Another Decision-Tree Approach for Identification of Critical Control Points

FRANK L. BRYAN*

Food Safety Consultation and Training, 8233 Pleasant Hill Road, Lithonia, Georgia 30058, USA

(MS# 95-306: Received 12 December 1995/Accepted 20 March 1996)

ABSTRACT

Decision trees have been used as an aid to selection of critical control points as part of the development of hazard analysis critical control point (HACCP) systems. The background for those in existence is described. Another decision-tree approach that follows the logic in the IAMFES manual Procedures to Implement the Hazard Analysis Critical Control Point Approach is presented. It takes into consideration impending hazards, the effect of actions exercised at the operation in question, whether control actions should be taken at this or subsequent operations and whether the CCP will be monitored and corrections made. Further, guidelines are given for selecting an operation as a critical control point. A decision tree to aid in the evaluation of risks is presented, considering whether illness will result, the severity of the illness and the likely occurrence of this outcome, based upon epidemiologic or challenge study of related events. These decision trees provide additional tools to aid in the development of HACCP systems.

Key words: HACCP, critical control points, food safety, risk assessment, food processing, food production

A critical control point is an operation (process, procedure, practice, or location) at which a preventive or control measure can be exercised that will eliminate, prevent, or significantly reduce, minimize, or delay a hazard (4). A hazard is an unacceptable contamination of a microbiological, chemical, or physical nature and/or survival or growth of microorganisms of concern to food safety or unacceptable production or persistence in foods of toxins or undesirable products of microbial metabolism (4).

A decision-tree approach for selection of critical control points (CCP) has been incorporated into some publications relating to either food safety or the hazard analysis critical control point (HACCP) concept. For example, it appeared in a report about the principles of the HACCP concept by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (14), in a technical manual and practical guide on the HACCP approach developed by a working group in the United Kingdom and published by the Campden Food and Drink Research Association (12), in guidelines for the application of the HACCP system in Codex Alimentarius international food law procedures (5), and in training considerations for the application of the HACCP system to food processing and manufacturing by a working-group consultation of the World Health Organization (21). This decision tree sought yes or no answers sequentially to a few questions, which were: “Do preventive measure(s) exist for the identified hazard?” “Is control at this step necessary for food safety?” “Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?” “Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable level(s)?” “Will a subsequent step eliminate identified hazard(s) or reduce the likely occurrence to an acceptable level?” The answers to this series of questions are used to evaluate whether each operation is a CCP.

Mayes (13) introduced another decision tree for selecting CCPs. He considered it to be a simple users’ guide to the application of the HACCP approach to food safety, particularly for microbiological hazards. As a basis, he used the HACCP concept developed by the International Commission on Microbiological Specification for Foods (ICMSF) (11). This decision tree sought answers to certain questions in a sequence leading to decision of whether an operation ought to be considered a CCP in reference to likely contaminants (e.g., Salmonella serovars, Staphylococcus aureus) of raw materials or to their introduction, survival, or multiplication during processing. The question dealing with each raw material asks: “Could a raw material realistically contain the hazard under study (e.g., Salmonella) at levels dangerous to the consumer?” “Will processing, including correct consumer use, guarantee removal of the hazard or reduction to the level regarded as safe?” A subsequent decision tree considers each process and asks: “Is the formulation, composition, or structure of the intermediate product or final product essential for preventing increase of the hazard under study to levels dangerous to the consumer?” “Could this process stage realistically allow contamination with the hazard under study to dangerous levels, or allow it to increase to a dangerous level?” “Is this process stage intended to remove, inhibit, or prevent contamination...
and/or increase of this hazard to dangerous levels?" "Will subsequent processing, including correct consumer use, guarantee removal of the hazard or reduction to a level regarded as safe?" This approach was further promoted in a guide for applying the HACCP system (16).

A further modification of this decision tree has been suggested by Tompkin (19). He felt that it worked for processes that have a kill step (13), but that it was not suitable for raw agricultural products such as meat and poultry (18). The following series of questions were posed in an attempt to devise a decision tree that is more suitable for this purpose (18). "Does this step involve a hazard of sufficient risk and severity to warrant its control?" "Does a preventive measure for the hazard exist at this step?" "Is control at this step necessary to prevent, eliminate, or reduce the risk of the hazard to consumers?" Tompkin (18) stated that these questions are suitable for raw material receiving and ingredient usage, thus negating the need to include the special questions proposed by Mayes (13).

Additionally, Tompkin (19) stated some important considerations when using a decision tree. These are: "The decision tree is used after the hazard analysis. The decision tree then is used at the steps where a 'significant hazard' has been identified. These are hazards that may reasonably be expected to occur. Nonsignificant hazards (i.e., of low risk and unlikely to occur) have been excluded. A process which does not have a significant hazard does not need a HACCP plan. Each step which is a CCP must agree with the definition. A subsequent step in the process within the control of the operator may be more effective for controlling a hazard and may be the preferred CCP. More than one step in a process may be involved in controlling a hazard. More than one hazard may be controlled by a specific preventive measure." This information gives more advice about whether an operation is a critical control point than the decision trees cited above.

These decision trees are used by some persons or industrial HACCP-study teams during development of HACCP systems, but they have certain shortcomings, as is typical for any oversimplified approach. For example, these decision trees do not provide guidance in determining either severity or risks or relationship to the type of CCP, all of which are considerations of the first principle of the HACCP concept (14). Additionally, these decision trees do not seek answers to all the concerns about selection of CCPs that have been set forth by the Committee on Communicable Diseases Affecting Man of the International Association of Milk, Food and Environmental Sanitarians (IAMFES) (4).

Because of a certain degree of confusion with the CCP1 and CCP2 approach introduced by the ICMSF (11), the Committee on Communicable Diseases Affecting Man introduced a further breakdown of CCPs that relates to more precise definitions of the types of CCPs. These were CCPe to eliminate, CCPp to prevent, and CCPr to significantly reduce, minimize, or delay a hazard or several hazards. This notation is consistent with the revised definition of a CCP at the beginning of this paper.

The decision of whether an operation is a CCP primarily relates to the definition of a CCP and the way it fits into the HACCP system. Hence, in this regard, there are at least six requirements for a CCP. These are:

1. There is a high or moderate risk of a disease outcome resulting from failure of an operation to prevent or minimize contamination, kill microorganisms of concern, or inhibit growth of bacteria or molds of concern. (Low risks do not call for CCPs.)

2. Actions are taken that either eliminate or prevent or significantly minimize, reduce, or delay a hazard or several hazards. (The hazard(s) may have been introduced at the operation under consideration, at preceding operations, or from ingredients.)

3. Criteria for control or critical limits have been established and implemented at this operation (the CCP).

4. Effective procedures are used to monitor the CCP to determine whether the criteria are met or critical limits satisfied.

5. The CCP is monitored during, just after, or occasionally just before the operation, as applicable to the process or situation. (Ideally, monitoring is continuous and automatically adjusted to maintain control, but this is not always either feasible or practicable.)

6. Prompt corrective actions are taken when criteria are not met.

Furthermore, for decisions to be epidemiologically linked, CCPs must be associated with previously identified hazards (4). Hence, CCPs are operations that affect the hazards by eliminating, preventing, or significantly reducing, minimizing, or delaying them. The operation at which hazards are introduced does not automatically call for a CCP, but control or preventive actions must be taken at a subsequent operation, which would either be a CCP or the hazards would be unabated.

A decision tree that is more compatible with the approach of the Committee on Communicable Diseases Affecting Man and the requirements for CCPs stated above is presented in Figure 1 for consideration along with the other decision trees and as an annex to the IAMFES HACCP manual (4). This decision tree is a series of questions seeking yes or no answers. Although it contains eleven questions, each one leads directly to the next. Some questions, however, may be skipped under appropriate situations as indicated by the lines on the left of the boxes.

The first question, "Do contaminants enter the product from ingredients or remain from previous operations?" relates to the raw product or ingredients at the beginning of the operation being evaluated as to whether the product is or the ingredients were initially contaminated. The second question, "Have any contaminants been introduced during this operation?" is a consideration of whether additional contaminants are introduced to the product as the operation is performed. The next question, "If these contaminants remain through operations, could illness result from ingestion of the food?" deals with the contaminant's ability to cause illness or injury when the food is ingested. This question defines whether the situation is a concern to food safety, spoilage, or aesthetics. If the answer is positive as to illness, there is a food-safety concern, and the questioning is continued. The fourth question, "Is the risk of the occur-
FIGURE 1. Decision for determination of whether an operation is a critical control point. The asterisk indicates an activity that may be in a subsequent process or preparation step within control of the establishment within which the HACCP system is being devised or further down the food chain.

As these questions are answered, the decision as to whether an operation is a CCP depends on the answers to these questions. For example, if a CCP is determined to be necessary, it is important to consider whether a subsequent operation will eliminate or significantly reduce the risk of contamination. If so, this calls for a CCP followed by a CCP with subsequent CCPs affecting the associated hazards. If not, the following question, “Will the operation delay development of the contaminant or toxic by-products?” is a consideration of whether the increase can be significantly delayed. If so, this calls for a CCP (or a lower-case d could be used as a more descriptive replacement for the r). The ninth question, “Will the operation minimize contamination?” is an evaluation of whether the operation is such that contamination might not be prevented, but it could be significantly minimized if properly performed. If so, this calls for a CCP (or a lower-case m could be used as a more descriptive replacement for the r).

As these questions are answered, the decision as to whether an operation is a CCP depends on the answers to these questions. For example, if a CCP is determined to be necessary, it is important to consider whether a subsequent operation will eliminate or significantly reduce the risk of contamination. If so, this calls for a CCP followed by a CCP with subsequent CCPs affecting the associated hazards. If not, the following question, “Will the operation delay development of the contaminant or toxic by-products?” is a consideration of whether the increase can be significantly delayed. If so, this calls for a CCP (or a lower-case d could be used as a more descriptive replacement for the r). The ninth question, “Will the operation minimize contamination?” is an evaluation of whether the operation is such that contamination might not be prevented, but it could be significantly minimized if properly performed. If so, this calls for a CCP (or a lower-case m could be used as a more descriptive replacement for the r).

As these questions are answered, the decision as to whether an operation is a CCP depends on the answers to these questions. For example, if a CCP is determined to be necessary, it is important to consider whether a subsequent operation will eliminate or significantly reduce the risk of contamination. If so, this calls for a CCP followed by a CCP with subsequent CCPs affecting the associated hazards. If not, the following question, “Will the operation delay development of the contaminant or toxic by-products?” is a consideration of whether the increase can be significantly delayed. If so, this calls for a CCP (or a lower-case d could be used as a more descriptive replacement for the r). The ninth question, “Will the operation minimize contamination?” is an evaluation of whether the operation is such that contamination might not be prevented, but it could be significantly minimized if properly performed. If so, this calls for a CCP (or a lower-case m could be used as a more descriptive replacement for the r).
1. **Are there hazards (possibilities of contamination by microorganisms, toxic chemicals, physical substances; survival of pathogens or toxicants; or growth of pathogenic bacteria or molds) associated with the operation?**
   - **yes**
   - **no** - not high risk

2. **If these situations would progress to the final product, would the outcome result in illness?**
   - **yes**
   - **no** - not high risk

3. **Is there either an epidemiologic or challenge study basis for the hazard(s) that have been identified?**
   - **yes**
   - **no** - not a known high risk

4. **Has this hazard been frequently cited as a contributory factor leading to foodborne illness?**
   - **yes** - a high risk
   - **no** - not a high risk

5. **Would the illness be life threatening?**
   - **yes**
   - **no**

6. **Would the illness be severe and either result in hospitalization or last several days?**
   - **yes**
   - **no**

7. **Would the illness be moderate or mild and result in illness of 2 days or less?**
   - **yes**
   - **no** - not high risk

8. **Is a faulty operation (i.e., contamination, survival or growth) likely to occur?**
   - **yes** - high risk
   - **no** - not high risk

9. **Are subsequent operations likely to eliminate the hazard(s) or significantly reduce the probability of occurrence to low risk status?**
   - **yes** - high risk, but hazards are controlled either at this or subsequent operations
either at this or subsequent operations
calls for a CCPs at appropriate operations
   - **no** - high risk, this calls for a CCPs at appropriate operations

**FIGURE 2.** Decision tree for accessing risks of food processing or preparation operations.

Whether the operation is a CCP and the type of CCP is made and summarized by question 10, **"Will a subsequent operation eliminate, prevent, or significantly reduce the hazard(s)?"** The questions mandate a decision of whether control or preventive measures are to be applied at this operation or whether these measures ought to be applied at a subsequent operation. The action may be taken at this operation, taken at this and subsequent operations, in which case both operations will have an impact on the associated hazards (most likely to minimize, reduce, or delay them, but possibly to continue to prevent them), or taken at a subsequent operation. The last choice is usually applicable when the hazards are eliminated at a subsequent operation. The last question, **"Will the CCP be monitored and corrective actions taken?"** relates to implementation of the action at the selected CCP. It is a determination of whether the CCP actually functions as such according to two of the six criteria for a CCP stated above, but the question could be extended to the other questions as well.

Question 4 of this decision tree relates to severity and risk. Severity, which is considered in selection of CCPs, differs from risks. Severity is the degree of consequences of hazards or the magnitude of the outcome. Degrees of (disease) severity are life-threatening illnesses (e.g., botulism, cholera, typhoid fever), severe or chronic illnesses (e.g., salmonellosis, shigellosis, *Escherichia coli* enteritis), and moderate or mild illnesses (e.g., staphylococcal food poisoning, *Clostridium perfringens* enteritis, *Bacillus cereus*).
gastroenteritis). Severity categories are defined in the IAMFES HACCP manual (4), which has a basis in the hazard categories used for sampling plans developed by the ICMSF (9, 10). This basis is in contrast to that of the risk categories presented as an appendix of the NACMCF paper (14) and to those presented by Corlett and Pierson (7). The latter has a basis in a National Research Council committee report (6) with subsequent modification by the Food and Drug Administration.

Risk is the likelihood or probability of occurrence of a hazard. Hence, the terms “hazard” and “risk” need to be differentiated. There is a difference in the meaning of “risk” and “consequences.” The latter relates to severity of possible outcomes. Risk ought to be a consideration in regard to the probability of contamination, survival and/or growth that either has or may occur at specific operations rather than what happens after a combination of these events results in foodborne disease illnesses, deaths, and costs. Data on risk of operations have been documented (1-3, 8, 15, 17, 20), and this information has been taken into consideration in Table F of the IAMFES manual (4).

Probability of occurrence (risk) must be evaluated at the site of food production, distribution, processing, preparation, or other links in the food chain where the HACCP system is being applied, with an understanding of the epidemiologic significance of the hazards and the ecological, chemical, or physical nature of the etiologic agents under consideration. This evaluation involves what is observed, measured, or tested during hazard analyses or HACCP verification visits, but it also covers unobserved processes or practices that have the potential to contaminate foods, to allow the contaminants to survive, or to permit growth of pathogenic bacteria. References on this topic are cited in the IAMFES HACCP manual (4).

For guidance in making decisions about risks, a second decision tree is presented in Figure 2. This tree is also a series of questions seeking yes or no answers leading to decisions about the risks posed by identified or perceived hazards. It interrelates severity of a possible outcome with likelihood of occurrence (risk) of operational deficiencies that influence contamination, survival, and growth.

The first question of this second decision tree, “Are there hazards (possibilities of contamination by microorganisms, toxic chemicals, physical substances; survival of pathogens or toxicants; or growth of pathogenic bacteria or molds) associated with the operation?” confirms from the first decision tree that there are indeed hazards. If so, there is some degree of risk. This is followed by two questions relating to whether illness could result and the bases for the rationale that this could occur. They are: “If these situations would progress to the final product, would the outcome result in illness? Is there either an epidemiologic or challenge study? Has this operation been demonstrated to be a hazard?” If either one is so, the risk would be confirmed. The third is followed by a fourth question, “Has this hazard been frequently cited as a contributory factor leading to foodborne illness?” If so, the risk would be judged to be high. Next, a series of questions consider the severity of the hazard. The first, “Would the illness be life-threatening?” results in a designation of life-threatening severity. The second, “Would the illness be severe and result in either hospitalization or illness lasting several days?” calls for a severe-illness designation. Obviously, both are food-safety issues. Last, “Would the illness be moderate or mild and result in illness of 2 days or less?” If so, this illness is given a mild illness designation and is also considered a food-safety issue. If all three of the answers are no, the risk would be nonexistent or low. If any of the answers is yes, another question is asked: “Is a faulty operation (i.e., contamination, survival or growth) likely to occur?” This question brings the matter back to the consideration of the risks of hazards. If the answer is yes, there is a high risk. The last question, “Are subsequent operations likely to eliminate the hazard(s) or significantly reduce the probability of occurrence to low-risk status?” evaluates the placement of a CCP either at this or at a subsequent operation. If there are no subsequent operations at which the hazard(s) can be eliminated, prevented, minimized, or delayed, appropriate action is called for at this operation and, hence, it becomes a CCP or the hazard remains. If there is a subsequent operation at which control or preventive actions can be exercised, a decision must be made as to which operation is the most appropriate CCP.

These two decision trees and their descriptions and interpretations are presented for further guidance toward developing HACCP systems. These systems, when properly designed, implemented, and maintained, can provide high assurance of food safety for food production, distribution, storage, marketing, processing, and preparation.

REFERENCES

5. Codex Committee on Food Hygiene. 1993. Guidelines for the application of the hazard analysis critical control point (HACCP) system (at steps 5 and 8 of the procedure). Food and Agriculture Organization of the United Nations, Rome.