thermophilus* (ST) and *L. bulgaricus* (LB) assure safety by generation of acid and other antimicrobial metabolites during a short (typically 3 to 6 hours) fermentation at 42 to 45°C (107 to 113°F), preventing

growth or causing death of numerous pathogens. Chilling of the acid food to <7°C (<45°F) within four hours after coagulating of the milk (pH ~4.6) serves to reduce additional acid production to diminish adverse flavor defects. However, rapid cooling does not appear to provide any safety advantage over slow cooling (to <7°C or 45°F, in 72 hours) because the higher levels of lactic acid production associated with extended fermentation provide an additional barrier to microbial growth.

Numerous studies have demonstrated that symbiotic growth of ST and LB results in greater acid production than when either strain is used individually (see Jay, 1991; Matalon and Sandine, 1986; for references). Both thermophilic bacteria are homofermentative, and generate lactic acid by fermenting lactose, while LB specifically demonstrates mild proteolytic activity in milk and is primarily responsible for production of flavor and aroma components (acetaldehyde, acetone, acetoin, and diacetyl). During the early stages of fermentation, amino acids generated by the proteolysis of casein stimulate growth of ST. The coccus begins to grow faster than the rod and is responsible for the primary acid production. During fermentation, ST utilizes excess oxygen and produces CO_2 and formic acid, which in turn, stimulates growth of LB. As the acid concentration increases to pH 4.2 to 4.4, ST growth is inhibited, but the lactobacilli continue to grow and produce acid until the substrates reaches pH 3.5 to 3.8.

The synergistic growth of ST and LB is not only important to the physical, chemical, and sensory characteristics of yogurt, but also to its safety. Dineen et al. (1998) reported that *E. coli* O157:H7 was more sensitive to the inhibitory properties exerted by *L. bulgaricus* than to *S. thermophilus*, but that co-culture of ST-LB reduced populations of *E. coli* O157:H7 more than either culture used alone.

Effect of Acidity:

In addition to use of GMPs and proper processing, the acidity of yogurt is a significant factor in inhibiting and inactivating bacterial pathogens should the product be inadvertently recontaminated and stored at temperatures >7°C (>45°F). Pathogens can survive for a short time if post-fermentation contamination occurs (see description of Challenge Studies below). In general, the lower the pH, the shorter the survival time (Minor and Marth, 1972a).

Although adverse pH, by itself, limits the function of bacterial enzymes and transport system, other factors such as type of acid, total acidity, and buffering capacity of the substrate are also pertinent (Caplice and Fitzgerald, 1999; Jay, 1992). For example, the minimal pH for growth in laboratory media under otherwise ideal conditions of *S. aureus* is 4.0 to 4.3 using inorganic acids; the pH limits are much higher when using organic acids such as lactic or acetic acid (ICMSF, 1996; Tatini, 1972). In addition, the lag phase for a microorganism increases if the pH of the substrate is outside the optimal growth pH (Jay, 1992). In acidified pasteurized milk stored at 37°C (99°F) for 24 hours, populations of *S. aureus* decreased >2-logs in milk acidified to pH 4.5 with lactic acid, but grew >2.5 log in milk acidified with HCl to the same pH value (Tatani et al., 1971). The pH requirements are more stringent for toxin production than for growth, with the minimum pH for staphylococcal enterotoxin production reported to be 5.1 (Scheusner et al., 1973). As with growth, toxin production is inhibited more effectively when the pH is reduced by lactic acid rather than by hydrochloric acid. (NZFSA, 2001).

Although spores of pathogens survive pasteurization, such as *Bacillus cereus*, Clostridium *botulinum*, and *Clostridium perfringens,* they are unlikely to grow at pH <4.8 especially when stored at ambient temperatures or lower. The USDA-ARS Pathogen Modeling Program 7.0 predicts probability <0.01 for growth at 20°C (68°F) through 29 days in media acidified to pH 4.8. Minimum pH for growth of common *B. cereus* strains is 4.8 in media acidified with HCl or 5.6 in media acidified with lactic acid; the organism is reported to die suddenly in yoghurt when the pH reaches 4.5 (ICMSF, 1996; NZFSA, 2001). *C. perfringens* growth is limited at pH 5.5, and is reported to be inactivated after several days at pH 5.0 (ICMSF, 1996; NZFSA, 2001).

Effect of Other Metabolites:
In addition to lactic acid production, the two primary thermophilic lactic acid bacteria used as yogurt starter cultures, *S. thermophilus* and *L. bulgaricus*, (and are required by the Standard of Identity 21 CFR 131.200 (a), 131.203 (a) and 131.206 (a)) are known to generate other antimicrobial metabolites. Gilliland and Speck (1972) demonstrated that lactic streptococci reduced growth of *Salmonella* and *S. aureus* in milk, even when the pH was maintained at pH 6.6 during starter growth. These researchers, as well as many others, have reported that metabolites such as hydrogen peroxide, bacteriocins, acetaldehyde, and diacetyl, were antagonistic to pathogens and spoilage microorganisms (Abdel-Bar and Harris, 1984; Barefoot and Nettles, 1993; Dahiya and Speck, 1968; Gilliland and Speck, 1972; Jay, 1982; Kang and Fung, 1999; van de Guchte et al., 2001.

Hydrogen peroxide is a toxic reduction product of molecular oxygen, which inhibits *S. aureus* and other pathogens (Attaie et al., 1987; Dahiya and Speck, 1968; van de Guchte et al., 2001; see review by Gilliland, 1985). Based on a study that neutralized hydrogen peroxide and acid produced by ST-LB cultures in yogurt, Attaie et al suggested that possible bacteriocin or other antimicrobial production by ST and LB may have contributed to the inhibition of *S. aureus* (Attaie et al., 1987). Numerous bacteriocins that are effective against pathogenic and spoilage bacteria produced by ST and LB, as well as adjunct starters, have been reported (see Barefoot and Nettles, 1993 for references). Most are active at the low pH values associated with yogurt (see Caplice et al., 1999). Several strains of ST produce the bacteriocin, thermophilin, which has activity against Gram-positive bacteria such as *L. monocytogenes* and *Clostridium tyrobutyricum* (Mathot et al., 2003; Villani et al., 1995). Adjunct lactic acid bacteria, such as *L. acidophilus* have been shown to produce the bacteriocin, acidophilin, which is effective against *S. aureus*, *E. coli*, *Pseudomonas fluorescens,* and *P. fragi* (Attaie, et al., 1987; Shahani et al., 1977; Singh, 1983). Benkerroum and associates also demonstrated greater kill of *S. aureus* and *L. monocytogenes* during yogurt fermentation and storage at 4 or 22°C (40 or 72°F) when using a bacteriocin-producing ST compared with using a starter did not produce bacteriocins (Benkerroum 2002; N. Benkerroum, personal communication, April 4, 2005).

Other metabolites, such as acetaldehyde and diacetyl, are inhibitory to pathogens. Diacetyl inhibited growth of *E. coli* O157:H7 and *Salmonella* Typhimurium when added to laboratory media at a concentration of 50 ppm (Kang and Fung, 1999). Acetaldehyde (at 500-1000 ppm) has been shown to be inhibitory to other lactic acid starter or probiotic bacteria (Vinderola et al., 2002). Levels of these compounds produced by LB when cultured alone are lower that are typically considered sufficient for antimicrobial activity

individually (Kulshrestha and Marth, 1974). However, when LB is co-cultured with ST in yogurt, studies have shown that 1400-1700 ppm acetaldehyde and 165-200 ppm diacetyl can be produced (Beshkova et al., 1998).

International Outbreaks Associated with Contaminated Yogurt:
There have been no recognized foodborne disease outbreaks associated with yogurt in the United States due primarily to the consistent use of multiple safeguards including proper GMPs (production in a sanitary environment, use of safe and suitable ingredients such as pasteurized milk), but also to use of active starter cultures for essential acid development. In contrast, several outbreaks associated with contaminated yogurt that have been reported in other countries in the past two decades, each of which were contributed to by improper processing, contamination with raw milk, and/or inadequate acid production. In the United Kingdom, 27 cases of botulism, including 1 death was associated with the consumption of yogurt that contained insufficient thermally-processed hazelnut puree. While the yogurt itself was properly manufactured, the botulinal toxin in the hazelnut puree was stable at the low pH during refrigerated storage (Critchley et al., 1989; O'Mahoney et al., 1990). Investigations into several outbreaks of *Salmonella* and *E. coli* O157:H7 in the UK, Scotland, and British Columbia revealed similar violations of good manufacturing practices including using a single pump for transferring raw milk and distributing pasteurized milk for fermentation without intermediate disinfection, no record of time/temperature for pasteurization and overall poor hygienic practices (BC Centre for Disease Control, 2002; Evans et a., 1999; Morgan et al., 1993; Upton and Coia, 1994). Two outbreaks of staphylococcal enterotoxin poisoning, resulting in a total of 47 cases, were reported to New Zealand authorities linking yogurt made in institutional kitchens (NZFSA, 2001). Both outbreaks were attributed to contamination of food by handlers and to slow growth of yogurt starter culture due to fermentation at room temperature (~25°C or 77°F) rather than at the prescribed 42 to 45°C (108 to 113°F) necessary for rapid acid development (R. Whyte, Institute of Environmental Science & Research Limited, New Zealand, personal communication, April 4, 2005).

Challenge Studies:
Numerous studies have evaluated the survival of pathogens during production and storage of yogurt; however, all conditions have not been tested for each pathogen. Table 1 (see below) summarizes inactivation or survival rates for pathogens in yogurt (pH $\leq$4.6) at various temperatures from representative studies. In the absence of challenge studies, minimum pH values for growth, and lag time and generation time USDA-ARS Pathogen Modeling Program 7.0 are reported. It is important to note that PMP data are derived from growth in media acidified to pH 4.8 with HCl, held at a constant 20°C (68°F), and without competitive microflora. We reported above that yogurt starter cultures provide an additional level of safety because they generate lactic acid (which is more antimicrobial at any given pH than HCl) and other antimicrobial metabolites such as hydrogen peroxide, and because they actively compete with pathogens for nutrients. As demonstrated by the challenge studies described in this paper, actual survival or growth of pathogens in yogurt would be considerably less in the presence of actively fermenting starter cultures than which would be observed in media. Therefore, use of the PMP would represent a "worst-case scenario" and should only be considered in the absence of challenge study data.

Table 1. Summary of inactivation in yogurt, minimum pH values for pathogen growth, and predicted growth potential at pH 4.8 adjusted with HCl and no competitive microflora.

	Survival in yogurt pH ≤4.6[1] *(lactic acid + competitive microflora)*	*Reference*	*minimum pH for growth in media*	*Reference (pH)*	*PMP 7.0 Predicted growth in media at pH 4.8 (HCl) at 20°C (68°F) (without competitive microflora)*	
C. botulinum	**NR**[2]	**NR**	**4.6 (HCl)**	**ICMSF**	**No growth**	
C. perfringens	**NR**	**NR**	**5.5 (NR)**	**ICMSF**	**No growth**	
B. cereus	**Inactivated (# log not reported)**	**NZFSA**	**5.6 (LA**[3]**)**	**ICMSF**	**14.5 h lag**	**1.7 h GT**[4]
L. monocytogenes	**3 log decrease in 12 h @4°C** **2-3 log decrease in 12 days H_2O_2 4°C** **Survival 28 d @ 8°C**	**Schaack and Marth, 1988a, 1988c; Choi et al, 1988** **Tipparaju et al 2004**	**4.5 (NR)**	**ICMSF**	**30 h lag**	**3.4 h GT**
S. aureus	**3 log decrease in 1 d @7 and 23°C** **2-log decrease in 10 d at 7 and 22°C**	**Minor and Marth, 1972a;** **Benkerroum et al 2002**	**4.5 (HCl)**	**Tatini, 1972**	**31 h lag**	**3.5 h GT**
Salmonella	**3-log decrease pH 4.15 at 42°C, 3 h**	**Rubin and Vaughan, 1979**	**4.4 (LA)**	**Park and Marth, 1972**	**not modeled**	
E. coli O157:H7	**2 log decrease 6-12 d at 4°C** **6 log decrease 17 days at both 4 and 10°C** **5 log reduction in 5 days at 4 and 25°C**	**Dineen et al 1994** **Hudson et al 1997** **Ogwara et al 2002**	**4.0-4.4 (NR)**	**Doyle et al 1997**	**15 h lag**	**2 h GT**

[1] Based on yogurt fermented at 42°Cwith standard ST-LB starter cultures
[2] NR=not reported
[3] LA=lactic acid
[4] GT=Generation time

Due to the harsh acidic properties of yogurt and the presence of active lactic acid bacteria that will continue to metabolize if stored at unrefrigerated conditions, few pathogenic bacteria are able to survive extended periods in this environment. While the pH of commercial yogurt is generally less than 4.4, some unusual varieties may have pH values that exceed 4.6. Regardless, provided the pH is <4.8, the probability of pathogen growth in yogurt at the non-standard pH values is very low.

The enteric pathogen *E. coli* O157:H7 is noted to be particularly acid resistant, and therefore would pose the greatest risk of extended survival in yogurt (Doyle et al., 1997). Factors that would control growth or survival of *E. coli* O157:H7 should be sufficient to ensure the overall safety of these products with regards to other pathogens. Any potential risks associated with *E. coli* O157:H7 can be mitigated by standard pasteurization of raw ingredients to eliminate the pathogens and good manufacturing practices to prevent any recontamination of the milk (BC Centre for Disease Control, 2002; Morgan et al., 1993). However, should the product be inadvertently contaminated, fermentation by the ST-LB culture and prolonged exposure to the high-acid environment (pH $\leq$4.6) provide an additional hurdle to inactivate pathogens such as *E. coli* O157:H7, especially when the product is stored at elevated temperatures.

Hudson et al. (1997) suggested that survival of *E. coli* O157:H7 in commercial yogurt with live cultures was dependent on both pH and storage temperature. Shorter survival times were reported in yogurt with initial pH of 4.17 than yogurt at pH 4.39 or 4.47. Similarly, at any given pH, pathogen viability was lower in yogurt stored at 10°C (50°F) than at 4°C (40°F). Populations of *E. coli* O157:H7 decreased 6-logs to undetectable levels within 5 and 8 days at 10 and 4°C, respectively for yogurt with pH 4.17, within15 and 7 days at 10 and 4°C (40°F), respectively for yogurt with pH 4.39, and within 17 days at both 10 (50°F) and 4°C (40°F) for yogurt with pH 4.47.

Other research confirmed that pH is critical to inactivation of *E. coli* O157:H7 and that storage temperature may be secondary in importance. Guyara and collaborators observed >3-log reduction of *E. coli* O157:H7 in inoculated retail yogurt (pH 4.4 or lower) stored at either 4 or 12°C (40 or 54°F)for 7 days (Guyara et al., 1998). Populations of the pathogen continued to decline in the pH 4.65 yogurt, with >3-log reduction at day 35. The final pH values for yogurt samples at the end of storage at 4 and 12°C were not reported.

Govaris et al, (2002) inoculated milk with ST-LB starter culture and 4.8-log *E. coli* O157:H7 prior to preparation of set yogurt. Products were fermented at 42°C (108°F) for 3 hours to coagulate the milk (pH 4.4), and then stored at 4 or 12°C. Populations of *E. coli* O157:H7 decreased approximately 1-log during the fermentation and to less than detectable levels in yogurt after 5 and 7 days storage at 12 and 4°C (54 or 40°F), respectively. Bachrouri et al. similarly observed accelerated inactivation at higher storage temperatures. In this study, the researchers inoculated finished, retail, plain yogurt (with live ST-LB cultures; initial pH 4.1) with >4-log cfu *E. coli* O157:H7 per g yogurt and stored the product at 4, 8, 17, and 22°C (40, 46, 63, and 72°F) (Bachrouri et al., 2002). Populations of *E. coli* O157:H7 decreased 0.8 and 2.7-log in yogurt stored 72 hours at 4 and 8°C, respectively. Storage at

ambient temperatures further increased the death rate, affecting a 3 and 4-log decrease in yogurt stored at 17 and 22°C, respectively.

Ogwara et al (2002) compared the behavior of *E. coli* O157:H7 in African yogurt in recontaminated milk fermented at 43, 37, 30, and 25°C, and then stored at 4 or 25°C. Data revealed that in spite of the recontamination, *E. coli* O157:H7 did not grow in milk rapidly fermented at 43°C (109°F; final pH 4.0 at 24 h), but did increase in recontaminated milk during slow fermentation at the lower temperatures (final pH at 24 h was 5.1, 4.6, and 4.4, for 25, 30, 37°C, respectively). When stored at 4°C, populations of pathogen decreased approximately >8 log and 2 cfu/g for product fermented at 43 and 25°C, respectively. In all fermented milk samples stored at 25°C, no viable *E. coli* O157:H7 were recovered after 5 days regardless of fermentation temperature. This study highlights the importance of using GMPs, and use of rapid starter activity (pH decrease to $\leq$4.6 within 6-8 hours such as what is currently used in the US today) to reduce the possibility of surviving pathogens). It also demonstrates that prolonged exposure to acid at elevated temperatures will *accelerate* inactivation of this pathogen should the product become recontaminated. Research conducted using other acidic foods, such as apple cider and mayonnaise, further supports that *E. coli* O157:H7 demonstrates greater tolerance to acid conditions when held at lower temperatures (Besser et al., 1993; Weagant, et al., 1994).

The effect of the adjunct culture, *Bifidiobacterium bifidum,* used in addition to the standard ST-LB cultures was evaluated by co-inoculating high and low levels of *E. coli* O157:H7 with yogurt starters in pasteurized milk (Massa et al., 1997). Product was fermented at 42°C (108°F) for 5 hours until pH 5.1-5.2, and then stored at 4°C (40°F) for 7 days. As seen with traditional yogurt, the pH continued to decrease during refrigerated storage to a final pH 4.5-4.6 and a concomitant decrease in viable *E. coli* O157:H7 was observed. No significant difference was observed between the traditional yogurt and the bifido yogurt, but continued acid production and pH decrease appeared to be important in reducing pathogen populations.

Dineen et al. (1994) demonstrated that populations of *E. coli* O157:H7 decreased from 2-log cfu/g to less than detectable levels in three brands of retail low-fat yogurt within 6 to 14 days storage at 4°C. The acidity remained constant during the 2-week refrigerated storage with pH values of 4.0, 4.0, and 4.2 for the varieties made with ST-LB only, ST-LB with *L. acidophilus*, and ST-LB with *L. acidophilus and L. bifidus*, respectively. These data suggest that survival of this pathogen is diminished in an acidic environment, even at refrigeration temperatures.

Survival of *E. coli* O157:H7 in yogurt has been shown to be influenced by the presence of colanic acid (CA), which is polysaccharide slime on the surface of the bacterial cell that increases the pathogen's resistance to acid (Lee and Chen, 2004). Wild-type cells with CA demonstrate the longer survival in yogurt (initial pH 4.7) stored at 15°C (59°F) than at 4°C (40°F) whereas there was little difference in survival in mutant strains without CA. However, *E. coli* O157:H7 declined in all treatments during the 3-weeks storage period.

Salmonella Typhimurium grows in laboratory media acidified to pH 4.4 with lactic acid, but is inactivated in cultured skim milk with the same pH value (Park and Marth, 1972). In spite

of the potential to tolerate extreme pH values, challenge studies suggest that *Salmonella* will not grow during early stages of yogurt production, and will be inactivated during extended fermentation (Rubin and Vaughan, 1979). Populations of *Salmonella* Typhimurium remained constant during the first 4 hours of fermentation in the presence of ST-LB culture as the pH decreased from 6.25 to 4.54 (0.34% lactic acid). *Salmonella* died rapidly thereafter, decreasing >3-log cfu/g to undetectable levels during the next 3 hours at 42°C (108°F) as the pH continued to decline to 4.15. Further study noted bactericidal activity when lactic acid reduced the pH of the environment to 4.5, causing the internal pH of the cell to be reduced to 5.3 and causing cell death (Rubin et al., 1982).

A study evaluating the survival of several serotypes of *Salmonella* in Egyptian yogurt demonstrated that *Salmonella* serotype Typhimurium was the most resistant to the adverse pH conditions (Ahmed and Ghonien, 1971). Interesting, survival was lower when yogurt was stored at room temperature (24°C) than at refrigeration temperatures (4°C). The pathogen was inactivated to less than detectable levels at 23 and 19 days when stored at 4 and 24°C, respectively.

The behavior of Gram-positive bacteria, including spore-formers which can survive pasteurization, is similar as the enteric pathogens when exposed to extreme acid conditions. While pathogens may be able to survive or grow in laboratory media with pH adjusted to <4.8 under otherwise optimal conditions, few can grow or produce toxin in acidic foods such as yogurt.

No data for studies evaluating the behavior of sporeforming pathogens have been published. However, the safety of yogurt related to these hazards can be predicted based on "worse-case scenarios" reported for growth in laboratory media. The addition of competitive microflora (starter cultures) will further inhibit growth or toxin production by these pathogens. *B. cereus* generally does not grow at pH 4.8 in media adjusted with HCl, or at pH 5.6 when using lactic acid as the acidulant (ICMSF, 1996). The pathogen has been reported to be inactivated by 0.1 M acetic, formic and lactic acids in nutrient broth and will die suddenly in yoghurt when the pH reaches 4.5 (NZFSA, 2001). The minimum pH for growth for Group I (proteolytic) *Clostridium botulinum* is considered to be 4.6; however, growth would be slow (ICMSF, 1996). Outgrowth of Group II (nonproteolytic) spores, which are also able to grow at refrigeration temperatures, are prevented at pH 5.0 or lower. *C. perfringens* growth is limited at pH 5.5 and cells will die at pH 5.0.

More extensive research has been completed studying the fate of *S. aureus* and *L. monocytogenes* in yogurt and acidified dairy products. Although it has been reported that *S. aureus* can grow at pH values as low as 4.5 in laboratory media, growth is slow (ICMSF, 1996). The lag phase of *S. aureus* at 27°C (81°F) is over 25 hours and generation time is 2 hours (USDA-ARS, 2004). If the pH of the substrate is less than 4.4, *S. aureus* will die at both refrigeration (7°C) and ambient temperatures (23°C or 73°F) (Minor and Marth 1972b). No growth and toxin formation was detected in milk acidified to pH 4.5 with lactic acid (Tatini et al., 1971), but additional reports suggesting the growth is limited in milk acidified to pH 5.1 to 5.2 (Minor and Marth, 1970) The minimal pH for enterotoxin production is more stringent than that required for multiplication and is generally limited to values greater than 5.1 (Minor and Marth, 1970; Scheusner et al., 1973; Tatini et al., 1971, Tatini, 1973).

S. aureus is noted for being a poor competitor. However, staphylococcal food intoxications are possible if a food is recontaminated and acid development by starters is inadequate and inhibitory pH is not reached quickly (Minor and Marth, 1972c). While acid production is important in preventing staphylococcal growth, Reiter et al (1964) reported that even when lactic acid in milk was neutralized, lactic acid bacteria starter culture still retained inhibitory activity against *S. aureus*. However, if starter activity was poor because of bacteriophage infection, the pathogen was able to multiply. For this reason, hygienic manufacturing practices are essential to prevent recontamination and starter activity should be monitored to verify proper fermentation.

Several published studies provide evidence supporting the safety of yogurt (Attaie et al., 1987; Benkerroum et al., 2002; Minor and Marth, 1972a). If *S. aureus* is present as a post-fermentation contaminant in retail yogurt (pH 3.7 to 4.1), populations of *S. aureus* decreased >3 log within 1 day, regardless if it was stored at 7 or 23°C (45 or 73°F) (Minor and Marth, 1972a).

When yogurt was produced in the laboratory by co-inoculating milk with *S. aureus*, *S. thermophilus, L. bulgaricus*, and *L. acidophilus, S. aureus* grew approximately 1.5-log during the first 4 hours of fermentation until the pH reached 4.8 (Attaie et al., 1987). After yogurt reached pH 4.8, populations of *S. aureus* decreased >3-log during an additional 4 hours at 42°C. To further demonstrate the effect of cultures beyond acid production, acidified yogurt was produced by adding lactic acid to milk, mimicking the pH changes during fermentation of standard yogurt. While the populations of *S. aureus* also decreased when the pH 4.8 was reached, the decline was much less dramatic. The greater bactericidal activity associated with standard yogurt and acidophilus yogurt was attributed to high levels of hydrogen peroxide (0.88 μg/ml) produced by the starters. Results for initial growth and subsequent kill of the pathogen during refrigerated storage were confirmed by Pazakova et al (1997). Trends were comparable regardless of concentration of *S. aureus* introduced at the onset of fermentation.

Similar results were observed when yogurt was produced with bacteriocin-producing ST and a non-producing strain of LB (Benkerroum, et al., 2002). *S. aureus* grew 1.5-log during the early stages of fermentation at 40°C, but decreased >3.5 log when the reached pH 4.4 at the end of an 8 hour fermentation. Differences in storage temperature appeared to have little effect on viability after fermentation. Populations of *S. aureus* continued to decrease during storage at 7 and 22°C (45 and 72°F) and were undetectable (additional 2-log decrease) at 10 days at both temperatures (N. Benkerroum, personal communication, email April 4, 2005).

Considering the potential for *L. monocytogenes* as an environmental contaminant, comprehensive studies have also been completed evaluating the behavior of *L. monocytogenes* in fermented milk products and yogurt (Benkerroum et al., 2002; Choi et al, 1988; Griffith and Deibel, 1990; Gulmez and Guven, 2003; Schaack and Marth, 1988a, 1988c; Siragusa and Johnson, 1988; Tipparaju et al., 2004)

Two studies by Schaack and Marth (1988a, 1988c) demonstrated that the behavior of *L. monocytogenes* during the fermentation and storage of yogurt was similar to that of the

other pathogens described in this review. Slow growth of *L. monocytogenes* (1-log increase) was observed during 5-hour fermentation of yogurt using either ST alone or ST-LB cultures. After the pH reached 4.8, populations declined as the pH continued to decrease to 4.5 or 4.0 during additional time at fermentation temperatures and during storage at 4°C. Greater acid production and greater kill of *L. monocytogenes* were reported for yogurt fermented with ST-LB cultures than with ST alone. The pH decreased more rapidly when product was fermented at 42°C (108°F) than at 37°C (99°F), which translated to decreased survival time of *L. monocytogenes* during refrigerated storage. *L. monocytogenes* survived 12 hours in refrigerated product previously fermented with 1.0% ST-LB culture at 42°C (108°F) (final pH 3.8-3.9), but 1-2 weeks in similar product fermented at 37°C (99°F) (final pH 4.0).

In addition, two research groups compared the differences in listerial survival in retail plain yogurt versus vanilla yogurt with sugar (Choi et al., 1988; Tipparaju et al., 2004). In one study, the type of yogurt (plain vs. with vanilla with sugar) had no obvious effect on pathogen survival when stored at 4°C (40°F) (Choi et al., 1988). *L. monocytogenes* decreased 2-3 logs during the first 8-12 days, while the pH values of 3.8-4.2 remained similar to 0-time samples. A second study evaluated survival of *L. monocytogenes* when low-fat and non-fat plain or flavored yogurt was stored at 8°C (47°F) (Tipparaju et al., 2004). The initial pH for the retail samples evaluated for Tipparaju study were higher than the products evaluated by Choi et al., having pH values ranging from 4.35 to 4.52. Listerial populations decreased more gradually, demonstrating <1-log decrease in 14 days at 8°C. The most significant decrease was observed at 28 days. Populations of *L. monocytogenes* decreased ~2.5 log in low fat plain and vanilla and fat-free plain yogurt, whereas a 3.5 log decrease was observed for the fat-free vanilla. Slight additional inhibitory effect by vanillin was observed.

As with the study on *S. aureus,* Benkerroum et al (2002) demonstrated that storage of pH 4.4 yogurt at either 7 or 22°C (45 or 72°F) had no effect on survival of *L. monocytogenes.* However, unlike *S. aureus,* survival of *L. monocytogenes* was significantly decreased when yogurt was fermented with a bacteriocin-producing strain of ST (Bac^+ ST). Populations of *L. monocytogenes* decreased >8-log between 8 and 24 hours with Bac^+ST, but only a 1-log decrease in the Bac^-ST. No viable *Listeria* was detected during remaining storage.

Discussion: This paper has reviewed the factors that contribute to the microbiological safety of commercial yogurt. Assuming that the milk used in yogurt production is pasteurized and adjunct ingredients are free of vegetative pathogens, good manufacturing practices and strict environmental sanitation will minimize the risk of post-processing contamination. Active fermentation using standard ST-LB starter cultures is essential to prevent the outgrowth of bacterial spores which survive milk pasteurization and will provide a significant barrier to vegetative pathogens in the unlikely event that the product be recontaminated during or after production.

Rapid acid production to pH values $\leq$4.8 will prevent the outgrowth of any surviving spores of mesophilic and psychrotrophic strains of *Clostridium botulinum* and *Bacillus cereus* during refrigerated or ambient temperature storage, or of *Clostridium perfringens* during slow cooling. Similarly, *S. aureus* will not produce enterotoxin at these low pH values.

While certain vegetative pathogens such as *E. coli* O157:H7 and *L. monocytogenes* are more acid tolerant than the sporeformers, modeling data indicates that pH 4.8 will inhibit growth *E. coli* O157:H7 and *L. monocytogenes*, especially at temperatures below 58°F. Growth would be expected to be further inhibited in the presence of lactic acid and competitive microflora.

Research has demonstrated as the pH decreases further to pH 4.6 (where milk coagulates), the substrate will not just inhibit growth but becomes bactericidal and cause populations of these pathogens to decrease. Studies comparing the effect of fermentation and storage temperatures in yogurt further suggest that elevated temperatures will enhance the demise of *E. coli* O157:H7 by increasing rate of acid production.

While acidity is a principal factor in controlling growth, other metabolites produced during the ST-LB fermentation contribute to the overall safety of yogurt. Although strains may vary in ability to produce bacteriocins or the level of hydrogen peroxide accumulated in the substrate during fermentation, utilization of nutrients by the high-populations of added starter bacteria will compete with low levels of contaminants.

Given the scientific studies presented, extending the cooling profile of yogurt to 7°C (45°F) over 72 hours will not cause any additional safety risks, provided the pH of the vat-fermented product is at or below 4.6 within 24 hours of filling, which is typically found in industry today. Furthermore, due to the acidic properties of yogurt and the presence of active lactic acid bacteria that will continue to metabolize lactose to lactic acid, extended storage times at temperatures above 7°C (45°F) can potentially inactivate pathogens when the pH is 4.6 or below. However, products should be cooled as rapidly as possible to decrease over-production of acid that may reduce quality of the product.

Conclusion/Recommendation: Yogurt with active cultures, at the pH of 4.6 or below before storage, and which is processed in compliance with GMPs currently prescribed by the PMO, is inherently safe and does not support the growth of pathogenic organisms. There is no increased safety risk when cooling to <7°C (<45°F) within 72 hours provided the manufacturer complies with the described processing parameters. Environmental controls are necessary to prevent recontamination with acid-tolerant microorganisms that may have long survival times.

Footnote: No published challenge studies have established the effect of extended cooling on the safety of vat-fermented yogurt with pH values greater than 4.6 at the point of filling. If fermentation continues to achieve pH $\leq$4.6 within 24 hours, several of the studies above clearly demonstrate that safety will not be compromised during extended cooling and all the recommendations would still apply.

However, for products varieties with pH values that are consistently between 4.65 and 4.8 at 24 hours, other considerations should be made. The PMP predicts that no staphylococcal enterotoxin production and no *Listeria* growth would be expected at pH $\leq$4.8 during 42 hours cooling to 7°C (45°F). Although the likelihood of recontamination with an acid-tolerant pathogen such as *E. coli* O157:H7 would be exceedingly rare in a facility which uses pasteurized milk and GMPs, a challenge study would confirm the safety of extended cooling. Without additional studies, adjusting the cooling profile of products with pH 4.65 to

4.8 to achieve ≤ 14.5°C (58°F) in 18 hours would inhibit potential growth (per PMP 7.0). Actual growth or survival is expected to be less in yogurt than shown in the predictive model because lactic acid is the predominant acid and competitive microflora is present.

References:

1. Abdel-Bar, N.M. and N.D. Harris. 1984. Inhibitory effect of *Lactobacillus bulgaricus* on psychrotrophic bacteria in associative cultures and in refrigerated foods. J. Food Prot. 47:61-64.

2. Ahmed, N., and M. Ghoniem. 1971. The viability of some *Salmonella* strains and their pH values in Egyptian yoghurt during different storage temperatures. Milchwissenshaft 26:218-

3. Attaie, R.; Whalen, P.J.; Shahani, K.M.; Amer, M.A. 1987. Inhibition of growth of Staphylococcus aureus during production of acidophilus yogurt. J Food Prot. 50:224-228.

4. Barefoot, S.F., and C. G. Nettles. 1993. Antibiosis revisited: Bacteriocins produced by dairy starter cultures. J. Dairy Sci. 76:2366-2379.

5. Benkerroum, N.; Oubel, H.; Mimoun, L.B. 2002. Behavior of *Listeria monocytogenes* and *Staphylococcus aureus* in yogurt fermented with a bacteriocin-producing thermophilic starter. J Food Prot. v. 65:799-805.

6. Beshkova, D., E Simova, G Frengova and Z Simov. 1998. Production of flavour compounds by yogurt starter cultures. J Ind. Microbiol Biotech 20:180–186.

7. Besser RE, Lett SM, Weber JT, Doyle MP, Barrett TJ, Wells JG, Griffin PM. 1993. An outbreak of diarrhea and hemolytic uremic syndrome from Escherichia coli O157:H7 in fresh-pressed apple cider. JAMA. 1993 May 5; 269(17):2217-20.

8. British Columbia Centre for Disease Control. 2002. Milk Safety Notes: Food Poisoning Outbreak Yogurt Production Plant *Escherichia coli* O157. www.bccdc.org/downloads/pdf/fps/reports/Outbreak_E.%20coli_Yogurt.pdf Accessed April 9, 2005

9. Bodnaruk,-P.W.; Williams,-R.C.; Golden,-D.A. 1998. Survival of Yersinia enterocolitica during fermentation and storage of yogurt. J Food Sci. 63:535-537.

10. Caplice, E., and FG Fitzgerald. 1999. Food fermentations: role of microorganisms in food production and preservation. Inter J Food Microbiol 50:131-149

11. Choi, H.K., M.M. Schaack, and E.H. Marth. 1988. Survival of *Listeria monocytogenes* in cultured buttermilk and yogurt. Milchwissenshaft 1988 43 : 791-792

12. Critchley EM, Hayes PJ, Isaacs PE. 1989. Outbreak of botulism in North West England and Wales, June, 1989. Lancet. 2(8667):849-53.

13. Dahiya, R.S, and M.L. Speck. 1968. Hydrogen peroxide formation by lactobacilli and its effect on *Staphylococcus aureus*. J. Dairy Sci. 51:1568-1572.

14. Dineen, S.S.; Takeuchi, K.; Soudah, J.E.; Boor, K.J. 1998.Persistence of Escherichia coli O157:H7 in dairy fermentation systems. J. Food Prot. 61:1602-1608.

15. Doyle, M. P., T. Zhao, J. Meng, and S. Zhao. 1997. *Escherichia coli* O157:H7. In: Food Microbiology: Fundamentals and Frontiers. (M. P. Doyle, L. R. Beuchat, and T. J. Montville, eds.). Amer. Soc. Microbiol. Press, Washington, D.C. Chapter 10, pp. 171-191

16. Evans MR, Salmon RL, Nehaul L, Mably S, Wafford L, Nolan-Farrell MZ, Gardner D, Ribeiro CD. An outbreak of Salmonella typhimurium DT170 associated with kebab meat and yogurt relish. Epidemiol. Infect. 1999. 22:377-83.

17. Gilliland, S.E. and M. L. Speck. Interactions of food starter cultures and foodborne pathogens: Lactic *Streptococci* versus *Staphylococci* and *Salmonellae*. J Milk Food Technol 1972 35:307-310.

18. Gilliland, S.E., 1985. Role of starter culture bacteria in food preservation. *In* Bacterial starter cultures for foods. S.E. Gilliland, ed. Boca Raton, FL. CRC Press, p. 175-185.

19. Govaris A, Koidis P, Papatheodorou K. 2002. Behaviour of Escherichia coli O157:H7 in sour milk, cows' milk yogurt and ewes' milk yogurt. J Dairy Res. 69:655-60.

20. Griffith, M.; Deibel, K.E. 1990. Survival of Listeria monocytogenes in yogurt with varying levels of fat and solids. J Food Saf. 10:219-230.

21. Gulmez, M., and A. Guven. 2003. Survival of *Escherichia coli* O157:H7, *Listeria monocytogenes* 4b, and *Yersinia enterocolitica* O3 in different yogurt and kefir combinations as prefermentation contaminant. J. Appl. Microbiol. 95:631-636.

22. International Commission on the Microbiological Specifications of Foods. 1996. Microorganisms in Foods: 5 Microbiological Specifications of Food Pathogens. Blackie Academic and Professional. An Imprint of Chapman and Hall, London.

23. Jay, J.M. 1982. Antimicrobial properties of diacetyl. Appl. Environ. Microbiol. 44:525-532.

24. Jay, J.M. 1992. Modern Food Microbiology, 4th ed. AVI. An Imprint of Van Nostrand Reinhold, New York, NY.

25. Kang, D-H., and D.Y.C. Fung. 1999. Effect of diacetyl on controlling *Escherichia coli* O157:H7 and *Salmonella* Typhimurium in the presence of starter culture in a laboratory medium and during meat fermentation. J. Food Prot. 62:975-979.

26. Kosikowski, F. V, and V.V. Mistry. 1997. Yogurt. *In* Cheese and Fermented Milk Foods, 3rd ed. Vol. 1. Origins and Principles. F. V. Kosikowski L. L. C., Westport, CT. Pp. 87-108.

27. Kulshrestha, D.C., and E.H. Marth. 1974. Inhibition of bacteria by some volatile and non-volatile compounds associated with milk. J. Milk Food Technol. 37:510-516.

28. Lee, S.M., and J. Chen. 2004. Survival of Escherichia coli O157:H7 in set yogurt as influenced by the production of an exopolysaccharide, colanic acid. J Food Prot. 67:252-255.

29. Massa, S.; Trovatelli, L.D.; Canganella, F. 1991. Survival of Listeria monocytogenes in yogurt during storage at 4°C. Lett Appl Microbiol. 13: 112-114.

30. Matalon, M.E., and W.E. Sandine. 1986. Lactobacillus bulgaricus, Streptococcus thermophilus and yogurt: a review. Cultured dairy products journal 21(4):6-12

31. Mathot AG, E. Beliard, and D. Thuault. 2003. *Streptococcus thermophilus* 580 produces a bacteriocin potentially suitable for inhibition of *Clostridium tyrobutyricum* in hard cheese. J Dairy Sci. 86(10):3068-74.

32. Minor, T.E., and E.H. Marth, 1970. Growth of *Staphylococcus aureus* in acidified pasteurized milk. J. Milk Food Technol: 33:516-520

33. Minor, T.E., and E.H. Marth, 1972a. Fate of *Staphylococcus aureus* in cultured buttermilk, sour cream, and yogurt during storage. J. Milk Food Technol: 35:302-306.

34. Minor, T.E., and E.H. Marth, 1972b. Loss of viability by *Staphylococcus aureus* in acidified media: Inactivation by several acids, mixtures of acids, and salts of acids. J. Milk Food Technol: 35:191-196

35. Minor, T.E., and E.H. Marth, 1972c. *Staphylococcus aureus* and staphylococcal food intoxications. A Review III Staphylococci in dairy foods. J. Milk Food Technol: 35:77-82.

36. Morgan D, Newman CP, Hutchinson DN, Walker AM, Rowe B, Majid F. 1993. Verotoxin producing Escherichia coli O 157 infections associated with the consumption of yoghurt. Epidemiol. Infect. 111:181-7.

37. New Zealand Food Safety Authority (NZFSA). 2001. Microbial Data Sheets. www.nzfsa.govt.nz/science-technology/data-sheets/ Accessed April 10, 2005.

38. Ogwaro, B.A.; Gibson, H.; Whitehead, M.; Hill, D.J. 2002.Survival of Escherichia coli O157:H7 in traditional African yogurt fermentation. Int. J Food Microbiol. 79:105-112.

39. O'Mahony M, Mitchell E, Gilbert RJ, Hutchinson DN, Begg NT, Rodhouse JC, Morris JE. 1990. An outbreak of foodborne botulism associated with contaminated hazelnut yoghurt. Epidemiol. Infect. 104:389-95.

40. Park, H.S., and E.H. Marth. 1972. Behavior of *Salmonella typhimurium* in skim milk during fermentation of lactic acid bacteria. J. Milk Food Technol. 35:482-488.

41. Pazakova J, Turek P, Laciakova A. 1997. The survival of *Staphylococcus aureus* during the fermentation and storage of yoghurt. J Appl Microbiol. 82:659-62

42. Reiter, B., B.G. Fewins, T.F. Fryer, and M.E. Sharpe. 1964. Factors affecting the multiplication and survival of coagulase positive staphylococci in Cheddar cheese. J. Dairy Res. 31:261-272

43. Rubin HE, Nerad T, Vaughan F. 1982. Lactate acid inhibition of Salmonella typhimurium in yogurt. J Dairy Sci. 65:197-203.

44. Rubin HE, Vaughan F. 1979. Elucidation of the inhibitory factors of yogurt against Salmonella typhimurium. J Dairy Sci. 62(12):1873-9.

45. Schaack, M.M.; Marth, E.H. 1988a. Behavior of Listeria monocytogenes in skim milk during fermentation with thermophilic lactic acid bacteria. J Food Prot. 51:607-614.

46. Schaack, M.M., and E.H. Marth. 1988b. Interaction between lactic acid bacteria and some foodborne pathogens: a review. Cult. Dairy Prod. J. 23(4):14, 17-18, 20.

47. Schaack, M.M.; Marth, E.H. 1988c. Survival of Listeria monocytogenes in refrigerated cultured milks and yogurt. J Food Prot. 51:848-852.

48. Shahani, K.M., J.R. Vakil, and A. Kilara. 1977. Natural antibiotic activity of *Lactobacillus acidophilus* and *bulgaricus.* II: Isolation of acidophilin from *L acidophilus*. Cult. Dairy Prod J. 12(5): 8-110.

49. Singh, J. 1983. Inhibition of growth of spoilage microorganisms by *Streptococcus thermophilus* and *Lactobacillus acidophilus* in cow, buffalo, and goat milk J. Food Prot. 46:497

50. Siragusa GR, Johnson MG 1988. Persistence of Listeria monocytogenes in yogurt as determined by direct plating and enrichment methods. Int. J Food Microbiol. 7(2):147-60.

51. Scheusner, D.L., L.L. Hood, and L.G. Harmon. 1973. Effect of temperature and pH on growth and enterotoxin production by *Staphylococcus aureus*. J. Milk Food Technol. 36:249-252.

52. Tatini, S.R. 1972. Influence of food environments on growth of *Staphylococcus aureus* and production of various enterotoxins. J. Milk Food Technol. 36:559-563

53. Tatini, S.R., J.J. Jezeski, J.C. Olson, Jr., and E.P. Casman. 1971. Factors influencing the production of staphylococcal enterotoxin A in milk. J. Dairy Sci. 54:312-320.

54. Tipparaju, S.; Ravishankar, S.; Slade, P.J. 2004. Survival of *Listeria monocytogenes* in vanilla-flavored soy and dairy products stored at 8°C. J. Food Prot. 67:378-382.

55. United States Department of Agriculture-Agricultural Research Service (USDA-ARS), Eastern Regional Research Center. 2004. Pathogen Modeling Program 7.0 www.arserrc.gov/mfs/pathogen.htm

56. Upton, P., and J.E. Coia. 1994. Outbreak of *Escherichia coli* O157:H7 infection associated with pasteurized milk supply. Lancet 344:1015

57. Vedamuthu, E. R. 1991. The Yogurt Story-Past, Present, and Futures, Parts 1, 11, and 111. Dairy Food Environ. Sanit. 11:202-203, 265-266, and 310-311.

58. Villani, F.; Pepe, O.; Mauriello, G.; Salzano, G.; Moschetti, G.; Coppola, S. 1995. Antilisterial activity of thermophilin 347, a bacteriocin produced by Streptococcus thermophilus. Int. J Food Microbiol. 25:179-190.

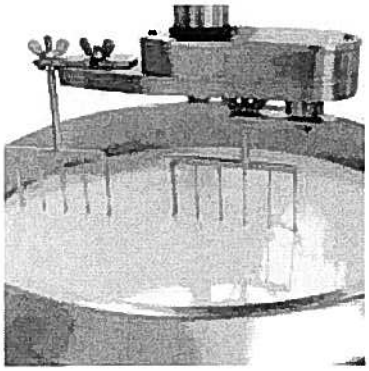
59. Weagent, S. D., M.L. Bryant, and D.H. Park. 1994. Survival of Escherichia coli O157:H7 in mayonnaise and mayonnaise-based sauces at room and refrigerated temperatures. J Food Prot. 57:629-631

Attachment 4

TESTING | April/May 2010

Shifting the Emphasis from Product Testing to Process Testing

By William H. Sperber, Ph.D.



To test the process or test the product? This question reminds me of the riddle that has probably been asked for thousands of years—"Which came first, the chicken or the egg?" Thanks to evolutionary biology, we know that the egg came first, by several hundred million years. However, the answer to the "test the process or test the product" question might never be so clear. I think today we must answer, "Both." There are times when it will be better to test the process, and other times when it will be better to test the product.

It could also be necessary to test both, or neither. In the modern food industry, product testing preceded process testing as a means to evaluate or assure food safety. For that reason, there remains today an undue reliance, even insistence, upon product testing. This article will discuss testing processed food products, raw foods and uncooked, ready-to-eat (RTE) food products as well as the process, and shifting the emphasis from product to process testing.

Testing Processed Food Products

In the 1960s, the National Academy of Sciences (NAS) and the International Commission on Microbiological Specifications for Foods (ICMSF) attempted to establish procedures for food safety evaluation by organizing and publishing a wide array of microbiological criteria based upon product testing. I will mention just two of the original reports here. They are the following:

• NAS/NRC. 1969. An evaluation of the *Salmonella* problem.[1]

• Microorganisms in foods. Book 2. Sampling for microbiological analysis: Principles and specific applications.[2]

These publications include hazard and risk categories, microbiological specifications and product sampling plans. This is where n = 13, 15, 30 or 60 originated. It must be pointed out that these procedures were developed for the analysis of materials of unknown origin and unknown means of control—for example, for materials that could have been procured at any point in the global supply chain—or they were used to evaluate acute problems such as *Salmonella* in dried eggs in the 1960s, just as today we might evaluate an acute problem of *Salmonella* in nut products. In the absence of information about the process, product testing is the only means to evaluate food safety, even though we know

it doesn't work very well.

Product testing for food safety is unnecessary today when processed foods are of known origin and produced under known means of control. The major advance in this area was the introduction of the Hazard Analysis and Critical Control Points (HACCP) system of food safety management in the 1970s, with the later recognition and accepted use of prerequisite programs. HACCP is a preventative system designed to control significant identified hazards by means of validated process control measures. It does not depend on product testing to assure food safety. In fact, HACCP was developed precisely because product testing cannot reliably detect low-level defects, such as low-incidence pathogen contamination in foods.

The application of HACCP is best epitomized by the canned food regulations that were developed in 1973. Based upon HACCP, finished-product testing of canned foods is not required and not necessary when the requirements of these regulations are met.[3] A similar food-processing application preceded HACCP and the canned foods regulations by 50 years—the first publication of the pasteurized milk ordinance (PMO) in 1923. Scientists and regulators back then learned that the safety of dairy products could be assured simply by heating them to a prescribed temperature and holding for a prescribed period of time. Pathogen testing in pasteurized dairy products is not required or necessary. However, the PMO does require indicator microorganism testing—coliform and aerobic plate counts—to verify pasteurization effectiveness and sanitary handling post-pasteurization.[4] In many current applications of HACCP and prerequisite programs, product testing for indicator microorganisms (rather than pathogenic microorganisms) may also be performed to verify process control.

Testing Raw Foods or Uncooked Food Products

The success of HACCP and prerequisite programs in assuring the safety of processed foods has lead to increasing political and public pressure for more testing of foods earlier in the supply chain, particularly those that are distributed raw, fresh or unprocessed to the retail and consumer levels—foods such as raw ground beef and fresh produce. Moreover, a number of recent and anticipated food safety regulations have fueled the expectation that raw and fresh foods can be rendered pathogen-free. I will point out two recent examples:

• The *E. coli* O157:H7 in raw ground beef adulterant rule, published by the U.S.

Department of Agriculture's Food Safety and Inspection Service (FSIS) in 1994.

• The Pathogen Reduction: HACCP rule, commonly called the "MegaRule," for raw meat and poultry products, published by FSIS. This rule includes *Salmonella* performance standards.[5] Contrary to the praise heaped on this rule recently, it has nothing to do with HACCP and precious little to do with food safety.[6]

Testing raw or fresh foods for pathogens such as *Salmonella* or *E. coli* O157:H7 is often futile because contamination, should it occur, typically occurs at a low level and incidence. Testing foods such as raw ground beef and fresh produce is impractical and inefficient and does not enable effective decision-making. Adulterant rules and pathogen performance standards contribute greatly to this inefficiency and ineffectiveness.

Let's do a thought exercise. Assume that over a period of weeks or months, your company produces 1,000 twenty-ton truckloads of raw ground beef or fresh produce. Further assume that to meet regulatory and/or customer requirements, you must perform pathogen testing on 15, 30 or 60 samples taken from each truck. After sampling 1,000 trucks, you would have tested a total of 15,000 to 60,000 samples, at great expense. Assume you find 10 trucks that tested positive for the target pathogen, while the remaining 990 trucks tested negative. Ten out of 1,000 trucks is an incidence of 1%. We know in practice that the incidence of pathogens in the few lots of food that are in fact contaminated is usually less than 1%, more like 0.1%—which would be one truckload in a thousand—or even less.

The question that all stakeholders in the food supply chain should find the courage to ask and honestly answer is the following: "What should be done with the 10 trucks that tested positive?" Do you think that these 10 trucks are any different from the 990 trucks that yielded negative results? Quite likely, they are not different. I think we can justifiably assume that any 20-ton truck of raw food will have some extremely low level of incidental pathogen contamination. FSIS itself conceded this point in its 2000 *E. coli* O157:H7 risk assessment. If you test enough truckloads, you will occasionally find a positive pathogen-test result. Why should a positive truck be flagged for special handling, including destruction? Why are we testing such trucks in the first place?

Pointless testing of this nature costs the affected industries many millions of dollars each year. This is an extremely poor use of resources. We must do better. I am not saying that

we should ignore the infrequent public health issues that may exist with certain raw or fresh foods. However, rather than more product testing, I think we need a major collaborative effort among the industry, public health, regulatory and other sectors to systematically expand our food safety focus to all parts of the global supply chain, from farm to table, and to implement HACCP and prerequisite programs where possible. Critical control points can usually be applied only in the processing and consumption links of the supply chain, while prerequisite programs can be applied at all or most of the links. Even if we can accomplish this, the bottom line remains the same. We must acknowledge that, despite our best efforts to implement HACCP and prerequisite programs throughout the supply chain, raw foods will never be 100% pathogen-free and will never be 100% correctly handled and prepared at the consumer level.

Testing the Process

The majority of processed foods now produced in developed countries are produced under known, controlled conditions that are established in HACCP plans and prerequisite programs. Under these conditions, product testing for pathogens can be replaced by process testing. "Testing the process" must be considered from two perspectives. The first would be testing finished products for indicator microorganisms that could be used to verify the effectiveness of process controls, as is done in the PMO.

The second perspective is the sampling of the food-processing environment to evaluate or verify sanitary operating conditions. The production area can be divided into zones that include product-contact surfaces, non-product-contact surfaces, floors and drains and employee and utility areas. Product-contact surface sampling is the most direct way to "test the process" and its potential impact on product contamination. Environmental monitoring can be performed for specific pathogens and/or for indicator microorganisms. Testing for Listeria is often done in wet production areas for refrigerated, perishable, RTE meat and dairy products. Testing for *Salmonella* is typically done in dry operations that produce items such as dried dairy products, dried eggs, confectionary products and peanut butter and other nut products.

Another kind of environmental monitoring can be very useful as an early warning signal of potential contamination, but it may be overlooked today. In a recent conversation I had with Dr. John Silliker, he reminded me of an important lesson he learned during his career in the evaluation of pathogen contamination in food-processing environments. Rather than relying solely on random microbiological monitoring of particular sites or

pieces of equipment, he found it helpful to test environmental samples that were highly representative of the finished product, except that they had received much greater environmental exposure than the finished product. His examples included food materials such as sifter tailings, product spillage in packaging areas, chocolate salvage or rework and peanut butter that accumulated on the scraper blade of a conveyor belt. Detection of a pathogen in such a sample indicated that the production area might be contaminated with the same pathogen and that an immediate investigation should be conducted. It is important that the size of the environmental sample be the same as the sample taken for finished product testing. Like many of you, I know this is a good idea because decades ago, we used a similar procedure, testing the dust collectors in Pillsbury bakery mix facilities. Even today, Cargill and many other millers use an environmental monitoring plan to verify the sanitary quality of milled cereal grains.[7]

Shifting the Emphasis from Product to Process Testing

In summary, while the circumstances vary as described previously, it is sometimes necessary to test the product and sometimes necessary to test the process. The current balance seems to be heavily in favor of product testing, a balance that will become more lopsided as expectations for pathogen-free raw or fresh foods continue to mount.

To more effectively assure the safety of all foods, I believe that we must spend more effort on validating and implementing process controls and process testing measures while eliminating unnecessary product testing. In our post-retirement careers, Dr. Silliker and I hope to stimulate research along these lines to enhance the safety of foods that are sometimes problematic. Now we are trying to organize a collaborative effort to increase the safety of fresh produce by developing microbiological testing methodologies that involve testing produce processes, not the products. If this effort is successful, such an approach could be applied to additional raw or RTE foods, enabling the producers of these foods to use their resources more efficiently while actually improving the microbiological safety of the foods. Insofar as possible, our goal should be to establish microbiological monitoring procedures that enable us to better ensure food safety by testing the process rather than testing the product.

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References

1. Foster, E. M. 1971. The control of salmonellae in processed foods. A classification system and sampling plan. *Journal of the Association of Official Analytical Chemists* 54:259–266.

2. International Commission on Microbiological Specifications for Foods (ICMSF). 1974. *Microorganisms in foods 2: Sampling for microbiological analysis: Principles and specific application.* Toronto: University of Toronto Press.

3. Code of Federal Regulations. 2002. Title 21; part 113, Thermally processed low-acid foods packaged in hermetically sealed containers; and part 114, Acidified foods. Washington, DC: U.S. Government Printing Office.

4. Food and Drug Administration. 2005. Grade "A" pasteurized milk ordinance. Pub. No. 229. Washington, DC: U.S. Department of Health and Human Services. www.cfsan.fda.gov/~ear/pmo05toc.html. Viewed May 1, 2009.

5. Code of Federal Regulations. 1996. Title 9; part 304. Pathogen reduction; Hazard analysis and critical control point systems; Final Rule. Washington, DC: U.S. Government Printing Office.

6. Sperber, W. H. 2005. HACCP and transparency. Food Control 16:505–509.

7. Sperber, W. H. and North American Millers' Association (NAMA). 2007. Role of microbiological guidelines in the production and commercial use of milled cereal grains: A practical approach for the 21st century. *Journal of Food Protection* 70:1041–1053.

This article is based upon a presentation at The Consumer Goods Forum, Feb. 4, 2010, entitled "Getting the Most out of Micro Testing...Test the Process or Test the Product?"

Categories: Regulatory: HACCP