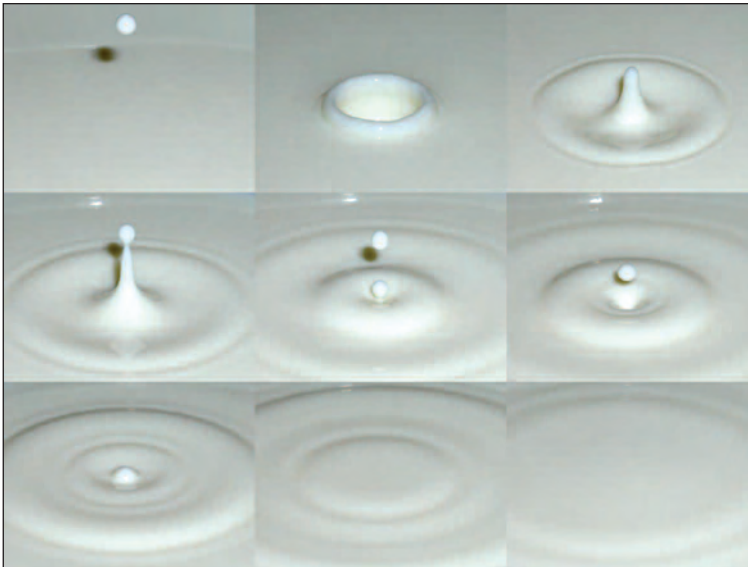


By John A. Beers

# NCIMS Voluntary HACCP Program Moo-ves Forward

Like cream rising to the top of the milk bottle, new progress in making the implementation of a Hazard Analysis and Critical Control Points (HACCP)-based food safety model a reality for dairy processing plants is gaining the attention of milk safety regulators and industry in the U.S. With the posting of the



recently completed “*Dairy Foods HACCP Hazards Control Guide*” and “*NCIMS HACCP System Audit Reports*” with pop-up references on the U.S. Food and Drug Administration (FDA) website coming soon, the National Conference on Interstate Milk Shipments’ (NCIMS) Dairy Grade A Voluntary HACCP Program guidance offers the most up-to-date resource to regulators and the dairy industry since the program’s inception in 1997.

The FDA website currently contains numerous HACCP forms and model documents for use in developing a complete HACCP System including developing a hazard analysis, prerequisite programs, monitoring, validation and verification records. The new guidance documents provide regulatory and industry personnel with responsibilities for milk and dairy product safety with updated information on participation in the NCIMS Dairy Grade A Voluntary HACCP Program, as well as next steps in the committee’s program implementation efforts.<sup>1</sup>

FDA, with responsibility for regulation of foods shipped in interstate commerce including milk and milk products, collaborates with NCIMS, a voluntary organization directed and controlled by the member states and open to all persons interested in its objective of “assuring the safest possible milk supply for all the people.” NCIMS is governed by an executive board comprised of representatives from state departments of health and agriculture, FDA, the U.S. Department of Agriculture (USDA), and the dairy industry. Together, 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, training and inspection assistance.

The result has been the establishment of a viable and effective certification and enforcement program for processors of Grade “A” milk and milk products and their raw milk supplies. This program has been of significant benefit to consumers by ensuring a safe milk supply from the cow to the consumer’s table.

## Got HACCP?

The Interstate Milk Shippers Program relies upon the Grade “A” Pasteurized Milk Ordinance (PMO) and related technical documents for sanitary standards, requirements and procedures it follows to ensure the safety and wholesomeness of Grade A

milk and milk products. During its biennial conference in 1997, NCIMS approved proposals to appoint a committee charged with defining a program that could be regulated under the HACCP model for both dairy farms and processing plants. The overarching aim of the NCIMS HACCP Committee was to provide dairy operators an alternative regulatory system to the traditional system under the PMO that would be accepted as equivalent to the PMO system. Between 1997 and 1999, the NCIMS HACCP Committee worked to develop a proposal to bring back to the conference delegates at the 1999 conference. Upon further review, the committee found that the estimated time and resources needed to develop both farm and plant HACCP models could not be realistically achieved. It was decided that the group would focus its efforts on the processing plant side, given the existing history of dairy plant experience in using HACCP and a lack of farm models. The result was the development of the Phase I pilot program designed to serve as a beta test for dairy processors interested in setting up and implementing a HACCP program in their facilities. The NCIMS HACCP Committee aimed to conduct a comparison study of plants operating

under the traditional PMO inspection system and those operating under a HACCP regulatory scheme to provide further information on reaching equivalency between the two, as well as further define the elements needed for implementation of HACCP in dairy plants. In 2001, the committee was granted an extension of this pilot program by the NCIMS conference delegates to allow more in-depth study of the accumulated data.

In 2003, the committee presented to delegates completed documentation of the voluntary HACCP pilot program comparison study and the proposed program that met the goals stated at the outset of the effort: that an inspection system under the HACCP model would be workable in the plants and that it would maintain milk safety at the same level as the traditional system, the PMO. The proposal was adopted and is now published as Appendix K of the PMO, which details the requirements for participation in the voluntary dairy HACCP program.<sup>2</sup> With the acceptance of the proposal in 2003 and the inclusion of HACCP as an alternative regulatory system in NCIMS and PMO, the role of the NCIMS HACCP committee changed from the initial task of developing a program to

## NCIMS Dairy HACCP FAQs

Here are a few highlights from the official Frequently Asked Questions (FAQs) page posted on the FDA website at [www.cfsan.fda.gov/~comm/dairyqa.html](http://www.cfsan.fda.gov/~comm/dairyqa.html). Questions and answers about the voluntary dairy HACCP program involve topics ranging from auditing and training, to regulatory and plant operation considerations.

**Q. What is wrong with the PMO that it requires new HACCP regulations?**

**A.** Nothing. The committee is developing guidelines for an alternative voluntary HACCP program. This is another tool the states and industry have available for assuring the safety of milk and milk products.

**Q. Is mandatory HACCP under the NCIMS program on the horizon?**

**A.** No, HACCP is a voluntary alternative to the traditional system under the Pasteurized Milk Ordinance.

**Q. How will the components of the PMO be addressed in HACCP?**

**A.** The PMO represents the cumulative wisdom and knowledge for producing safe dairy products. The expectation of the committee is that food safety controls addressed in the PMO will be addressed in HACCP to provide an equivalent margin of safety to the consumer.

**Q. How much of HACCP did the committee have to "reinvent"?**

**A.** The committee turned to the 1997 National Advisory Committee on Microbiological Criteria for Foods (NACMCF) document for guidance on the HACCP system. This

document provided guidance for the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) "MegaReg," the FDA seafood HACCP regulation, and the FDA juice regulation, as well as being harmonized with Codex Alimentarius international guidelines. The committee did not make major departures from the structure of the internationally accepted HACCP system.

**Q. Why do we need a voluntary alternative to the PMO? If there are two programs available, that makes it harder to manage and support. Is the goal for HACCP to replace the PMO system if it is proven to work? Why was HACCP formed? Is it that the current operating system is not adequate?**

**A.** The pilot was formed from two 1997 NCIMS conference proposals. The HACCP pilot was proposed as an alternative to the current system. It has never been said that the current system is not adequate. HACCP allows processors to take a systematic approach in identifying and managing food safety hazards when the NACMCF principles are applied. HACCP is a science-based system used to ensure that food safety hazards are controlled to prevent unsafe food from reaching the consumer.

**Q. How does the fact that some plants could be under the HACCP program and others under the current program promote uniformity within the NCIMS?**

**A.** FDA State program evaluations will continue to be conducted and include plants utilizing the traditional system and plants utilizing the HACCP system to promote uniformity within NCIMS.

*Source: U.S. FDA CFSAN. FAQs on NCIMS Dairy HACCP*

assisting and overseeing the implementation of the program. Currently, the committee is charged to work with FDA and industry to provide guidance and direction for program implementation, including standardization and training of FDA and state milk rating and listing officers.

### Proactive Progress, Current Challenges

In 2005, the NCIMS HACCP Implementation Committee is fully in the process of implementing the program, working

with industry, state inspectors and federal regulators to expand participation in the program, continue standardization, and address implementation challenges identified in the past few years. Currently, there are 13 dairy plants in nine states participating in the NCIMS Dairy Grade A Voluntary HACCP Program: Tropical Cheese and Farmland Dairy (New Jersey); Publix Dairy (Florida); Oakhurst and Garelick Farms (Maine); Safeway Inc. and Wilcox (Washington); Yo Farm (Connecticut); Gosner Foods (Utah); Clover Stornetta (California); Meadow Brook Dairy and Dutch Valley (Pennsylvania); and St. Albans Cooperative Creamery (Vermont). The participation of these plants and state regulatory personnel in the pilot program has provided a wealth of information and feedback to the NCIMS HACCP Committee as it develops a workable implementation plan.

As part of setting the foundation for the implementation process, NCIMS has set minimum training requirements for program participants, including mandatory participation in the program's core curriculum (i.e., training specific to NCIMS dairy HACCP in the PMO). The core curriculum covers HACCP basics, prerequisite programs, general recordkeeping requirements, and the specific, unique requirements of the NCIMS program. The latter include the necessity of drug residue testing and laboratory testing of finished products, requirements that are not necessarily required under a conventional HACCP system in other food production categories.

All training is open and available to both industry and regulatory personnel to ensure that these stakeholders receive the same message at the same time. This approach has been very successful. However, to date, the most significant voluntary dairy HACCP implementation challenges involve the provision of audit training, particularly for state regulatory personnel for whom this training is mandatory. Under the program, state personnel responsible for auditing and listing dairy plants must take an NCIMS HACCP auditing course, which is put on by members of the committee from industry, academia and regulatory. NCIMS works with the FDA's State Training Branch, the office that manages these programs, procuring training facilities and providing staff for course management and instruction. NCIMS HACCP auditing training courses were held in 2005 in Sacramento, CA, in 2004 in Albany, NY, and in 2001 in Baltimore, MD. Although the courses have been well-received by regulators and industry alike, the infre-

quency of the offerings is problematic. Training courses offered once a year or less poses problems when trained personnel leave positions, creating a knowledge gap at the dairy plant or state agency until another course is offered.

The committee's current challenge is to determine how to provide core curriculum and auditing training in less time-intensive segments with increased frequency to allow more flexibility for those who want to participate in the NCIMS Dairy HACCP Program. To address the problem posed by



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lengthy waits between courses, for example, NCIMS is proposing the development of a web-based or CD-based course in conjunction with classroom instruction by a two-member team of trainers to make training more accessible to a wider range of interested parties. The committee is also considering the potential benefits of creating a one-day “start up” course for industry and state regulatory personnel to communicate the basics of how to get into the program and the elements of NCIMS HACCP, prerequisites and recordkeeping, and to share information on the resources available to assist facilities and agencies in the implementation process.<sup>3</sup> In addition, the FDA State Training Branch is in process of getting the existing auditing training course accredited as continuing education credit hours, which will assist interested parties in justifying the expenditure. Ultimately, an increase in the number of participating dairies and state regulatory agencies will allow FDA and NCIMS to offer an expanded number of training courses.

### Weighing the Benefits of Dairy HACCP

Although both regulatory inspection systems under the PMO are considered equivalent, from the dairy plant's perspective, there are a number of inherent advantages to implementing a HACCP system over a traditional system. As reported to the NCIMS HACCP Committee by the pilot plant program dairies, these advantages include:

**1. Controlling Product Loss.** The pilot plants reported that product losses are greatly minimized because HACCP allows the operation to better control production processes. For example, plants found that the monitoring aspect of a HACCP program was extremely beneficial in making early determinations when a process was awry or out of specification and thus, limited the amount of product involved before a correction could take place. That “sooner rather than later” troubleshooting approach translated into money saved.

**2. Gaining a Competitive Edge with Customers.** Several plants have reported that they've attracted new customers as a result of having a HACCP system in place, specifically when competing for contracts with dairies that do not operate under a dairy HACCP system. The plants relayed that prospective buyers indicated that a HACCP program gave their operations an definite edge over the competition.

**3. Better Trained Employees and Staff.** HACCP training helps employees learn why they do what they do and empowers them to take immediate corrective action when a process is not in control. According to the pilot plants, this motivated employees to take more responsibility for getting the job done right, rather than performing only the basics of the job. Knowing how to monitor the limits on plant processes enabled employees to take corrective actions when they saw a problem, independent of the availability of a supervisor, saving time and money for the plant.

**4. Ability to Capitalize on Extended Product Runs.** Plants that apply to operate extended product runs must conduct studies and hazard analyses under the NCIMS program in order to receive approval from the appropriate state regulatory agency and FDA (for an extended run beyond one day). With HACCP in place, the dairy applying for extended run approval has an advantage in that it already has experience conducting the necessary hazard analysis, has prerequisite programs in place and has a system in place to verify monitoring and effective implementation of process controls. Plants operating under a traditional system may not have this type of training and records in place and would have to implement these before it could implement an extended run proposal even if its proposal was accepted by regulators.

**5. Sleeping More Soundly at Night.** Plant management and QC personnel reported a higher level of confidence in terms of the assurance of both safety and quality systems and outcomes in their plants when using the HACCP system, as compared with their previous system. The plants stated that with the additional oversight and record systems required in a HACCP operation, they were better able to show what they were doing and how they were doing it right the first time.

Dairies must also factor in the challenges of and impact on plant operations posed by implementing a HACCP system when considering participation in the NCIMS program. One consideration for plants, especially small-sized operations, is the additional upfront costs associated with hiring specialized, dedicated program staff, such as a HACCP coordinator and/or records maintenance manager, if these duties cannot be handled by the current employee. In addition, training can take time away from employees' regular production activities and the need for continuous and ongoing training of staff and records development and management tasks may require additional resources.

Plants should also consider the impact on operations and staff from an audit-versus-inspection time standpoint. As compared with inspections, audits are more time-intensive, generally requiring three days on average to conduct and can tie up staff time as plant personnel collect the requested records and take them to the auditor for review or participate in plant audit review tours, and so on. Compared with an average inspection that takes around two days, plants must consider carefully the impact of committing additional resources and staff time required when using a HACCP audit approach.

A plant that is operating under the NCIMS HACCP alter-



“From the dairy plant’s perspective, there a number of inherent advantages to implementing a HACCP system over a traditional system.”

native and meets certain strict requirements may be audited less frequently than under the traditional program. The plant and regulatory personnel would be involved in fewer audits with each audit requiring a greater commitment of time. This is seen as an advantage by some participants because it allows for better utilization of resources by both the plant and the regulatory staff.

Advantages to regulators who elect to participate in the voluntary NCIMS Dairy HACCP Program include:

**1. Ability to Better Evaluate Plant Operations.** Overall, audits offer a more in-depth way to assess a plant’s performance than inspections. Unlike an inspection in which the inspector marks what he or she sees during the on-site visit, audits allow the regulator to evaluate what goes on in the plant at all times, even when he or she is not on-site, through record and plant performance documentation review.

**2. More Informed Independent Assessment.** The record keeping and documentation components of a HACCP program results in a greater amount of information available to the regulator. In HACCP plants, additional plant information may be available to the regulator, whereas in a traditional system, many of those records are typically considered proprietary and the regulator is not allowed to see them. With the additional information gained from HACCP documentation, auditors are able to better provide a fully informed independent evaluation of the effectiveness of implementation.

**3. Better Trained and More Knowledgeable Personnel.** Under the NCIMS HACCP program, auditors have to be more familiar with every aspect of dairy operations—not just

from a public health and safety standpoint but from the processing perspective. In other words, auditors must understand the plant's processes in order to assess the safety and management of those systems. With this additional knowledge base, regulatory personnel will be able to work in tandem with plant personnel to identify potential areas of food safety risk and correct problems before product is released to consumers.

State regulatory agencies that are interested in developing a regulatory HACCP program for dairies will also need to consider additional front-end training and implementation costs involved with administering the program, as well as increased staff time needed to conduct audits. Also, because state laws and regulations have not been amended, modified or adopted that specifically allow HACCP/auditing as an alternative to the traditional inspection system, there will be some additional up-front work needed on the part of regulators to incorporate it into licensing or other systems.

### Moo-ving Forward

An important advantage for both the state regulatory agency and the dairy processing plant is that HACCP implementation fosters a cooperative team approach. Both stakeholders make a commitment to the other to work toward the same goal—safe dairy products—under the NCIMS HACCP alternative regulatory inspection program.

The success of the NCIMS Voluntary Grade A Dairy HACCP Program will be driven by industry as individual dairy plants step forward, commit to HACCP implementation

and participate in the program. The NCIMS HACCP committee can be a good resource in this regard, as can the International Dairy Foods Association (IDFA), which offers a number of educational programs and networking resources to industry.<sup>4</sup> □

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### References

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## NCIMS HACCP Implementation Committee Members

The HACCP Implementation committee welcomes and encourages outside input that will assist it in accomplishing its tasks. Observers are welcome at meetings and are welcome to provide relevant input during deliberations. NCIMS HACCP Implementation Committee Chair John Beers can provide a history of deliberations and other information for those wishing to ask questions or provide input.

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