Use of Microbial Data for Hazard Analysis and Critical Control Point Verification—Food and Drug Administration Perspective

JOHN E. KVENBERG* AND DARRELL J. SCHWALM

Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, HFS-601, 200 C Street S.W., Washington, D.C. 20204, USA

ABSTRACT

This paper examines the role that the microbiologist and microbiological testing play in implementing hazard analysis and critical control point (HACCP) programs. HACCP offers a more comprehensive and science-based alternative for controlling food safety hazards compared with traditional sanitation programs based upon good manufacturing practices. Controlling hazards under an HACCP program requires a systematic assemblage of reliable data relating to the occurrence, elimination, prevention, and reduction of hazards. These data need to be developed in a transparent environment that will ensure that the best scientific methodologies have been employed in developing the needed data. The two mechanisms used in HACCP to assess the adequacy of the database are validation studies and the verification assessments. Microbiological testing is an important mechanism for collecting data used in developing and implementing an HACCP plan. Microbial sample data can help establish standard operating procedures (SOPs) for sanitation, assess the likelihood of the occurrence of hazards, establish critical limits, and assess the validity of the HACCP plan. The use of a performance standard to assess whether microbiological hazards have been reduced to an acceptable level creates an especially important use for microbial analysis. Microbial testing is also useful in implementing an HACCP plan by helping to monitor the effectiveness of sanitation SOPs, the compliance of incoming ingredients with safety criteria, the safety of product being held for corrective action, and the safety of the finished product. The verification audits demonstrate that all control measures have been applied as designed in the HACCP plan. Although auditing HACCP records is the primary means of verification, microbial sampling can play an important role as well.

The food-manufacturing industry has historically relied largely upon experience from consumer complaints, product recalls, and reports of illnesses; general scientific studies; and common sense manufacturing practices to determine the best methods to use in controlling food safety hazards. As more and more manufacturers begin to develop hazard analysis and critical control point (HACCP) systems to control food safety hazards, the traditional roles of the food microbiologist and microbial sampling are being re-examined. Specifically, firms implementing an HACCP program often find that they need: enhanced methods to identify and prioritize hazards to control, and updated criteria for selecting control measures and selecting the operation parameters that will yield the most effective results.

Firms are willing to make these changes because the advantages of having a more detailed, science-based and process-specific hazard analysis, as well as scientific validation and verification data to document the adequacy of a control system, quickly becomes apparent when adopting an HACCP program.

Enhancing food safety controls often necessitates that a manufacturer conduct in-house scientific studies of their processing control measures to determine whether a particular hazard should be controlled under the firm’s prerequisite programs or under the HACCP plan. The following is an example cited in the Food and Drug Administration’s (FDA’s) “Second Interim Report of Observations and Comments” on the HACCP Pilot Program (3):

One example encountered during the pilot program involved a bakery product. The hazard analysis determined it is reasonably likely that the raw ingredients could contain microbial hazards. During the processing, the product is baked in order to produce a product of a quality that can be marketed. Studies conducted of the internal temperatures during baking showed that the baking processing step is lethal to any microbial hazard. The studies also showed that any product that was incompletely baked to such an extent that the microbial hazards might survive would be too doughy on the inside to undergo a further processing step and would not be suitable for marketing.

The microbiologist plays a key role in developing and conducting such studies, as well as other studies that are instrumental to the proper implementation of an HACCP plan.

CHANGING ROLE OF MICROBIOLOGICAL TESTING

An important goal of HACCP is to help the food processor build safety into the process through a small number

* Author for correspondence. Tel: 202-205-4180; Fax: 202-205-4121; E-mail: kvenber@bangate.fda.gov.
of key or critical control measures that prevent, eliminate, or reduce hazards to acceptable levels. An HACCP program shifts the focus of controls toward monitoring in-process preventive control measures. At the same time there is a diminished focus on monitoring the quality of the finished product. This shift in focus also changes the role of microbial testing. HACCP substantially reduces the need to test the finished product for the purpose of assessing the safety of individual lots of product.

This shift in focus is important because of the increased awareness of the shortcomings of microbial testing of finished products. Reliance on end-product testing is particularly inefficient and ineffective when a large sample size and high frequency of sampling is needed to provide statistically reliable data. The reliability of finished product test data is especially poor when trying to detect a pathogen that occurs in low numbers, occurs sporadically, and originates from an unknown source using unidentified pathways. As FDA reported in the Federal Register (1):

End-product testing does not address the root causes of food safety problems; it is not preventive by design and requires that a large number of samples be analyzed to ensure product integrity.

**MICROBIOLOGICAL TESTING IN AN HACCP SYSTEM**

An HACCP plan provides a safety-net of preventive measures to control hazards. The purpose of microbial testing is to confirm that all possible avenues of contamination have been identified and that these avenues are being controlled. To accomplish this, an HACCP program often changes the role of the microbiologist, and the location, timing, and frequency of sampling. Each of these changes will be briefly discussed in order to provide a basis for a more detailed discussion of the role that microbial testing plays in validating and verifying an HACCP plan.

**The Microbiologist as a member of the HACCP team.** A firm’s food microbiologist needs to be part of the HACCP team because of their specific knowledge and expertise regarding hazard assessment, food safety control, and monitoring. They can contribute to the multidisciplinary composition that is needed for an effective team and for a team that will have the respect and confidence of management. For firms that must control microbial hazards, the microbiologist should be one of the team members that receive specific HACCP training. The importance of this was emphasized by several of the firms participating in FDA’s HACCP Pilot Program (2). In FDA’s first “Interim Report of Observations and Comments,” it was reported that “training of employees is instrumental to their success and attitude . . . (it) seems to empower employees . . . and employees know the importance of their job and what to do if there is a problem.” HACCP training will also allow the microbiologist to play a role as a person qualified to validate a firm’s HACCP plan under FDA’s HACCP rules.

**The role of microbial testing in the prerequisite programs.** Microbial testing of the processing environment can be an important component of an HACCP program. FDA found in its HACCP Pilot Program (2) that most firms try to maximize the use of their prerequisite programs to control hazards in order to avoid the strict requirements of the controls associated with a critical control point (CCP). FDA reported in its first Interim Report that “in some instances, the same type of hazards were controlled under the prerequisite programs at one firm and under the HACCP plan at another firm.” Either approach was effective as long as the prerequisite programs were well documented with standard operating procedures (SOPs), were fully implemented, and included monitoring records and verification procedures. These verification procedures typically included microbial testing. One firm, for example, utilized environmental sampling extensively to monitor cleaning and sanitizing of food-contact surfaces and potential sources of environmental contamination such as floor drains. The sampling plan was designed with the purpose of finding hidden areas that harbored microorganisms. This sampling plan required greater ingenuity and the type of special knowledge that a microbiologist can bring to an HACCP team.

**The role of microbial testing in conducting a hazard analysis.** The development of an HACCP plan starts with the identification of the hazards that are reasonably likely to occur and to cause illness or injury in the absence of control. The National Advisory Committee on Microbiological Criteria for Foods explains in its “HACCP Principles and Application Guidelines” (adopted 14 August 1997) (4) that during the hazard analysis, a firm must evaluate the severity of a potential hazard and its likely occurrence. A microbiologist can help the HACCP team assess a number of factors that can influence the likelihood of occurrence of a hazard and the safety of a food product. These factors include water activity, pH, use of preservatives, and time and temperature profiles.

The FDA found during its HACCP Pilot Program that the hazard analysis is often one of the most challenging steps in developing an HACCP plan. Normally an HACCP team will develop a long list of potential hazards during the initial brain-storming phase of the hazard analysis. The team must then evaluate each potential hazard to determine which hazards merit being addressed in the HACCP plan. Firms often lack sufficient data to determine whether a hazard is likely to occur and whether the potential injury or illness that might result is severe enough to warrant a control measure being applied. As a result, many of the firms involved in the FDA HACCP pilot program found they needed to design and conduct studies to assess these factors. These studies normally include microbiological testing if a microbial hazard is being assessed.

**Incoming ingredients.** One common area where additional studies are often needed concerns the assessment of hazards in incoming ingredients. Firms participating in the pilot program reported that an important means of limiting the number of hazards to be controlled is to use raw ingredients and materials that are free of hazards. All of the firms developed controls for incoming ingredients that had the affect of extending control of hazards backward in the food production chain to the primary producers and sup-
pliers. Controls using microbial testing include: Certificates of Analysis for selected contaminants, in-house laboratory samples to confirm acceptability, quick tests of indicator parameters to assess acceptability, and screening of new vendors including sampling by outside laboratory.

For example, three of the pilot firms listed the pathogens Salmonella spp., Escherichia coli O157:H7, and Listeria monocytogenes as potential microbial hazards that may be present in incoming ingredients such as pasteurized milk, cheese, whey powder, and other dairy products. In the course of developing and validating their HACCP plans, these firms conducted in-house studies to assess the significance of contamination from these incoming ingredients. They also required testing by their suppliers to assess the adequacy of the control measures being applied by the suppliers to eliminate or prevent survival and growth of the pathogens. These firms eventually decided, based upon their test results and the absence of reported problems in the scientific literature, that these pathogens were not likely to occur and need not be controlled in the HACCP plans as a CCP. Nevertheless, the firms also decided that because E. coli O157:H7 has a high tolerance to low pH environments and because there had been reported problems from cross-contamination and recontamination of processed products from Salmonella and Listeria, that microbial data would continue to be collected for use in periodic revalidations of the hazard analysis.

The use of microbial testing as a monitoring tool.

Generally it is not feasible to use microbial testing to monitor critical control points because: results of tests for pathogens often cannot be obtained in a timely manner, and establishing a sampling schedule to detect pathogens that occur at low levels and on a sporadic basis may require a level of frequent sampling that is too costly and time consuming.

It may also be difficult to use indicator organisms as a monitoring tool because of the problem of determining what are appropriate levels to use as critical limits. Critical limits are used to determine when a deviation occurs that requires corrective action.

Monitoring a CCP that controls a microbial hazard is normally accomplished by using indirect methods of measurement. Indirect measurements may include, for example, measuring the temperature at which the food is held and the time held at a particular temperature rather than testing for the presence of pathogens or growth of microorganisms. Indirect measurements are also commonly used to monitor incoming ingredients. If fresh unpasteurized orange juice is being used as an ingredient, for example, it may not be feasible to test a lot for pathogens and wait for results before using the product. Instead, manufacturers normally rely upon periodic inspections of the supplier, assurances from the supplier that proper controls were applied on a lot-by-lot basis, and an inspection of the containers to assess their integrity.

Microbial testing also can be used to monitor the effectiveness of sanitation SOPs especially with respect to cleaning operations. Rapid tests can detect whether organic matter or microorganisms remain on surfaces that have been cleaned and sanitized. The assemblage of these types of sampling data can be another important component of the firm’s monitoring efforts. At least one firm participating in the FDA’s HACCP Pilot Program used such sample results as a criterion for an incentive and reward program for clean-up crews.

Use of microbial tests in a corrective action program.

When there is a deviation from a critical limit, the affected product needs to be segregated and corrective actions taken. It is preferable that the required corrective action be developed in advance and be specified in the HACCP plan. However, FDA’s HACCP rules provide a processor with the option of holding and evaluating product on a case-by-case basis. In these situations a firm needs to make two types of assessments. First, an assessment is made concerning the immediate action required to identify and control any product affected by the deviation from critical limits. Once the product is controlled and segregated, microbial testing may be helpful in assessing the safety of a product that deviates from critical limits. However, making such an assessment is subject to the same difficulties discussed earlier regarding end-product testing. The second type of assessment concerns the integrity of the HACCP plan. When a deviation occurs, a firm evaluates whether the HACCP plan is properly designed to control the hazard encountered. There may be a role for microbial testing in this type of assessment, as well.

Use of microbial testing in validating the HACCP plan.

Microbial testing can play a major role in a firm’s validation studies if microbiological hazards are being controlled by the HACCP plan. There are two types of validation studies and each may include microbial testing. First, a processor must conduct an initial validation of the HACCP plan to determine whether the plan is scientifically and technically sound: all hazards that are reasonably likely to occur have been identified, and the control measures and the critical limits will effectively control the hazards.

The type of activities that are needed to perform an initial validation include: a review of the scientific documentation used to develop the HACCP plan; a review of the scientific literature for other studies demonstrating that control measures are effective and critical limits are appropriate; a review of any challenge studies, such as for pasteurization units, used to determine the limits of the processing equipment and the parameters that need to be set to achieve effective results; and a review of product testing and other in-plant evaluation records that confirm that microbial hazards are being adequately controlled.

If standard industry control measures or other widely accepted measures are used, data in the scientific literature can be used to document that the control measures and critical limits are effective. If unconventional or unique control measures and/or critical limits are used, scientific studies need to be conducted by the firm to demonstrate their effectiveness. These studies need to include microbial testing if a microbiological hazard is being controlled.

Designing a microbial study involves careful planning.
The effectiveness of an HACCP plan is measured by the extent to which each hazard is eliminated, prevented from occurring, or reduced to acceptable levels. This is normally relatively easy to assess if the food-manufacturing processes include a kill step. In these cases, microbial testing can confirm that the kill step achieves 100% elimination under the most adverse conditions expected.

For food-manufacturing processes without a kill step, especially those involving raw agricultural products where pathogen contamination cannot be effectively eliminated or prevented, designing a validation study is often more complicated. In these instances the manufacturer needs to apply control measures that will reduce the pathogens to acceptable levels. This usually involves the application of a performance standard that defines the acceptable level of reduction. If the process has one control measure that will achieve the entire reduction required, then the study design is simplified. However, if the processor is relying upon a series of control measures that result in a cumulative reduction, the validation study design will likely be more complicated. Some of the issues that arise in designing a validation study include: whether to use a surrogate organism for an in-plant study; whether to use pathogens in a laboratory study that duplicates in-plant controls; which control measures are critical to achieving the needed level of reduction; whether the reduction provided by each control can be measured separately; and whether the overall reduction provided by the control can be measured collectively.

Recent studies conducted by several fresh citrus juice manufacturers provide examples of the important role that microbial testing plays in validating processing controls. These firms used recognized consulting laboratories to design studies that involved both laboratory simulations using pathogens and in-plant confirmation studies using surrogate organisms. Pathogens studied included several strains of *E. coli* O157:H7 implicated in illness outbreaks, as well as *Salmonella* strains. Control measures tested to simulate in-plant operations included a variety of sanitizers as well as steaming, washing, brushing, culling, and waxing. Studies were also conducted to examine the impact of juice extraction equipment on the microflora of the juice.

Similar studies are currently being conducted by the apple cider industry and other parties interested in apple cider production including academia and government groups. The FDA, for example, is conducting research at a cider processing facility in Placerville, Calif., and at its MOFFETT and CFSA microbiology laboratories. The research includes microbial studies to examine: the sources of contamination in the orchards and processing facility; the microbial flora associated with different types of apples including tree-picked and drops; the microbial build-up in the processing operation under normal and adverse processing conditions; and the effectiveness of a variety of processing controls including sanitizers, washing, brushing, hot dips, steam, ozone, UV treatment, and warming–freezing–thawing regiments.

The second type of validation is the as needed or at least annual reassessment studies. Revalidation is needed when a firm experiences an HACCP system failure, when deviations from critical limits occur on a regular basis, or when there are significant changes in the product, process, or packaging. The FDA's experience with the HACCP Pilot Program provided examples of situations that required revalidation studies. In one instance a firm found that their critical limits for incoming ingredients were routinely exceeded. They determined that their limits for aerobic plate counts and total coliforms were set to control quality parameters rather than safety parameters. The HACCP plan was re-evaluated and the critical limits were changed so that aerobic plate counts and total coliforms were used as operational limits, and fecal coliforms and pathogens were used as the critical limits.

The need for revalidation studies also applies to the prerequisite programs. Such studies are needed to evaluate whether prerequisite controls are effective in providing the level of control and prevention that is required for the HACCP plan to be effective.

**The role of microbial testing in verifying the HACCP plan.** The HACCP provision for verification requires that a processor determine and document that all control measures have been applied as designed in the prerequisite program SOPs and the HACCP plan. The traditional view is that verification normally does not need to include microbial testing because, in large part, verification is accomplished by reviewing HACCP monitoring records. The National Advisory Committee on Microbiological Criteria for Foods guidelines support this view and advise in the section on verification that: An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

Neither FDA's Seafood HACCP rule nor the proposed Juice HACCP rule requires any microbial testing, although it is recommended.

Nevertheless, FDA's HACCP Pilot Program confirms that many processors have extensive environmental and product-testing programs, and that microbial testing often plays an important role in HACCP verification. Firms participating in the pilot program report several ways to use microbial testing in a firm's verification program. These include the following.

**Verification of prerequisite programs.** Microbial sampling is commonly used to verify that the sanitation operations are effective. Typically, samples are taken from food contact surfaces to assess cleaning and sanitizing SOPs, from environmental surfaces including floor drains to assess environmental cleaning programs, and of the product at the market level to assess retail storage controls and shelf-life. Records are kept of the sample results and followup corrective actions are taken if elevated microbial levels are found. These records are reviewed under the firm's daily HACCP record audit procedures. The results are also
reviewed monthly as part of the assessment of the verification procedures and yearly as part of the annual reassessment.

Verification of monitoring and corrective action records. Microbial testing is often used to verify that incoming ingredients have been subject to effective controls. This testing includes in-house samples collected by the processor and tests results provided in Certificates of Analysis by the supplier. Microbial testing is also used to verify that a lot of product that is segregated when a critical limit is not met, meets, or does not meet food safety criteria.

HACCP system verification. Microbial test results are normally tabulated and analyzed to identify any trends that indicate whether or not sanitation and HACCP controls are being effectively applied. Firm management can also use microbial test data tabulations to verify to buyers, upon request, that a safe product is being produced. Finally, firms that have in-house microbiological testing capabilities routinely perform quality assurance analyses to verify that standard procedures are being followed in the laboratory.

Although there are advantages to incorporating microbial testing into a verification program, there are also some issues that arise if this is done. The first issue regards the sampling plan and analytical method. A firm must decide what samples are to be taken, what type of tests are to be conducted, and for what organisms are the tests to be conducted. The sampling plan is important because pathogens often contaminate a food sporadically, and it is not practical to sample large quantities of the product. The degree of confidence that can be placed upon the sample result is dependent upon the sampling plan that is chosen.

The analytical method is important because it determines whether samples will be analyzed for pathogens or indicator organisms. Normally, sanitation and in-line process samples are analyzed for indicator organisms. If indicator organisms are used, guidelines need to be established as to what levels indicate a problem that requires followup and corrective action. If samples are analyzed for pathogens, guidelines need to be established by the firm on followup and corrective actions if a positive sample result is obtained. The analysis of samples may need to be conducted before the product is shipped so the firm will not be placed in the position of needing to conduct a recall if a product is found to contain a pathogen. The firm also needs to recognize that a regulatory agency will be interested in any sample results that indicate a hazard in the product. The firm will need to document what actions were taken to keep any unsafe products out of the market place and that the source of the problem was investigated and corrected.

CONCLUSION

HACCP has created the need for important changes in the role of the microbiologist and microbial testing in the food industry. Under an HACCP program, the microbiologist is a key member of a firm’s HACCP team and an active participant in developing the HACCP plan. The microbiologist plays a lead role in designing microbial studies, developing monitoring strategies, and generating validation data to help the HACCP team assess the effectiveness of the processing controls being used. When the team determines that improved controls are needed, the microbiologist can help develop the scientific justification needed for management to understand, fund, and adopt the improvements. In many instances these enhanced responsibilities increase the challenge and rewards of the microbiologist’s job.

REFERENCES