

How to Implement a HACCP Program

Robert P. Wooden, Presenter*
Howard E. Bauman (Co-author)
Robert N. Terrell, Facilitator
Edward W. Mills, Recorder

There are some basic steps that must be taken within a company prior to embarking on a HACCP program.

Top management must unequivocally take a position that they will accept and produce nothing less than safe food and that all employees must conduct themselves in a manner that will ensure this objective. The company must continually follow through on its commitment. Food safety is not negotiable. If this rule is violated, the program will fail.

Employees must be taught the basics of the system and how it operates. HACCP requires that all employees participate, since the monitoring and recording of data at critical control points is done by people on the line. It will be important to develop a three-way partnership in the plants between the plant manager, the quality assurance manager and the rest of the personnel in the plant.

It will be necessary to appoint someone to be responsible for the implementation and maintenance of the program. This person should establish and chair a committee whose responsibility will be to aid and assist in the development of the HACCP plans and to review and approve the final plans. This committee should consist of a cross-section of disciplines, such as microbiology, chemistry, engineering, procurement, etc. It is the responsibility of the chairman of the committee to enforce the uniform application of the program.

HACCP requires judicious adherence to the principles of HACCP. The seven principles as developed and defined by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF) are the basic components of a uniform HACCP program. I would also recommend that the overall HACCP document developed by this committee be used as the basis for plan development. It is impossible in a short presentation to cover the lengthy rationale for each principle and how it must be applied. I will, however, cover each with a brief description. If the principles are understood and judi-

ciously applied, the resulting system will work well.

HACCP is a preventative program designed to avoid potentially hazardous products from entering the market. HACCP has a number of benefits.

It will tie the design, manufacture, distribution and the consumption of a food into an integrated system with established procedures for monitoring the system for deviations that might result in a hazard. Reports of deviations allow management to monitor the effectiveness of the program.

Product design in the future, if done on the basis of the principles, will ensure that the necessary data will be collected at an early stage.

Since the regulatory agencies have adopted the HACCP concept, the program can be worked out cooperatively with the regulatory agencies, thus ensuring early agreement with the plans.

The HACCP program is cost-effective in that it reduces the cost of inspection, less testing of ingredients and less product rejected. It will be a major factor in avoiding costly recalls of product from the market.

Principle One

Assess hazards associated with growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation and consumption of the food.

The components of the system are assessed on the basis of the likelihood of physical, biological, environmental, chemical, transportation, distribution and consumer abuse hazards occurring. The assessment of the hazards and risks is an important step in the process since it is the basis for determining where the critical control points will be established in the system. An accurate assessment by technically skilled personnel allows one to anticipate potential problems; and in many cases, this information can be shared with suppliers, the distributor and retailers so they can aid in the prevention of any hazards. Since microbiology is by far the greatest hazard in food, the NACMCF developed an expanded list of hazards in this area.

Hazard A: The most critical since it deals with any nonsterile foods that are consumed by special at-risk populations. Infants, the aged, the infirm and immunocompromised individuals.

Hazard B: The product contains "sensitive ingredients." Those ingredients that historically have been known to harbor pathogens or other hazards, such as toxins.

Hazard C: The process does not contain a controlled processing step that effectively destroys or excludes harmful microorganisms.

Hazard D: The product is subject to recontamination after

*R. P. Wooden, Manager Regulatory Affairs, Pillsbury, Inc., 311 2nd St. S.E., Minneapolis MN 55414

H. E. Bauman, Consultant, Howard Bauman Inc., 1433 Utica Avenue South, St. Louis Park MN 55416

R. N. Terrell, Vice-President R. & D., Kahn's & Company, 3241 Spring Grove Ave., Cincinnati OH 45225

E. W. Mills, Pennsylvania State University

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| FOOD INGREDIENT OR PRODUCT | HAZARD CHARACTERISTICS (A,B,C,D,E,F) | RISK CATEGORY (VI,V,IV,III,II,I,O) |
|-------------------------------|--|--|
| T | A+ (SPECIAL CATEGORY)* | VI |
| U | FIVE + 'S (B THROUGH F) | V |
| V | FOUR + 'S (B THROUGH F) | IV |
| W | THREE + 'S (B THROUGH F) | III |
| X | TWO + 'S (B THROUGH F) | II |
| Y | ONE + (B THROUGH F) | I |
| Z | NO + 'S | O |

*Hazard Characteristic A automatically is Risk Category VI, but any combination of B through F may also be present.

processing, before packaging.

Hazard E: There is substantial potential for abusive handling in distribution or in consumer handling that could render the product harmful when consumed.

Hazard F: There is no terminal heat process after packaging or when cooked in the home (e.g. microwave).

(Note: Similar lists can be made for chemicals, physical objects, etc.).

Risk categories were expanded by the NACMCF, based on the number of hazards that may be involved in a food from highest risk (VI) to lowest (O). It is recommended that a chart be utilized that provides assessment of a food by hazard characteristic and risk category.

Principle Two

Determine the critical control points required to control the identified hazards.

A critical control point is defined as "Any point or procedure in a food system where loss of control may result in an unacceptable health risk." The critical control points should be kept separate from other types of controls since hazards are nonnegotiable, while quality may be. It is important whenever a point is selected to ask the question "If there is a deviation at this point, might it cause injury to a consumer?" Only if the answer is "yes" may it be designated as a critical control point. The critical control points are generally few in number for any given product and process.

Principle Three

Establish the critical limits that must be met at each identified critical control point.

This principle was added by the NACMCF since it is recognized that a critical control point may have more than one limit or tolerance. For instance, rare roast beef cooked in a bag must have records of the maximum thickness of the product, related to the records of the time and temperature of the cook. Other critical limits may be pH, water activity, salt levels, etc. Microbiological data would rarely be used at a monitoring station. The critical limits establish the critical parameters that will insure control at that station. Any deviations call for action.

Principle Four

Establish procedures to monitor critical control points.

Monitoring of a critical control point is done to make sure that if there is a deviation, it will be detected and action taken.

The monitoring ideally should be continuous and in many instances can be. Temperature, pH, time, and moisture level all lend themselves to continuous recording. If it is impossible to measure continuously, then statistical process control techniques may be used. In many instances, visual observation such as checking a wire screen for breakage is sufficient. It is important to establish frequent monitoring times so that if there is a deviation, it will be detected before too much product is produced. Ideally, product produced during this period will still be in control of the plant.

Principle Five

Establish corrective action to be taken when there is a deviation identified by monitoring of a critical control point.

There should be written instructions for the person monitoring a critical control point as to what action should be taken if there is a deviation. This may result in immediate shut-down of the processing line. It will also require immediate notification of certain designated personnel who will know what steps to take before production is resumed. There are deviations that may only require corrective action, such as a freezer operating at a higher than desirable temperature. The instructions may at this station require notification of maintenance for immediate repair. All deviations will not result in a safety issue; therefore, before any product is destroyed or released, there must be an assessment made as to whether there is a hazard. This approach is much the same as that for the low-acid canned food wherein a process deviation is assessed by a process authority. All of these possibilities must be part of the HACCP plan.

Principle Six

Establish effective record-keeping systems that document the HACCP plan.

Records must be kept which will record any deviations that have occurred, the action taken and the disposition of the product. Whether or not a product may be recalled or destroyed will be dependent on the records of the operation. These records will include the testing of ingredients and raw materials, the monitoring of the CCPs as well as deviations, processing, packaging, storage, distribution and consumer complaints. Record keeping is a normal function in a food plant; the primary difference is that in a HACCP program, they are well organized and integrated.

Principle Seven

Establish procedures for verification that the HACCP sys-

tem is working correctly. Verification procedures may include physical, chemical and sensory methods; and when needed, establishment of microbiological criteria.

The purpose of this principle is to ensure verification of the system for its effectiveness. This is done by the company and may be done by the regulatory agencies if they so wish. Verification consists of assuring that the HACCP plan is up to date and approved, that direct monitoring data is being collected at the stations and that appropriate instructions are in place to ensure that deviations are handled properly. The action taken on any deviations and disposition of product must be verifiable. Calibration of instruments at appropriate intervals must be verified. Some critical microbiological criteria may also be used if deemed necessary. In other words,

verification is to determine if the plant is under control and operating according to plan.

Operation

Once HACCP has been installed and people become familiar with the system, it will operate smoothly. One decided advantage of the monitoring stations is that it will involve people on the plant floor, since detection and action takes place where the food is processed by the people who process the food. This will result in job enrichment and more pride in a job well done and a high level of cooperation by the employees.

Discussion

D. Pilkington: Some of the information I have seen suggests that a HACCP program should have a maximum of 5 control points. Can that be true in the meat industry?

R. Terrell: Some production processes may be very simple so that any particular one may lead to only 5 critical control points. But I don't see many of them fitting only five in our business.

R. Wooden: I've never heard the number five—I really haven't. Let me give two examples; maybe it will help. When we can food, we have a lot of steps but, if you get really serious about it, there are three critical control points. The first would be ahead of the filling process, assuring the absence of physical contamination. The second would be in the seaming process and the third would be the heating process itself. That conceivably could be a HACCP program with three critical control points. You can argue that some others are needed but three would do a pretty good, safe job.

Terrell: When you get into the physical systems part of it, for example checking the heating step, you have to get into statistics. How many times a day are those temperatures measured? So, the three may break down into four or five subsets.

Pilkington: You're saying you couldn't accept expanding that a bit.

Terrell: What I was really saying was that there are probably 4 or 5 key points, Dwain, in any process operation that you need to focus on. Where I see the frustration with this whole concept is in trying to include economic and quality indicators that have been the mentality of our industry and USDA for 100 years. You get too much data to manage and nobody can handle it. That is a real problem I see coming.

Wooden: Let me respond to that. In our HACCP course, we have an example that deals with this. In the hypothetical process, we are going to receive fresh refrigerated, boxed chicken legs. And we are going to manufacture packaged, frozen, breaded, battered, fried chicken legs. And the question is "What is the schematic for the process and what are the critical control points?" We went through that process with USDA headquarters staff and they came up with 33 critical control points that they felt were absolutely critical to public

health. Now all the other students in that course, including some in the chicken processing business, picked about 7 or 8 critical control points. Many of the 33 points dealt with economic factors. They were on all the parameters that had nothing to do with food safety.

C. Kastner: What is the role of rapid techniques for microorganisms in a HACCP program?

Wooden: Rapid microbial procedures are often shaky at best. They are not used for go/no-go testing of final product.

R. Tumerlin: There are a lot of the rapid analytical techniques, microbiological and chemical analyses, that are not fast enough to provide useful information for process control.

Wooden: That's right, that's why I've been talking about monitoring techniques such as time, temperature, pH, salt, moisture level. You can predict for most things what the outcome is going to be if you know your product and process well enough. If those are all in line, then we don't worry. If the heat process is proper for a low-acid canned food, you don't worry about a can of beef stew—it's safe—that's the principle that's followed.

Terrell: So really these rapid techniques, that take a little bit longer than the production process, can then be used to help refine and develop the actual control points. They may indicate if other criteria might need to be included in the control scheme.

Wooden: Exactly, that's the research and design function of HACCP. There are very rapid methods for *coliform*. You can do a lot of environmental work in a plant based on *coliform*. It's not going to tell you for sure whether or not you have other organisms such as *listeria* in the environment but it's going to give you an awful good indication of the overall sanitation of the facility.

Anonymous: How do you evaluate the effectiveness of a HACCP system?

Wooden: One of the functions of your QA department in the plant is to maintain the record-keeping system. Then on some kind of a basis, depending on what the plant is and what product you are manufacturing, you should take an outsider, possibly a corporate headquarters auditor, and go in and do a food safety audit to verify whether or not that

HACCP system is working. That audit might be on an annual basis but I have seen plants that do it quarterly.

R. Osborne: What technique are you using for rapid determination of *coliform* as an indicator organism?

Wooden: The Bactometer is what they are using.

N. Webb: The frankfurter process is certainly not sterile but we have a zero tolerance for *listeria* in the packaged product. How do you assure this?

Wooden: By creating as close to a sanitary environment and process as you can get. Then there must be a complete barrier between raw and cooked product to prevent cross-contamination. Some of this may take changes in thinking. Let me turn the question around a little bit. How many microbiological samples for *listeria* or *salmonella* would you have to take from a lot of hot dogs to prove that every hot dog in the lot was free of *listeria* and *salmonella*? The sample becomes so horrendous that you can't really deal with it.

Terrell: When you started at Pillsbury with the concept of HACCP, how many years did it take until your management felt comfortable that they had a HACCP program that worked?

Wooden: Well, I'll give you a couple of answers to that. I mentioned previously that some people went for three years without getting a raise and then they were terminated. At that point in time, we had a HACCP program operating and operating pretty well.

Terrell: So it took three years.

Wooden: Now let me give you another answer. Once you put HACCP into operation, a critical thing is to keep it operating. People change. The first CEO, that particular gentleman we were talking about, contracted lung cancer and died. We have had four CEO's since then; some with more emphasis, some with less. The important thing now is that it is passed all the way along to all levels of the company.

Terrell: The point I wanted to make (it hasn't been made before) is that there is a tremendous amount of human behavior change which must take place to break from traditional mentality and shift over to the HACCP frame of mind. It's not going to happen just by corporate decree. We have big-time human behavior changes that are going to have to take place. It's going to take time.

Wooden: The HACCP comes from the top down but everybody on the production line has to get with the program. They have to understand it. They have to do it.

B. Breidenstein: If you have an existing quality assurance program and you superimpose a HACCP program, won't there be duplication of efforts?

Wooden: Probably not. They will be parallel rather than have one superimposed on the other. There are parts of existing QA programs today that really are food safety and they would become part of a HACCP program. There are other parts of the QA program today that are quality-related and those are going to remain a part of the quality program. For example, there is no need to test our chocolate cake mix for *salmonella* before shipping. Basically, we do the ingredients work upstream to assure that the cocoa and the nonfat dry milk are not contaminated; therefore the cake mix is not contaminated. But in the QA program, we certainly take a sample to make sure it makes a cake.

Terrell: The reason I bring that up is that I see USDA trying to make the total quality control programs with all their

economic and quality parameters into HACCP programs by adding human health and public health issues. It's not going to work because it's just too much information to manage when you put it all together. You go out to a manufacturing plant or organization and say "Here, Mr. graduate student, here are your requirements for your degree; you have a double dose of them now." It's mind boggling. I speak on behalf of the industry, that's one of the arguments we are going to have with Cathy Adams on this whole program. It will be unmanageable. It will be like trying to put AQL process standards into the HACCP program.

Tumerlin: Does HACCP provide for risk/benefit considerations?

Wooden: FDA and USDA regulations do not require that. In fact, FDA has the Delaney clause stuck in there which forbids that in the case of a carcinogen.

Terrell: More and more of the sensitive ingredients are going under lot certification from the supplier that certifies that they have analyzed that lot for the following things before they shipped it. We spot-check various lots on arrival. We share that information back and forth because it is a cost factor.

Wooden: We do the same kind of thing with defect action levels in spice ingredients. It is not a public health issue, not a food safety hazard, but the same kind of thinking applies. We haven't had a problem in seven years now.

Tumerlin: If one of your suppliers has their own program for truck sanitation and maintenance inspection, how will that affect your program?

Wooden: It will be a separate program. They are going to be inspecting the truck and looking it over to make sure that it is an appropriate vehicle, properly cleaned, there is no infestation in it, the refrigeration unit has been working. When we get the truck at our dock and unload it, our man will have a look at it also.

D. Kropf: How often should you monitor your water supply?

Wooden: It is a good practice to test for total plate count every 6 months. You should also include an analysis for heavy metals and organics.

Terrell: If you have a manufacturing plant within 15 miles of a solid-waste landfill or a nuclear power plant, you had better start looking at your water quality more than once a year.

Wooden: You are going to see more and more concern for water quality.

D. Schafer: Please comment on the interaction between processor and retailer in product recalls.

Terrell: I'll give you part of the answer for a "small" retail chain based in Cincinnati, Ohio. When you have a recall, you pay them \$10,000 up front to go and get all the merchandise. As the supplier, they don't even want you in the store picking up stuff. Food distributors have the same procedures. If you have a recall, you might as well get out your billfold.

Wooden: Recalls are very expensive. In addition to being embarrassing and hurting business, they are very expensive financially. You are going to have your sales force out there trying to find the product. While your sales force is doing that, they are not selling product. That's expensive.

Schafer: If problems are due in part to mishandling, to what extent is the store liable and when does the liability go

back to the manufacturer?

Terrell: If they are the manufacturer, legally they are responsible for their own product and their establishment number. There is starting to be an awareness on the part of retailers that they are selling this merchandise, not manufacturing it. They don't have much experience with product safety liability.

Wooden: Some of those things are changing. Some larger retailers have become manufacturers and they are very aware of what a recall is and what to do about it. And, they do recall their own copacked product when they are required to do so.

If you think about how many recalls there are in a year and add to that the number of market withdrawals, the number is quite large and the cost is unbelievable. At Pillsbury, if we have one we think that is about two times too many.

K. McMillin: USDA is presenting informational meetings on HACCP all around the country. I would advise all the academicians to attend at least one of these regional meetings.

Terrell: If you stop to think, when most of our food preparation procedures were developed we didn't know about *listeria*. I will share with you some of the work that we are doing with frozen ready-to-eat meat products. When the handling and preparation instructions on these items are put up against *listeria* testing, they don't pass. So, we are in the process of getting a little better handle on what we are going to say on that package. I know that eventually it'll be mandatory that we have something besides "keep refrigerated" on all ready-to-eat as well as raw meat products. It will be mandated by law.

S. Schwartz: What organisms other than *listeria* are of concern to public health?

Wooden: There are several including *Salmonella* and *Staphylococcus*. The main concern with *listeria* or the other kinds of pathogens comes when they are found in the post heat processed plant environment. In that area, they may be transferred to ready-to-eat products. That's where most of the danger lies.

D. Cornish: Many of today's convenience meat products are pasteurized, then vacuum packaged. With some temperature abuse, this could lead to serious problems.

Wooden: Yes it could. In the past we cooked fresh meat strictly in the home and it was consumed pretty quickly. You certainly have landed right smack on a real serious problem. If you destroy the vegetative organisms in a process in the plant, then keep it in an oxygen-free environment during distribution and temperature-abuse it, you could end up with a botulism problem and kill somebody.

Terrell: One of the things that we're looking at is in the area of instrument calibration. We don't want to look just at thermometers. We want to look at pressure gauges, valves, and continuous metering devices for different materials. I think if you take that approach with the maintenance people, you will feel a lot more comfortable and so will they. You may be surprised to find that meters are not delivering what you might think they are delivering.

Wooden: Our specification calls for controlled pH. If it is out of control, that is a hazard. It might be that you want to deal with economic hazards and regulatory hazards also. Let me comment about pumps, heaters and things of that sort.

You've got to keep track of these things or you are going to end up with problems because you don't meet the standard of identity. It's not going to hurt anybody but it sure is an economic and regulatory problem. So yes, anything that needs calibration, you've got to maintain the calibration. Some of it will truly be food safety.

J. Francis: We have to consider the liability question. What about the people who buy the product. Is there a liability question with them?

Wooden: I will give two answers: First, to a lawyer, anything can be a part of a liability lawsuit. It can be whatever the lawyer wants to make it. For the other response to the question, I have had personal experience that says a HACCP program is important in determining whether or not there is a potential liability. The regulatory agency has always taken a good operating HACCP program, at least in my experience, and said "There is no liability here, the program is working, the problem came from somewhere else." In an instance a few years ago, there was glass found in some baby food. The company president and FDA commissioner Young got up before 2000 people at an FDL I meeting and said, "The glass did not come from our plant. It came from somewhere else. We know because we have a good operating HACCP program."

Kropf: Is HACCP being applied in the retail store for display temperature control?

Wooden: HACCP is supposed to be going into retail stores right now. The Food Marketing Institute (which is the supermarket organization) has developed a HACCP program for that industry.

There are a couple of other things that are getting attention also. We have been in the refrigerated dough business since 1948. Since 1948, there have been many more refrigerators at 50°F than there have been at 40°F. There are two points: first we can hammer at the retailer to do something about fixing their refrigeration systems. The other thing is that we've got to build safety into our food product. In the case of our refrigerated dough products, they self-destruct before they become hazardous. The cans open because the lactics grow inside when they are severely temperature-abused. You could build protection into a food product by adding a lactic acid culture. If it is temperature-abused, the lactics will grow, pH will drop, the pathogens are stopped, the food is spoiled and you have food safety.

Kropf: Who bears the cost when spoilage is caused by temperature abuse in the retail store or delivery truck?

Wooden: If you have a branded food product and you sell it to a retailer, you may bear the cost if it spoils, no matter who's fault it is. The other thing that is happening is that the regulatory agencies (and this includes the state and local people as well) are lowering the recommended highest temperature for refrigeration. In the regulations that they are considering now, you are seeing 40°F, not 45°F, as we used to. And the local public health inspectors are going to be around starting to enforce that.

Cornish: You mentioned lactic cultures; are there other temperature-abuse indicators available?

Wooden: Avoidance of temperature abuse can be built into good operating methods and equipment design. I will give you an example. You go into a Burger King restaurant, the place where they talk about flame-broiled hamburgers.

That broiler has a continuous moving belt. The speed of that belt is controlled by sprockets which are pressed onto the shaft. Even if somebody wanted to, they couldn't take them off and change them to change the speed of the belt without going into a machine shop. Certainly no employee in the store would be able to change that drive. The gas jets are controlled by a fixed regulator valve on the gas line. The amount of gas and the speed of the belt are absolutely controlled. The insulation and the design of the shell of the oven are specified. That broiler is designed so there doesn't have to be a thermometer in the Burger King store. When the hamburger patty comes out of that broiler, it is cooked. And, you know that it is cooked because of the research work that was done up front in the design of the broiler. We have taken the temperature measurements with a multipoint thermocouple down in the middle of the patty. There was a lot of microbiological research that went on with that. When the research was done, the specifications for time and temperature of the broiler were set. If there is some other quick indicator, it might be useful. But, I would argue with you that if the broiler is not modified, the result will be consistent.

Terrell: We are about on schedule; there are about 2 or 3 more minutes. Bob, you may want to summarize.

Wooden: This is about establishing a working HACCP program. It's really pretty simple. You've got to have a product specification and in that product specification there has to be a detailed formula and process. It should tell you how to make whatever it is you are going to make. Then there are the specifications that this food has to meet. With that information, then you can begin your risk assessment. Are there sensitive ingredients? Is there a step in the process that is a kill step? From where do you get your ingredients and materials? What are the specifications for them? How do they get approved? What are the things that the supplier has to do? How do you control from week to week and month to month that the ingredients coming into your plant are what

you expect them to be? It's got to be sanitary in the plant in the building design and in the layout. There has to be a pest control program. All of the things that are a part of good manufacturing practices. In fact, a good GMP program could be considered a critical control point. Of course you can't make a critical control point out of every single GMP activity that goes on in the plant. For example, I believe that in one USDA proposal they have insisted on a critical control point that would stress that an employee washes his/her hands before entering a processing area. Now how are you going to control that? Are you going to have someone standing there with a clip board checking off the employees as they walk in the door? No! But certainly you put the handwash station there. It is an education program, it is a way of life. But it is not a critical control point because there is no way to monitor it each time someone walks in the door. I was in a meat plant where as I walked into a raw product area from a ready-to-eat area, I had to put on a smock, wash my hands and step in a foot bath. At the exit, there was no foot bath or handwash station. That plant had a complete misunderstanding of microbiology. Finally, when you did everything right and someone else abuses your product, you're still going to have to go get it in the marketplace. You need a recall system and it has to be effective. That's kind of a blue-print for your food safety program and it works pretty good.

Terrell: Much of the material represented here was presented at the RMC last year. We have tried to have a series of seminars on the concepts and that sort of thing. However, the most effective way to understand HACCP is to take a process, lay out the design, then get your team together to identify the critical control points. You can't do it with just one person. You need to interface disciplines here. The key to HACCP is the interfacing of disciplines because often we don't talk to one another. If you take that process flow diagram and you get some discussion going, you will see how it fits logically.