

Evolution and Current Trends in HACCP and Risk Assessment

EXTENDED ABSTRACT

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Abstract: International concerns over food safety have accelerated the evolution and implementation of HACCP and risk assessment. Risk assessment and HACCP are constituents of the overall risk analysis process. Risk analysis includes risk management and risk communication in addition to risk assessment.

Risk assessment is an integral constituent of the series of activities that starts with Good Manufacturing Practices and culminates in microbiological criteria used for the management of microbial hazards for food in international trade. Good Manufacturing Practices (GMP's) or Good Hygienic Practices (GHP's) address the possible contamination or adulteration of foods. These practices consider: (1). personnel; (2). plants and grounds; (3). sanitary operations; (4). sanitary facilities and controls; (5). equipment and utensils; (6). processes and controls; (7). warehousing and distribution. A valid program of risk assessment, HACCP, and microbiological criteria must rest on a comprehensive foundation of effective GMP's. The subsequent risk analysis process involves risk assessment, risk management, and risk communication.

Risk assessment is the first of several key steps in managing hazards for foods. Initially the parameters and scope of the problem must be defined. Risk assessment next addresses hazard identification, including not only identification of the hazard, but also assessment of its impact on human health, and the determination of when, where, and how it has an impact on human health. Hazard identification can use LD₅₀ or ID₅₀ concepts, laboratory or challenge studies, and epidemiological studies or observation of related products in similar environments. The potential hazards must be qualitatively characterized, quantitatively assessed, and generally evaluated for adverse effects on human health. Exposure to potential hazards must be evaluated qualitatively and quantitatively based on the extent of consumption or intake of the product, as well as the dose response anticipated with the potential hazard and the target consumer. Any and all characteristics of the product, raw material, food processes, product distribution, and route of consumption influence exposure.

Risk characterization takes place after defining the purpose for the activity, identifying the hazard, assessing the exposure, and predicting the dose response. Risk characterization integrates the sequential process to estimate the adverse effects likely to occur in the target population. The overall probability is determined from the product of dose response assessment X exposure assessment. The severity is factored into the risk characterization. Unfortunately, scientific data are

frequently unavailable for some of the situations, so uncertainty must be part of the equation. This is a dynamic characterization and any changes in the process would require a re-assessment of the risk.

Subsequent to risk assessment, appropriate risk management steps should result in safe handling procedures and practices, food processing quality and safety assurance controls, and food quality and safety standards and criteria. Risk management is a responsibility of government regulatory agencies, industry, and the consumer.

Scientists need to better communicate risk to the public. Risk communication is required to adequately address and respond to needs for criteria, hazards, risks, safety, and general concerns about food. Risk communication provides the public with results of expert scientific review of food hazard identification and assessment of risk to the general population or target group. It also provides the private and public sectors with information necessary to prevent, reduce, and minimize food risks through systems of quality and safety. It is essential that risk communication provides sufficient information for populations with greatest risk in terms of any particular hazard to exercise their own options to achieve protection.

Risk assessment is only one integral component in a series of steps leading to the management of microbiological hazards for foods in international trade. It

is imperative that key information about the food be available concerning the technologies and handling practices used from production to consumption. Initially, several risk evaluation steps are recommended: (A). identify any food safety problems; (B). establish a risk profile; (C). rank the hazard for risk assessment and management priority; (D). establish a risk assessment policy for conduct of risk assessment; (E). commission a risk assessment. Upon completion of the preliminary risk evaluation, risk assessment is conducted that provides the scientific basis for risk management and assessment and decisions.

The next step after risk assessment and food safety management involves establishing a food safety objective (FSO), i.e. a statement of the maximum level of a microbiological hazard in a food considered acceptable for consumer protection. The FSO is a risk management tool linking risk assessment and effective measures to control identified risks. The FSO should be achieved through the application of general principles of food hygiene and HACCP program. The FSO requires a performance criterion defined as the mandatory outcome of an action that assures that the FSO is met. The process criterion is subsequently established by defining the control parameters of actions that can be applied to achieve the performance criterion. It is imperative that adequate GMP's are in place and that a HACCP program be developed by industry to assure that the FSO has been achieved with the use of performance and process criteria. Finally, experts with experience in the food industry can establish microbiological criteria where appropriate. These criteria could be based upon established methods of certification, inspection, and/or microbiological testing.

The HACCP system is a well-established and tested program that was pioneered over 30 years ago and has become a principal food safety program around the world. It has been recognized by many governments and Codex Alimentarius. HACCP is best when applied to every step in the food chain from raw material production through processing to retail sale and consumption by the consumer. The seven principles of HACCP are: (1). conduct a hazard analysis and identify preventive measures; (2). identify critical control points; (3). establish critical limits; (4). establish CCP monitoring requirements; (5). establish corrective actions to be taken; (6). establish verification procedures; (7). establish record keeping procedures. Benefits of HACCP revolve around it being (a). a preventative system fully compatible with Total Quality Management and ISO 9000, (b). a systematic approach to increase assurance of safety in a cost effective fashion, (c). recommended by regulatory agencies, and (d). encouraged by food processors and suppliers.

The establishment of microbiological criteria should consider: (a). evidence of actual or potential hazards to health; (b). microbiology of the raw materials; (c). effects of processing; (d). likelihood and consequences of contamination and growth during handling, storage, and use; (e). category of consumers at risk; (f). the distribution system and potential for consumer abuse; (g). the reliability of the methods used to determine product safety; (h). cost/benefit ratio of the application; and (i). intended use of the food. Microbiological criteria are used to assure safety of food, adherence to GMP's, the keeping quality of certain perishable foods, and/or the suitability of a food or ingredient for a particular purpose. Microbiological criteria when appropriately applied, can be a useful means for ensuring safety and quality of foods, which in turn, elevates consumer confidence. It also can provide the food industry and regulatory agencies with guidelines for control of food processing systems. Internationally accepted criteria can advance free trade through standardization of food safety and quality requirements.

References

- Baird-Parker, T.C. & Tompkin, R.B. 2000. Risk and microbiological criteria. In: *The Microbiological Safety and Quality of Foods*, B.M. Lund, T.C. Baird-Parker, & G.W. Gould, eds. Aspen Pub., Gaithersburg, MD, USA. Pp. 1852-1885.
- Blanchfield, R.J. 1999. Good Manufacturing Practice: You cannot manage without it! *Food Science and Technology Today* 13 (1): 37-40.
- Bryan, F.L. 1999. HACCP approach to food safety: past, present and future. *Food Testing & Analysis* (Feb/Mar) 13-19.
- Buchanan, R.L. 1997. National Advisory Committee on Microbiological Criteria for Foods "Principles of Risk Assessment for Illnesses Caused by Foodborne Biological Agents. *J. Food Protection* 60, 1417-1419.
- Buchanan, R.L., & Whiting, R.C. 1998. Risk assessment: a means for linking HACCP plans and public health. *J. Food Protection* 61: 1531-1534.
- FAO-WHO 1996. Codex Alimentarius Commission. Report of the Twenty-Ninth Session of the Codex Committee on Food Hygiene. 21-25 October, Washington, D.C., USA
- FAO-WHO 1997. Codex Alimentarius ALINORM 97/13A Volume One B General Requirements (Food Hygiene) Supplement. Pre-Publication.

- Hathaway, S.C. 1997. Development of food safety risk assessment guidelines for food of animal origin in international trade. *J. Food Protection* 60, 1432-1438.
- Henry, C.J. 1997. Risk assessment, risk evaluation, and risk management. In: *Food Safety & Toxicity*, J. DeVries, ed., CRC Press.
- ICMSF. 1989. *Microorganisms in Foods. Book 4. HACCP in Microbiological Safety and Quality*. Blackwell LTD., Oxford, England.
- ICMSF. 1996. *Microorganisms in Foods. Book 5. Characteristics of Microbial Pathogens (Microbiological Specifications of Food Pathogens)*. Blackie Academic and Professional, London.
- ICMSF. 1996. The International Commission on Microbiological Specifications for Foods: Update. *Food Control* 7, 99-101.
- ICMSF. 1997. Establishment of microbiological safety criteria for foods in international trade. *World Health Stat. Quart.* 50, 119-123.
- ICMSF. 1997. Managing microbiological food safety in a global market. . *Proceedings of the General Conference*, Annecy, France, 28 October-7 November
- ICMSF. 1998. *Microorganisms in Foods. Book 6. Microbial Ecology of Food Commodities*. Blackie Academic & Professional, London.
- ICMSF [van Schothorst, M.] 1998. Principles for the establishment of microbiological food safety objectives and related control measures. *Food Control* 9: 379-384.
- IFT 1998. Guiding principles for optimum food safety oversight and regulation in the United States. *Food Technology* 52 (5), 30, 50, 52.
- Jouve, J-L. 2000. Good Manufacturing Practice, HACCP, and Quality Systems. In: *The Microbiological Safety and Quality of Foods*, B.M.Lund, T.C.Baird-Parker, & G.W.Gould, eds. Aspen Pub., Gaithersburg, MD, USA. Pp.1627-1655.
- Lammering, A.M. 1997. An overview of microbial food safety risk assessment. *J. Food Protection* 60, 1420-1425.
- McCone, J.T. E. 1996. Overview of the risk analysis approach and terminology: the merging of science, judgment, and values. *Food Control* 7, 69-76.
- National Academy of Sciences, USA. 1983. *Elements of risk assessment and risk management*. National Academy Press, Washington, D.C. USA
- National Advisory Committee on Microbiological Criteria for Foods. 1998. *Hazard Analysis and Critical Control Point Principles and Application Guidelines*. *J. Food Protection* 61: 762-775.
- Newslow, D. 1997. HACCP/ISO 9000: commonalities and distinctions. *Dairy, Food, and Environ. Sanitation* 17 (3), 156-161.
- Notermans, S., Hoornstra, E., Northolt, M.D., & Hofstra, H. 1999. How risk analysis can improve HACCP. *Food Science and Technology Today* 13 (1): 49-54.
- Risk Assessment Series. 1998. *J. Food Protection* 61 (11): 1535-1540; 1541-1549; 1550-1559; 1560-1566; 1567-1570; 1571-1578; 1579-1582.
- Silliker, J.H. 1998. Sampling criteria: yardsticks of measurement. *Food Quality* June/July: 26-32.
- Smith, M. 1997. Basic requirements of risk evaluation and standard setting. In: *Food Safety and Toxicity*, J. DeVries, ed., CRC Press, Boca Raton.
- Vanne, L., Karwoski, M., Karppinen, S. & Sjöberg, A. 1996. HACCP-based food quality control and rapid detection methods for microorganisms. *Food Control* 7 (6), 263-276.
- VanSchothorst, M. 1997. Practical approaches to risk assessment. *J. Food Protection*. 60, 1439-1443.
- Vose, D. 1997. The application of quantitative risk analysis to microbial food safety. *J. Food Protection* 60, 1416.