#### *WORLD HEALTH ORGANIZATION*

# **HAZARD ANALYSIS CRITICAL CONTROL POINT EVALUATIONS**

**A** guide to identifying hazards and assessing risks associated with food preparation and storage

# **CORRIGENDA**

Page 32, *Examples*, line 3:

Delete...  $( > 74 °C (165 °F))$ *Insert...*  $($  > 70 °C (158 °F))

Pages 60-63:

Under column heading Control actions, the hot holding temperature of Rice, lentils, beans, pulses, chickpeas; Potatoes; Vegetables; Chicken, meat dishes; Egg dishes; and Fish dishes should read  $\geq 60$  °C in each case.

Page 65:

Under column heading Monitoring procedures, the heating temperature of *Khoa*-based confectionery should read  $> 70$  °C.

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# HAZARD ANALYSIS CRITICAL CONTROL POINT EVALUATIONS

A guide to identifying hazards and assessing risks associated with food preparation and storage

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World Health Organization Geneva 1992

WHO Library Cataloguing in Publication Data Bryan, Frank L.

Hazard analysis critical control point evaluations: a guide to identifying hazards and assessing risks associated with food preparation and storage / Frank L. Bryan.

1. Food handling - standards 2. Food contamination - prevention & control **3.** Food microbiology I. Title

ISBN 92 **4 154433 3** (NLM Classification: WA 695)

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Typeset in India Printed in England 91/8764-Macmillan/Clays-5000

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Foodborne diseases cause considerable morbidity and mortality throughout the world, even though the principles for controlling most of these diseases are well established. Traditional approaches may therefore be considered to have failed to deal with the problem.

A relatively new approach to the prevention and control of foodborne diseases is the hazard analysis critical control point (HACCP) system. This system seeks to identify the hazards associated with any stage of food production, processing, or preparation, assess the related risks, and determine the operations where control procedures will be effective. Thus, control procedures are directed at specific operations that are crucial in ensuring the safety of foods.

This publication is intended for use by public health personnel who have been trained in food microbiology and technology and who are concerned with food safety and the prevention of foodborne disease. Drawing on principles used by a number of food-processing companies, it provides guidance on the assessment of risks that occur during the processing, preparation and storage of foods in homes, schools, food service establishments, cottage industries, and street markets. Emphasis is placed on assessing hazards and risks and identifying critical control points, rather than on control criteria and monitoring. This has been done because many of the places where HACCP evaluations will be made (e.g., homes, cottage industries and street stalls) do not readily lend themselves to sophisticated monitoring. Follow up of the hazard analyses should therefore focus on educating the people who prepare and store the foods.

This guide will assist in the planning of food safety and health education activities that focus on the hazards and technologies associated with the types of food commonly eaten and on foods that are processed and prepared by local inhabitants. Use of this approach should result in the best possible health protection at the lowest cost.

Many of the ideas presented here have been developed as a result of discussions with colleagues from the International Commission on Microbiological Specifications for Foods (ICMSF). The procedures for collecting clinical specimens and water samples have been taken from publications by the International Association of Milk, Food and Environmental Sanitarians (IAMFES)." The author is grateful to ICMSF and IAMFES for stimulation in this endeavour.

<sup>&</sup>quot; Bryan, F.L. et al. *Procedures to investigate foodborne illness,* 4th ed. Ames, IA, International Association of Milk, Food and Environmental Sanitarians, 1987.

Thanks are also expressed to the following people, who reviewed early drafts of this guide:

Professor M. Abdussalam, formerly World Health Organization, Geneva; Dr R.H. Charles, Senior Medical Officer, Food and Hygiene, Department of Health, London, England; Dr L. Cox, Quality Assurance Department, Nestec, Vevey, Switzerland; Dr S. Michanie, Food Protection, Pan American Zoonoses Center, Buenos Aires, Argentina; Dr B.A. Munce, Microbiologist/Food Technologist, Qantas Airways Ltd, Qantas Jet Base, Mascot, New South Wales, Australia; Dr F. Quevedo, Head, Food Protection, Pan American Health Organization, Washington, DC, USA; Dr P. Teufel, Institute of Veterinary Medicine, Berlin, Germany; Dr M. van Schothorst, Head, Quality Assurance Department, Nestec, Vevey, Switzerland; Dr J.I. Waddington, WHO Regional Office for Europe, Copenhagen, Denmark.

Particular thanks are due to Dr T.A. Roberts, Head, Microbiology Department, AFRC Institute of Food Research, Reading, England, for detailed technical review.

From the earliest religious edicts concerning food, innumerable ordinances, codes of practice, and laws concerning processing, handling and sale of foods have been promulgated by local, national and international bodies with the intention of protecting the public from adulterated food, fraud and foodborne illness. Several approaches have been used to implement these laws and to reduce the risks of foodborne diseases. These approaches can be classified into six categories (Bryan, 1986):

- surveillance of foodborne diseases:
- $\bullet$  surveillance of foods;
- surveillance and training of people who handle foods;
- $\bullet$  surveillance of facilities and equipment used for production or preparation of food;
- **u** surveillance of food operations;
- education of the public.

Each of these approaches has its merits and its limitations. The degree of usefulness varies with time, place, and type of food operation (production, processing, preparation, storage, distribution, etc.).

Surveillance of foodborne diseases is essential to any rational control programme. Preventive and control measures must be based on the problems commonly found in the community, region or country. Surveillance data can indicate the prevalent foodborne diseases, common causative agents, places where mishandling occurs, and factors that contribute to outbreaks. In many developing countries, there are no such surveillance activities, and the information available may be scanty and unreliable. In that case, reliance must be put on data collected elsewhere for similar foods.

Surveillance of foods employs organoleptic evaluations, measurements of physical properties, chemical analyses, and microbiological testing. Microbiological testing, as a means of assessing whether a product is hazardous, is a relatively recent innovation (ICMSF, 1986a). It has been successfully used to evaluate the quality of drinking-water, but there are few examples of its successful application to food control. The primary limitations of this approach are:

- (a) the difficulty of collecting and examining enough samples to obtain meaningful information;
- (b) the time required to obtain results (usually several days); and
- (c) the high cost.

**A** number of approaches have been used by health and food regulatory agencies to detect infected food workers and to prevent them from

contaminating food. These have been based on medical history, physical examination, blood analysis, X-rays, and examination of faeces for parasites, shigellae, *Salmonella* typhi and other salmonellae. There are significant limitations to each of these examinations (WHO, 1989). People diagnosed as free from infection on the day of an examination may be in the incubatory phase of a disease, or may have mild, abortive, or atypical illness. Furthermore, infections may be acquired and terminated between examinations, which can never be scheduled at a frequency sufficient to prevent the spread of pathogens. Except for epidemiological purposes, such tests are unacceptably costly. Many microorganisms that are transmitted by foods are seldom, if ever, sought during routine examination of specimens from food handlers. Other conditions (e.g., tuberculosis and venereal diseases) that may be sought during examinations are not, in fact, transmitted by food.

An alternative to clinical examination of food handlers or the testing of specimens from them is training in safe food-handling practices. Understanding of such practices would give a far greater assurance of food safety than clinical examination. Managers of food-handling establishments have the primary responsibility for preventing conditions that can lead to outbreaks of foodborne disease stemming from their establishments. They have daily supervisory control of operations, whereas public health personnel may inspect each establishment only infrequently, and spend a relatively short period of time at each visit. Because of their policy-setting and supervisory responsibilities, managers can effect improvements in their establishments. They must, therefore, be aware of the kinds of operations that can lead to outbreaks of foodborne disease and insist that appropriate preventive measures be taken and monitored routinely. Food handlers must also be aware of hazards associated with faulty food-handling practices. They should understand the principles of food safety and the importance of specific food-handling practices associated with their job. Food hygiene professionals and specialists in food safety need to understand the epidemiology of foodborne diseases and the microbial ecology of foods and foodprocessing operations, so that measures to prevent diseases and spoilage can be devised or selected and given appropriate emphasis.

History has taught us that certain facilities  $-$  potable running water, adequate plumbing systems, toilet and hand-washing facilities, and functioning sewage disposal systems  $-$  are essential for preventing contamination and promoting personal hygiene in food-handling establishments. In many such establishments in developing countries, there is a need to improve the physical facilities; however, it is even more important to ensure the safety of food processing, preparation and storage operations, many of which can lead to proliferation of microorganisms, e.g., if food is prepared several hours before serving, or kept at room temperature.

Inspections for food safety should focus on the processes that the foods undergo, with particular attention to *(a)* possible sources of contamination to which foods are exposed, (b) modes of contamination, *(c)* effects of the process on the level of contamination, (d) probability of microorganisms surviving processing, and *(e)* chances that bacteria or moulds will multiply during processing or storage. Hence, food safety rests on controlling food operations from receipt of ingredients until the processed or prepared foods are distributed, sold, or eaten. Surveillance should emphasize operations rather than physical facilities.

Education of the public is essential to food safety. Teachers and students who are preparing to teach must be given information about food safety which they can introduce into their lessons at school. For immediate impact, however, adults must also be informed of hazardous practices associated with preparation and storage of the common foods in the area and appropriate measures to counter the hazards.

and appropriate measures to counter the hazards.<br>This guide describes a system for ensuring food safety — the hazard<br>analysis critical control point  $(H\Delta CCD)$  system which combines This guide describes a system for ensuring food safety — the hazard<br>analysis critical control point (HACCP) system — which combines<br>several of these approaches (in particular, survaillance of diseases, food several of these approaches (in particular, surveillance of diseases, foods, and operations, and education) into an action-oriented programme to identify and reduce the foodborne disease problem. It concentrates mainly on the hazard analysis portion, since monitoring is often impracticable in the places for which this guide is intended (homes, street markets, etc.).

The hazard analysis critical control point (HACCP) concept is a systematic approach to the identification, assessment and control of hazards. The system offers a rational approach to the control of microbiological hazards in foods, avoids the many weaknesses inherent in the inspectional approach and circumvents the shortcomings of reliance on microbiological testing. By focusing attention on the factors that directly affect the microbiological safety of a food, it eliminates wasteful use of resources on extraneous considerations, while ensuring that the desired levels of safety and quality are met and maintained.

#### **Components of the system and definitions of terms**

The HACCP system (Fig. 1) comprises the following sequential steps:

1. Identification of hazards and assesssment of the severity of these *hazards and their risks (hazard analysis), associated with growth, harvesting, processing, manufacture, distribution, marketing, preparation andlor use of a raw material or food product.* 



Fig. 1. Components of the HACCP system.

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- **Hazard** means the unacceptable contamination, growth or survival in food of microorganisms that may affect food safety or lead to spoilage, and/or the unacceptable production or persistence in foods of products of microbial metabolism, e.g., toxins and enzymes.
- <sup>m</sup>**Severity** is the magnitude of the hazard, or the seriousness of the possible consequences.
- **m Risk** is an estimate of the probability of a hazard occurring.

**Hazard analysis** consists of an evaluation of all procedures concerned with the production, distribution and use of raw materials and food products to: (1) identify potentially hazardous raw materials and foods that may contain poisonous substances, pathogens, or large numbers of food spoilage microorganisms, and/or that can support microbial growth; (2) identify the potential sources and specific points of contamination; (3) determine the probability that microorganisms will survive or multiply during production, processing, distribution, storage and preparation for consumption; and (4) assess the risks and severity of the hazards identified.

- 2. *Determination of critical control points (CCPs) at which the identijied hazards can be controlled.* 
	- **m A CCP** is an operation (practice, procedure, location or process) at which control can be exercised over one or more factors to eliminate, prevent or minimize a hazard.

In some food processes, control of a single operation (CCP) can completely eliminate one or more microbial hazards, e.g., in pasteurization. It is also possible to identify control points at which a hazard can be minimized but not completely eliminated. Both types of CCP are important and must be controlled.

- 3. *Specijication of criteria that indicate whether an operation is under control at a particular critical control point.* 
	- **m Criteria** are limits of characteristics of a physical (e.g., time or temperature), chemical (e.g., concentration of salt or acetic acid), biological or sensorial nature.

It is important to select appropriate means to check that the hazard has been controlled at the CCP. Factors to be monitored may include: time and temperature for thermally processed foods; water activity  $(a<sub>w</sub>)$  of certain foods; pH of fermented foods; chlorine level in can cooling water; humidity in storage areas for dry products; temperature during distribution of chilled foods; depth of product in trays to be chilled; instructions on labels of finished products describing recommended procedures for preparation and use by the consumer. All criteria selected should be documented or specified clearly and unambiguously, with tolerances where appropriate. Choice of control criteria will depend on usefulness, cost, and feasibility but they must provide high assurance of control.

- *4. Establishment and implementation of procedures to monitor each critical control point to check that it is under control.* 
	- **Monitoring** involves the systematic observation, measurement and/or recording of the significant factors for control of the hazard. The monitoring procedures chosen must enable action to be taken to rectify an out-of-control situation, either before or during an operation.

The monitoring must detect any deviation from the specification (loss of control) in time for corrective action to be taken before the product is sold or distributed. Five main types of monitoring are employed: observation, sensory evaluation, measurement of physical properties, chemical testing and microbiological examination.

- *5. Implementation of appropriate corrective action when monitoring indicates that criteria specified for safety and quality at a particular critical control point are not met.*
- *6. Verification, i.e. the use of supplementary information and tests to ensure that the HACCP system is functioning as planned.*

Verification may be done by either quality control staff or health or regulatory agency personnel. It includes a review of the HACCP plan to determine whether all hazards have been detected, all critical control points identified, criteria are appropriate, and monitoring procedures are effective in evaluating operations. Records are reviewed and supplementary tests done to evaluate the effectiveness of the monitoring.

The HACCP approach can be applied to food safety in homes as well as in food processing and food service establishments (WHO/ICMSF, **1982).** A Joint FAO/WHO Expert Committee on Food Safety recommended that studies using the HACCP approach be carried out in homes in developing countries, so that more information about the causes of food-associated hazards and preventive measures could be obtained (FAO/WHO, **1984).** Such information could be used to focus health education and food safety programme activities on the factors of greatest importance in causing foodborne illness.

Unlike most traditional food-inspection activities, the HACCP approach is based on an understanding of the factors that contribute to outbreaks of foodborne disease and on applied research on the ecology, multiplication, and inactivation of foodborne pathogens. Even where data are not available, a hazard analysis can detect potential problems and identify the critical control points of an operation. Thus, food safety agencies can target their resources on the greatest public health risks in an establishment, rather than on general sanitation and superficial improvements. Although the initial hazard analysis will take longer than an inspection, valuable information about the food process will be obtained. Follow-up inspections to verify that the operators are monitoring the critical control points take less time. The benefits derived from greater assurance of food safety should offset the time spent on the initial hazard analysis and verification. Additional benefits will ensue from inspections of potentially hazardous operations to determine whether they are being monitored effectively, rather than from random inspections, when only a few high-risk operations may be in progress.

Experience has shown that the HACCP system provides a greater assurance of food safety than other approaches, such as traditional quality control by testing the end product. Furthermore, monitoring of critical control points is less costly and more effective than analysis of samples and inspection of processing plants.

In attempting to identify potential hazards, it is necessary to consider three areas:

- **a** the raw materials used,
- **a** processing procedures,
- the manner in which the product is used.

# **Food processing operations**

In any particular processing plant, the hazards will depend upon:

- the source of ingredients,
- the formulation.
- the processing equipment.
- **a** the duration of the process and storage, and
- the experience and/or attitudes of the personnel.

Hazard analyses should be carried out on all existing products and processing lines, and on any new products that a processor intends to manufacture. Changes in the source of raw materials, product formulation, processing procedures, packaging, distribution, or use of a product indicate the need for re-evaluation, because any of these changes might adversely affect safety or shelf-life.

The HACCP approach can be applied to foods processed in cottage industries as well as to those processed in complex, technically advanced manufacturing plants. In the former, it may be necessary to use simple monitoring procedures, but they must be sufficiently accurate and reproducible to provide unambiguous and quantifiable results.

# **Food service operations**

A wide variety of foods are prepared in food service establishments. The main food service systems can be classified as cook/serve, cook/hold hot, cook/chill, cook/freeze or assemble/serve. The HACCP system is applicable to food prepared by any of these systems. Critical control points are similar in any one system, but more than one system may be in operation in an establishment.

Raw foods of animal origin, freshly caught fish, shellfish, raw products of vegetable origin, cereals, fruits, dairy products, ices, juices and iced drinks are sold on streets and in markets in many countries. Some of these foods are cooked on the street, or are processed, prepared and cooked in cottage industries, food service establishments or homes long before they are sold or eaten. Risks will vary depending on:

- the food source:
- **a** the methods used to freshen, preserve, process and prepare the foods;
- **a** the duration and conditions of holding and display; and
- the interval between heating and consumption.

The HACCP approach can be used to identify hazards and evaluate risks associated with the preparation and holding of foods sold on the street (Bryan et al., 1988). Preventive measures can then be applied at the most hazardous stages of preparation, storage or display and wherever control is feasible.

#### **Homes**

One might expect considerable variation in food preparation practices in individual homes, but the types of food, fuel and energy sources, cooking facilities, economic resources and cultural influences often result in considerable uniformity within subgroups of a society. Therefore, the **HACCP** approach can be used to obtain information about hazards associated with preparation and storage of foods in homes, to assess risks, and to identify critical control points. The data generated from such analyses can be used in health education courses and campaigns, and in school curricula to disseminate information on foods and practices that entail a high risk.

#### **Other**

The **HACCP** approach can also be applied to the production and harvesting of crops, raising of livestock and poultry, fishing, harvesting of shellfish and the transportation, storage and marketing of foods (ICMSF, 1988).

Data accumulated during hazard analyses and experience in monitoring critical control points can be used to train professional staff and food workers and to educate the public. Training and educational programmes must become an integral part of food safety activities and should be given high priority.

It is not practicable to try to conduct a hazard analysis in every home and every commercial food establishment. Priorities must be established depending on the incidence of disease, recognized food-associated problems, the qualifications of quality control personnel in industry and of food safety officers in regulatory agencies, and the targets and goals of the food safety agency. The selection of places to perform the analyses should be based on a classification of the population or establishments (e.g. by region, ethnic and/or socioeconomic group, presence of infants or young children in the family, type of food service establishment, class of food). Whenever possible, epidemiological data should be used in making the selection.

The selection of places to be studied can be based on four factors (Bryan, 1982): food property, food operation, volume of food prepared (measured as average daily patronage), and susceptibility of consumer.

The "food property" factor primarily concerns the epidemiological history of foods prepared and served in an establishment and is determined from local, national or international data. It takes into account the characteristics of the food (e.g. pH, water activity) and gauges its potential for supporting rapid growth of infectious or toxigenic microorganisms.

The "food operations" factor assesses the procedures that the foods usually undergo that expose them to contamination, that might fail to destroy contaminants, or during which the contamination increases, e.g., improper holding of foods. It takes into account the cultural patterns of food preparation, equipment and facilities available, and the food service system used.

The "volume of food prepared" or average daily patronage is another risk factor. Often, when the same dish is served to many people, a large amount of the food is prepared hours, or even days, in advance to ensure quick service. If, during the interval between preparation and serving, these foods are not held under conditions that prevent bacterial growth, a hazard is created. The risks increase with the time of holding.

The susceptibility of the consumer is another risk factor. People who are more susceptible to disease than the general population (e.g. hospital patients, infants or the elderly) are examples of high-risk populations.

If hazard analyses are to be performed in homes, to gather information and focus attention for education of the public, they should be conducted

in the regions with the highest incidence of diarrhoea1 disease. Families with children being treated for diarrhoea should be studied first. In areas with high infant mortality, households with children of weaning age should also be selected for analysis. Matched control families, with no recent history of diarrhoea, may also be investigated. Alternatively, households may be selected where there has been a recent episode of typhoid fever, non-typhi salmonellosis, hepatitis A, cholera, or other foodborne disease. If outbreaks of foodborne disease or reported cases of illness are attributed to food processed in homes or cottage industries, hazard analyses should also be performed in those places if feasible.

In selecting commercial establishments in which to conduct HACCP analyses, priority should be given to: those associated with outbreaks of foodborne disease; those that prepare foods known to be common vehicles of etiological agents of foodborne disease; and places where hazardous foods are prepared in advance of serving, where they are likely to be stored in a way that allows microbial growth, and where reheating may not be sufficient to inactivate the pathogens or toxins. Where diarrhoea is common among visitors to the area, programmes should include places frequented by tourists.

Where there is no national or local surveillance of foodborne disease, epidemiological or research data from other countries where the same foods are prepared in a similar way may indicate probable vehicles of foodborne pathogens or toxins. For example, Chinese-style boiled and fried rice dishes prepared in restaurants in Australia, Europe, Japan, and the United States of America have been reported to be vehicles of Bacillus cereus; such dishes prepared in restaurants and homes in other countries may thus be expected to pose similar risks. Processed food that has been identified as a health hazard, e.g. one that has been frequently rejected by importing countries or that is highly likely by its nature to cause disease, is also a logical candidate for a HACCP investigation.

# ANALYSING HAZARDS AND ASSESSING THEIR SEVERITY AND RISKS

A hazard may be an unacceptable level of foodborne disease-causing agents or of products of microbial metabolism. An "unacceptable" level may be only one cell of salmonella or shigella or 100 000 or more Bacilllus cereus or Clostridium perfringens per ml or gram. A hazard can also mean contamination of food by organisms that cause spoilage, so that spoilage occurs within the expected shelf-life of the product. Hazards also relate to survival of undesirable microorganisms or persistence of toxins after heating, and to multiplication of microorganisms when food is held: (a) at room temperature or warm outside temperature for several hours;  $(b)$  warm — but not hot — in ovens or other hot-holding devices; (c) in cold storage facilities, in large quantities or at an insufficiently low temperature. Hazards may also be caused by chemical substances that reach food inadvertently through various agricultural practices, or during food processing, preparation or storage. Hazards may also result from chemicals that are added to foods in excess of functional or culinary needs; that leach into highly acidic foods from containers, pipes or their toxic coatings; or that reach foods accidentally.

The first step in the HACCP system is hazard analysis. Technical expertise is required to assess hazards and their severity, and to predict risks. Incorrect predictions will not provide the security desired and will increase costs.

### **Review of epidemiological data**

Data on factors that are known to have contributed to outbreaks of foodborne disease, or practices or situations that have led to outbreaks can help to identify potential hazards. Contributory factors have been found to be remarkably similar in Australia (Davey, 1985), Canada (Todd, 1983), the United Kingdom (Roberts, 1982), and the United States of America (Bryan, 1978, 1988), and can be classified according to whether the outbreak was the result of contamination, microbial survival, or microbial growth. Listed below are the most common contributory factors in outbreaks of foodborne disease in the above-mentioned countries.

# Factors related to contamination

• Raw foods (e.g., raw meat and poultry) are often contaminated at source with salmonellae, Campylobacter jejuni, Clostridium perfringens, Yersinia enterocolitica, Listeria monocytogenes, or

Staphylococcus aureus. In some regions, raw fish are often contaminated with Vibrio parahaemolyticus and non-01 Vibrio cholerae. Rice and other grains often harbour Bacillus cereus, and herbs and spices may be contaminated with C. perfringens.

- $\bullet$  Infected persons (e.g. nasal carriers of S. *aureus*, persons in the incubation period of hepatitis **A,** persons infected with Norwalk agent, or carriers of Shigella) touched foods that were not subsequently adequately heat processed.
- Contaminants were spread by workers' hands, cleaning cloths, or equipment, from raw foods of animal origin to cooked foods or to foods that were not subjected to further heating (cross-contamination).
- Equipment (e.g. slicers, grinders, cutting boards, knives, storage vats, containers, pipelines) was not properly cleaned.
- Foods were obtained from unsafe sources (e.g. shellfish, raw milk, raw-egg products, home-canned low-acid foods, mushrooms).
- High-acid foods were stored in containers, or conveyed through pipelines, that contained toxic metals, such as antimony, copper, cadmium, lead, or zinc, causing leaching or migration of the toxic substance into the food.
- Contaminated food or ingredients were eaten raw or not sufficiently heat processed.
- Substances were added to foods in excess of culinary needs (e.g., monosodium glutamate) or processing needs (e.g., sodium nitrite).
- Poisonous substances, such as pesticides, reached foods as a result of carelessness, accidents, improper storage, or because they had been mistaken for food ingredients.
- Food became contaminated during storage, e.g. through exposure to leaking or overflowing sewage, or to sewage backflow.
- Contaminants penetrated cans or packages through seam defects or breaks.
- Food was contaminated by sewage during growth or production.

# Factors related to survival of microorganisms

- Food was cooked or heat-processed for an insufficient time or at an inadequate temperature.
- Previously cooked food was reheated for an insufficient time or at an inadequate temperature.
- Food was inadequately acidified.

# Factors related to microbial growth

- Cooked food was left at room temperature.
- Food was improperly cooled (e.g., stored in large pots or other large containers in a refrigerator).

- Hot food was stored at a temperature that permitted multiplication of bacteria.
- Food was prepared half a day or more before serving (and then stored improperly).
- **Fermentation (and thus acid formation) was inadequate or slow.**
- **o** Inadequate concentrations of curing salts were added or curing time was too short.
- Low- and intermediate-moisture foods had elevated water activity  $(a_w)$ , or there was condensation on these foods.
- The environment selectively permitted certain pathogens to multiply either by providing favourable conditions, e.g. vacuum packaging, or by inhibiting competitive microorganisms.

During hazard analysis of an operation, each phase should be evaluated to determine whether any of the above situations have occurred, are occurring, or are likely to occur.

# **Reviewing operations**

#### Preparation for analysis

Visit several establishments of the type in which hazard analyses are planned. Observe the situation and talk to the people in charge, such as the manager of a food establishment, shopkeeper, street vendor, or homemaker to obtain information about the type of foods usually prepared, the ways in which they are prepared, and when they are prepared. Explain the purpose of the study and its expected duration. Try to determine the degree of cooperation that can be expected and whether any special equipment will be needed. Choose the place where the analyses will be performed, make arrangements for the visit, and coordinate date and time of arrival. Emphasize that you are performing a scientific investigation, not an inspection, and that the data will not be used to condemn or embarrass anyone. Tell the people involved that their tolerance and cooperation will greatly assist the Ministry of Health (or other agencies involved in the study) to understand patterns of food preparation and processing within the country or cultural group, and that the results of the study will be used as a basis for a health education campaign. Ask them to prepare or process foods in their usual way, telling them that you will be watching, taking certain measurements, and possibly collecting samples.

#### Interviewing responsible persons

Ask the managers and the people who prepare foods about each step of the operation. Take as complete a history of the processing or preparation of the foods under investigation as possible. This history should include the sources of foods and ingredients, the people who

handled the items, the procedures and equipment used, all potential sources of contamination during handling, and the time and temperature conditions to which the foods were exposed. Talk to the people responsible for each operation. Obtain recipes or product formulae or composition, if possible. Note the sequence of operations, from arrival of the ingredients until their distribution, sale, or consumption; note all temperature settings and the duration of each step. At processing establishments, for example, the investigation may cover the conditions under which animals are held prior to slaughter, the slaughter itself, dehairing, defeathering, washing, eviscerating, heat-processing, cooling, freezing, drying, fermentation, acidification, smoking, packaging and storage. At food service operations and in homes, the investigations will probably study receipt of food, storage, preparation, cooking, handling after cooking, hot-holding, cooling, reheating, and serving of foods. Study also the operations in establishments where the ingredients were previously stored or processed, and the storage methods and preparation practices used after the products left those establishments. For more information see Bryan et al. (1987).

# Observing operations

During a hazard analysis, specific evaluations of products and operations are necessary. Concerns about products include formulation, processing, and conditions of intended distribution and use. Answers to the following questions should be obtained:

# *Regarding formulation or recipe*

- 1. What raw materials or ingredients are used?
- 2. Are microorganisms of concern likely to be present on or in these materials, and if so what are they?
- **3.** Do any of the ingredients have toxic properties or contain toxic substances?
- 4. If preservatives are used, are they at concentrations able to prevent the growth of microbes of concern?
- 5. Are any of the ingredients used in quantities too high or too low for culinary needs?
- 6. Will the pH of the product prevent microbial growth or inactivate particular pathogens?
- 7. Will the  $a_w$  of the product prevent microbial growth?

# *Regarding food processing and preparation*

- 1. Can a contaminant reach the product during preparation, processing, or storage?
- 2. Will microorganisms or toxic substances of concern be inactivated during cooking, reheating, or other processes?
- **3.** Could any microorganism or toxin of concern contaminate the food after it has been heated?

- 4. Could any microorganism of concern multiply during preparation or storage?
- 5. How does the package or container affect survival and/or growth of microorganisms?
- 6. What is the time taken for each step of processing, preparation, storage and display?

# Regarding the expected use of prepared foods

- 1. Is the food expected to be held hot, chilled, frozen or at ambient temperature after it leaves the plant or store?
- 2. Will the time-temperature exposure during reheating inactivate microorganisms and toxins of concern?
- 3. If the food is held after reheating, will it be held hot or at ambient temperature?
- 4. Will the food be handled or otherwise exposed to potential contamination?

Answers to these questions may indicate possible hazards and provide information on severity and risks. It may sometimes be necessary to inoculate a product with particular foodborne pathogens and to subject it to the conditions that exist during distribution, storage, use and handling, to determine whether those conditions permit multiplication of the microorganisms. The protocol and interpretation of the test results should be supervised by a food microbiologist. If appropriate, samples of foods should be collected and tested for microorganisms such as *S.* aureus, Escherichia coli, or salmonellae, to confirm observations or to detect problems that may have occurred during periods when observations were not made. Testing of samples can never take the place of observation, but results can provide supportive data and perhaps confirm hypotheses. Small numbers of microbes may not be detected, however, and the reliability of counts is limited if only a few samples are tested.

Evaluate the effectiveness of cleaning of utensils and equipment by:

- observing the cleaning procedures;
- measuring the temperature and/or concentration of detergent and disinfectant solutions, and the contact time;
- **•** examining the appearance of equipment after cleaning; and, under some circumstances,
- swabbing or taking contact samples from surfaces.

# Measuring temperature of food

Measure the temperature of foods with thermocouples or thermometers, to evaluate whether they will support microbial growth (see pp.  $31-34$ ). Use bayonet-type thermocouples long enough to reach the point in the internal regions of the food (often the geometric centre) at which temperature is to be measured. If practicable, insert most of the shaft of the probe into the product being examined.

If a bayonet-type thermometer is used, insert the tip of the thermometer beyond the geometric centre. Raise or lower the thermometer to locate the highest temperature of a food being cooled, or the lowest temperature of a food being heated.

To measure the temperature on the surface of a product press or attach a thermocouple with a button end on the surface, insert an open-ended thermocouple just under the surface, or point a reflecting potentiometer at the surface. Plug the thermocouple leads into a potentiometer and take readings at appropriate time intervals or record the data automatically. Measure time with a watch, or a chart moving at a known speed.

Measure the temperature of foods during or after certain operations (e.g., during or on completion of cooking or reheating, and during the period immediately following, when the temperature continues to rise). For food cooked in a retort or pressure cooker, evaluate the functioning of the retort, the pressure and time of processing, the venting procedure, the adequacy of the container seals, and whether the cooling is done hygienically.

Measure the temperatures and holding time of foods being held hot or cold, to determine whether they could permit multiplication of bacteria; if so, evaluate whether bacteria are likely to multiply rapidly or slowly. Note the rate at which foods cool during storage at room temperature and in refrigerators or other cooling devices. Estimate probable cooling rates and the potential for microbial growth from the dimensions of the containers and the depth of the food in them. See whether lids are used (they impede cooling but may prevent further contamination and transfer of moisture and odour), whether containers are stacked on top of or against each other (which impedes cooling), and the location of containers in refrigerators (which may affect cooling and likelihood of cross-contamination). (For further information, see Bryan, 1981; Bryan & Bartleson, 1985.)

If you suspect that any step in the processing or preparation of the food may have permitted survival or growth of microorganisms, collect samples of foods at appropriate stages and test for total numbers of aerobic mesophiles or for pathogens of concern (see pp. 19-23). Use caution in interpreting the results of the laboratory analysis as the counts follow a probability distribution and individual measurements may be distributed over a considerable range.

Clean and disinfect thermocouples and thermometers between each use. Heat-treat thermocouples by inserting the sensors into a pan of boiling

water, or dipping them into 95% ethanol (ethyl alcohol) and immediately flaming them. Repeat the flaming three times. Make sure that the flame is extinguished before the sensor is returned to the ethanol. If the ethanol in the container catches fire, immediately replace the lid on the container to cut off the supply of oxygen. Disinfect thermometers by inserting the bayonet or bulb into boiling water for a few seconds, or into a tube containing a 100 mg/l (100 ppm) solution of sodium hypochlorite for 30 seconds. In certain situations, it may be feasible to keep a pot of water boiling to disinfect thermometers and thermocouples.

# Measuring pH of food

Several types of electrode can be used to measure the pH of foods. Some electrodes are encased in bayonet shafts that can be inserted into food. Others commonly used for testing the pH of laboratory media have a flat end that can be placed on the surface of the food being tested. If a conventional laboratory probe made to test the pH of liquids is used, the food to be tested must either be in liquid form, or be ground, or blended with distilled water that has recently been boiled and cooled (pH 7). The electrode is attached to a pH meter which must be calibrated, as recommended by the manufacturer, with at least two standard buffers (usually pH 4.0, 7.0 or 10.0). Compensate for temperature before each series of tests. Clean the electrode and rinse three times with boiled distilled water or buffer of pH 7 between each measurement. **A** squirttype water bottle is useful for this purpose.

# Measuring water activity of food

To measure the water activity  $(a_{\infty})$  of a food, put a sample in a vapourtight holder; the holder should be large enough for a representative sample, but small enough to permit equilibration of the sample within a reasonable time. Since temperature influences  $a_w$ , the holder should be placed in a constant-temperature cabinet, in which the temperature does not fluctuate more than 0.3 "C. **A** fan within the cabinet will help maintain a uniform temperature. Temperature fluctuations in the sample will be minimized if the holder with attached sensor is kept in a polystyrene box. With some instruments, the holder assembly is kept in a water-bath or is automatically cooled or heated to maintain a constant temperature. (See Troller et al., 1984, for more information.)

Use a standard salt (e.g.,  $MgCl_2$ , NaCl, KCl, KNO<sub>3</sub>, K<sub>2</sub>SO<sub>4</sub>) or sulfuric acid solution to calibrate the hygrometer to specific  $a_w$  values, according to the manufacturer's instructions. The equilibrium relative humidity values for certain salts at 30 °C are: MgCl<sub>2</sub>, 32.44  $\pm$  0.14; NaCl, 75.09  $\pm$  0.11; KCl, 83.62  $\pm$  0.25; KNO<sub>3</sub>, 92.31  $\pm$  0.60; K<sub>2</sub>SO<sub>4</sub>, 97.00  $\pm$  0.40 (Greenspan, 1977). Select standard salts or  $H_2SO_4$  solutions with  $a_w$ values close to those of the samples to be tested. Calibrate the instrument

frequently to ensure a high degree of accuracy (e.g., whenever the drift exceeds 2-3%). This may require monthly recalibration.

Place the sample in a small plastic dish and put the dish in the holder with the sensor attached. Allow the sample to equilibrate; this may take from 20 minutes to 24 hours, depending on the size of the holder, the equipment used, and the type of sample. The water activity is determined from the digital readout, recorder plot or calibration curve. Whenever possible, test duplicate samples and take the average of the results. Equilibrium is usually considered to be achieved when two consecutive hourly readings differ by less than 0.01 units (for direct readout equipment), or when a plateau is reached (on recording equipment) (Troller et al., 1984).

# Collecting food samples

If laboratory facilities are available to support the study, take samples of foods at different stages during, before or after an operation, to determine the impact of all previous operations on contamination and survival and multiplication of microorganisms. Collect samples of food aseptically using sterile or disinfected utensils, and place them in sterile jars or sterile plastic bags.

The sample of food should be large enough for all the analyses to be performed; a sample of approximately 200 g or 200 m1 is usually enough. If only one test is to be done, a smaller portion may be sufficient. Check the amounts needed with the laboratory. In situations where it is impractical to collect the amount of food needed (e.g., from homes or street stalls), collect smaller portions and request the laboratory to adapt its procedures accordingly.

Before collecting the samples, record the temperature of the room, refrigerator, or hot-holding unit in which the food is stored. Then either *(a)* measure and record the temperature of the food remaining after the sample has been collected, or  $(b)$  if plastic bags are used to hold the samples, remove the excess air from the bag, wrap the filled bag around the sensing portion of the thermometer, and hold it in place until the temperature stabilizes.

Label all containers with a code that identifies the establishment, together with a sample number. If the sample is hot, immerse it in running water, or in a bowl of water or container of ice, until it is cold to the touch. Rapidly chill samples of perishable foods that are not frozen at the time of collection to below  $4.4^{\circ}$ C, and keep them below this temperature until they can be examined. Do not freeze food samples because certain foodborne bacteria (such as Gram-negative bacteria and vegetative forms of C. perfringens) die off rapidly during frozen storage. Pack samples with a refrigerant that will maintain the desired temperature during transit,

and transport them to the laboratory in an insulated container as quickly as possible.

Send to the laboratory a copy of a log with code number, date, time of sampling, type of sample, and type of test required, together with the sample. Keep a copy of the log.

The equipment needed for collecting, holding, and transporting samples includes the following (Bryan et al., 1987):

*Sterile sample containers:* disposable plastic bags (e.g. 'stomacher'-type); wide-mouth jars (capacity 150-1000 ml) with screw caps; bottles for water samples (bottles for chlorinated water should contain enough sodium thiosulfate to provide a concentration of 100 mg per m1 of sample); foil or heavy wrapping paper; metal cans with tight-fitting lids.

*Sterile and wrapped implements for sample collection:* spoons, scoops, tongue-depressor blades, butcher's knife, forceps, tongs, spatula, drill bits, metal tubes (1-2.5 cm in diameter, 30-70 cm in length), pipettes, scissors, swabs, sponges, Moore swabs (compact pads of gauze made from  $120 \times 15$  cm strips, tied in the centre with long, strong twine or wire).

*Sterilizing agents:* 95% ethanol, propane torch.

*Refrigerants:* commercial refrigerant in plastic bags; liquid in cans; rubber or heavy-duty plastic bags or bottles that can be filled with water and frozen; heavy-duty plastic bags for ice; canned ice.

*General equipment:* fine-point felt-tip marking pen; roll of adhesive or masking tape; cotton; electric drill (if frozen foods are to be sampled); matches; 0.1% peptone water or buffered distilled water (5 ml in screw-capped tubes); test-tube rack; insulated chest or polystyrene box; reporting forms.

*Clothing (optional):* laboratory coat, hat, disposable plastic gloves and boots.

# Collecting environmental samples and clinical specimens

Depending on the circumstances and the hazards, it may be useful to collect other types of samples and specimens. Collection of water samples, for instance, while not usually part of a HACCP evaluation, may be needed if the source of the water is subject to pollution, since water is an ingredient in many foods, and is used for washing hands, utensils and food containers, and in certain operations that may be critical control points.

In certain regions, water may be thought to be the main vehicle for enteric pathogens that cause diarrhoeal diseases, while, in reality, food may be a more important vehicle. Testing is required to confirm or refute the various hypotheses. A HACCP evaluation might also be done in conjunction with an environmental survey, to evaluate risks associated with the environment and with food. Instructions for collecting water samples are given in Annex 1.

The collection of specimens from people is not usually part of a hazard analysis. However, when the analysis is part of an investigation of a disease outbreak or a follow-up of people being treated for diarrhoeal disease, it may be appropriate to collect specimens in order to find additional cases, to trace sources of contamination, or to compare cases with matched controls. It may also be useful to collect appropriate specimens if the street vendor or people in the household, cottage industry, or food service establishment being investigated complain of, or are reported to have, symptoms of diarrhoeal disease, or if signs of other gastrointestinal disease are observed. In particular, wherever possible, faecal specimens should be obtained from infants with diarrhoea.

The equipment needed for collecting specimens includes: cartons with lids for stool specimens; bottles containing preservative solution for transport of specimens; protective canisters or cartons; sterile swabs; sterile sponges; rectal swab sets; sterile gauze pads,  $10 \times 10$  cm; and tubes of transport media. Procedures for collecting specimens are described in Annex 2.

# Testing samples for microorganisms

A description of the procedures for testing food samples is beyond the scope of this manual (see ICMSF, 1978; Speck, 1984). The tests to be performed will depend on what information is needed to support the hazard analysis, the type of food concerned, and the types of microorganisms expected in the samples or specimens.

Plate counts for samples of foods obtained immediately after cooking, and again after holding, provide information on the microbial growth occurring during the holding period. Information on microbial inactivation can be obtained from counts on raw materials, on samples taken immediately after cooking, and on samples of the cooked foods after storage, before and after reheating. When only a few samples are taken, considerable variation in counts may occur. Nevertheless, these tests have been found to be useful and can be performed in most laboratories.

E. coli, coliforms, faecal coliforms, and Enterobacteriaceae are useful indicators of contamination of heat-processed foods. Staphylococcus aureus can be used as an indicator that cooked food has been handled by

human beings, as well as an indicator of time-temperature abuse of food carrying a risk of foodborne disease. Salmonellae have been used as indicators of the inadequacy of heat processing (e.g., in egg pasteurization) or of contamination of heat-processed foods of animal origin.

Epidemiological information may indicate that certain foods should be tested for particular pathogens or indicator organisms (Table 1). For

Food	Appropriate tests
Acidified food	рH
Beans, pinto, red, black or navy Canned food (primarily home-	C. perfringens, B. cereus рH
canned)	
Cereals and food containing cornstarch	B. cereus
Cheese	S. aureus, Brucella spp, pathogenic E. coli, L. mono- cytogenes
Confectionery products	salmonellae, aw
Cream-filled baked goods, custards	S. aureus, salmonellae, B. cereus; pH, a <sub>w</sub>
Eggs and egg products Fish	salmonellae, β-haemolytic streptococci V. parahaemolyticus, V. cholerae
Fruits and vegetables, raw	parasites, Shigella spp, pathogenic E. coli, L. mono- cytogenes
Ham	S. aureus
Mayonnaise	pH (S. aureus, salmonellae if $pH > 4.5$ )
Meat, meat products, and foods	salmonellae, C. perfringens, S. aureus, C. jejuni, L. mono-
containing meat Meat, fermented	cytogenes, Y. enterocolitica, pathogenic E. coli
Meat, ground or shredded	S. aureus; pH, a <sub>w</sub> C. perfringens, B. cereus, Shigella spp, salmonellae,
	S. aureus
Milk, dried, and milk formula	salmonellae, S. aureus, B. cereus
Milk, raw	salmonellae, S. aureus, C. jejuni, L. monocytogenes, Y. enterocolitica, β-haemolytic streptococci
Potatoes and tubers	B. cereus (S. aureus if cooked items handled)
Poultry, poultry products, and	salmonellae, C. perfringens, S. aureus, C. jejuni,
foods containing poultry	L. monocytogenes, Y. enterocolitica
Rice Salads containing cooked and cut	B. cereus S. aureus
ingredients (e.g., ham, tuna, potato, egg)	
Salads of mixed vegetables, meat,	S. aureus, L. monocytogenes, salmonellae, $\beta$ -haemolytic
poultry or fish	streptococci, Shigella spp, pathogenic E. coli; pH
Shellfish	V. parahaemolyticus, V. cholerae, possibly other vibrios
Smoked or dried meat, poultry, fish products	salmonellae, S. aureus, L. monocytogenes, a <sub>w</sub>
Soft drinks, fruit juices and	Metals such as copper, zinc, cadmium, lead, antimony,
concentrates held in metallic	tin; pH
containers or vending machines	
Soups, stews, gumbos,	B. cereus, C. perfringens
chowders, gravies	
Vegetables, cooked	B. cereus

**Table 1. Tests that may be considered for specific foods** 

example, rice, cereal products, beans, milk and potato products could be tested for B. cereus, fish and shellfish for V. parahaemolyticus, cooked meat and poultry products, gravies, and beans for C. perfringens. If laboratory resources are limited, enrichment procedures may be used with both raw foods (to determine the source of contamination) and recently cooked foods (to determine whether microorganisms have survived cooking), and counts made on cooked foods that have been held for long periods after cooking (to determine whether microorganisms have multiplied).

Close collaboration between field and laboratory personnel is essential. The field investigator should tell the laboratory why the sample was collected and what tests are required. Information on the use of routine microbiological tests for foods and their limitations is given in Annex **3.**  The significance of specific microorganisms in foods is considered in the above-mentioned texts (ICMSF, 1978; Speck, 1984) and in the report of the Subcommittee on Microbiological Criteria for Foods (1985).

# **Analysis of specific operations**

#### **Homes**

When conducting a hazard analysis in a household, describe the characteristics of the family and the environment as well as any techniques used that could affect food safety. The information recorded should include the following:

- family name and address or location;
- number of persons living in the household, the number of children and their ages;
- occurrence of diarrhoea in the last month;
- number of rooms or bedrooms (this gives an indication of crowding and may relate to person-to-person spread of disease);
- types of foods usually eaten and those prepared on the day of the visit, including recipe and source of ingredients;
- types of foods fed to infants alone or in combination (e.g., breast milk, raw milk, pasteurized milk, dried milk, canned milk, milk formula, family foods, special foods);
- facilities for preparing, preserving and storing foods, including type of fuel and availability of a refrigerator;
- foods epidemiologically associated with illness, if applicable;
- source of water, method of treatment (if any), and method of storage;
- method of sewage disposal;
- season of year, and date.

**A** simple form, relevant to the local situation, should be devised to record appropriate aspects of this information. The information should be

considered in relation to possible sources and modes of contamination, and the likelihood that pathogens will survive cooking or processing and multiply during storage. The following factors are of particular importance.

- **•** Ingredients and recipe. Whenever possible, obtain the recipe for the food being investigated; at least, list the ingredients and relative proportions. Note the use of meat, poultry, fish, eggs, milk, and other foods of animal origin, spices, cereals and foods grown in soil or water. Ascertain whether pathogens are likely to be associated with these foods.
- **•** *Preparation and processing.* Determine each step of the preparation and processing. Consider any operation that has an effect on microorganisms, e.g., heat, acidification, drying, modification of atmosphere. Determine the type of equipment used and the fuel source. Observe actual or potential modes of contamination, including contamination from persons handling the foods and cross-contamination. Measure temperatures and times of each step of the procedure. Collect samples for measurement of pH and  $a_{\mathbf{w}}$ , for testing to determine the presence of microorganisms, or for time-temperature simulations or other studies, as applicable.
- **•** *Storage.* Measure the length of time that foods are stored and, if possible, the temperature of the foods during storage. Pay particular attention to any period during which they are within the temperature range that permits rapid microbial growth  $(21-49 \degree C,$  $70-\overline{1}20$  °F). Observe the type and size of container in which the foods are stored, whether they are covered, and where they are kept.

Annex 4 gives more detailed information on potential hazards and appropriate control action for a number of specific foods that might be prepared in homes.

# Food processing in cottage industries

The hazards associated with food processing operations in cottage industries will vary with the type of food and the process used; however, some general principles can be described.

- Certain ingredients, especially those of animal origin, are likely to contain pathogens; for example, raw meat, poultry, and fish frequently harbour a variety of enteric pathogens; spices, sugar, and starch may contain bacterial spores; water may be contaminated by enteric pathogens or microorganisms that cause spoilage; mycotoxins may form in cereals and nuts. If the process does not inactivate the microorganisms or toxic substances, the ingredients become of considerable concern, particularly for people who are more susceptible than healthy adults, such as infants, the elderly, and those who are sick or malnourished.
- **Processes that fail can create hazards. For example, pasteurization,**

retorting, and sometimes preheating are intended to kill particular groups of microorganisms, but inadequate heating times or too-low temperatures can permit their survival. Certain chemicals (e.g., salt, nitrites, acids) inhibit microbial growth, but if concentrations are too low or the mixture is not properly blended, the process can fail. During fermentation, the fermenting flora inhibit growth of undesirable microbes, and their metabolic products kill pathogens. If fermentation is delayed, however, microbial growth may occur, with the formation of toxins which will survive subsequent fermentation. Slow or incomplete drying, or defective packaging of dried products, may also permit growth of microorganisms. Improper refrigeration or prolonged storage of perishable foods in refrigerators can result in either spoilage or growth of certain foodborne pathogens.

• Another concern to food processors is the possibility of mishandling of the product by food handlers or preparers of food in homes; when assessing product stability, the potential consequences of such abuse should be borne in mind. Factors to be considered include the extent of the heat process, the pH and water activity of the product, the presence of preservatives that inhibit growth of certain microbes or germination of bacterial spores, and temperature during distribution and storage. Any change in packaging should be evaluated for its effect on the growth of microbes that survive processing. Particular attention should be paid to products that can support the growth of foodborne pathogens. Information should be gathered about the ways in which the product is likely to be handled by the public. The processor may need to build additional safeguards into the process, place a warning on the label, or alert purchasers in other ways.

Annex 5 gives more detailed information on critical control points and monitoring procedures for a number of specific foods that might be processed in cottage industries.

#### Food service establishments, food stalls, and other retail outlets

In establishments where foods are prepared, displayed, served, or sold, the source of the foods, and the likelihood of their being contaminated on arrival at the establishment or during handling, should be evaluated. Recipes of formulated (composite) foods should be assessed for the types and amounts of ingredients that are likely to contain pathogens, as well as for other substances (e.g., acid, salt, sugar, garlic) that act as stabilizers. Cooking and reheating practices should be evaluated to determine whether they are sufficient to inactivate pathogens and denature any toxins. The conditions after heating should be assessed to determine whether spores that survive heat treatment are likely to germinate, whether the resulting vegetative cells will be able to multiply, and whether microorganisms that reach the food after heating will be

able to multiply. For this purpose, some or all of the following actions will be necessary at the various steps of the operation.

- **<sup>m</sup>***Receiving.* Assess incoming foods for appearance, quality, temperature, pH,  $a_w$ , and type of packaging. Note any damage to packaging and estimate the possible types and quantities of contaminants. Note the source of the food and, if possible, the processing history. It may be appropriate to obtain information on the manufacturer's quality assurance or HACCP programme.
- *Storage.* Appraise methods of storing raw, frozen, chilled and dry foods, to identify any situations that could permit contamination or promote microbial growth.
- **<sup>m</sup>***Handling of raw products.* Assess the handling of raw products, reconstitution of dehydrated foods, thawing of frozen foods, and preparation of foods to be served without subsequent heating, to identify operations during which contamination could occur.
- **•** Formulation. Review the formulation of foods and, if appropriate, measure pH and a...
- Cooking. Measure the highest temperature attained at the geometric centre of foods after cooking, or record the time-temperature exposure of foods during cooking, to determine whether pathogens of concern could survive the cooking.
- **Handling of cooked foods. Appraise the handling of cooked foods to** identify potential modes of contamination.
- **•** Hot holding of cooked foods. Measure the time for which foods are held hot and their temperature to determine whether pathogens could survive and multiply.
- **Holding of cooked foods at room temperature. Observe whether cooked** foods are kept at room temperature and, if so, measure the temperature and the duration to determine whether pathogenic bacteria could multiply or generate toxins.
- Cooling. Measure the depth of food being cooled, or the temperature of food at intervals during cooling, to determine whether pathogenic bacteria could multiply.
- **•** Reheating. Measure the highest temperature attained at the geometric centre of foods after reheating, or record the time-temperature exposure of foods during reheating to determine whether pathogens could survive reheating.
- **<sup>m</sup>***Cleaning of equipment and utensils.* Determine whether cleaning and disinfection procedures are adequate to remove pathogens from equipment and utensils or to inactivate them.
- Storage of final product. Determine the characteristics of prepared food  $(pH, a_w,$  and microbiological quality, as applicable) to assess the type of storage needed.
- **•** Personnel. Assess the knowledge of personnel regarding the safe handling of foods.

Annex 6 gives more detailed information on potential hazards and

appropriate control action for a number of specific food service operations.

# **Food-f low diagrams**

From the information obtained during the interviews and from observations, draw a food-flow diagram. (Use pencil so that changes can be made later, if necessary.) Draw a separate flow chart for every food that was investigated. Represent each operation by a rectangle and use arrows to indicate direction of flow. Notes or symbols can be used to indicate hazards, including: *(a)* the probable type of contamination, (b) the possibility of survival of microorganisms or toxic substances during heating or other potentially lethal processes, and (c) the possibility of multiplication of pathogenic bacteria or toxigenic moulds. Examples of symbols are given in Table 2. Indicate on the chart critical control points and, if space permits, criteria for control and parameters to be monitored. For each operation, note the temperature and duration of the process, the size of any containers used, the depth of food in the containers, and any other relevant information.

Examples of food-flow diagrams are given in Fig. 2-4. Potential sources of contamination and operations that might allow survival or multiplication of contaminants are illustrated by the symbols given in Table 2. Fig. 2 represents preparation of rice in households in a ricegrowing village. Rice may be associated with foodborne illness caused by B. cereus, the spores of which are frequently found in raw rice. Cooking does not control the problem because the spores survive. The critical control point is the holding of the cooked rice between preparation and serving; the time of holding should therefore be monitored. Significant







Fig. 2. Food-flow diagram for preparation of rice in village households

microbial growth can occur in rice that has been held at room or warm-outside temperatures for 4 hours or more. Covering the rice may increase the hazard by trapping moisture.

Fig. **3** represents the preparation of acidified shrimp paste. Acidification is the critical control point. The type and amount of acid ingredients and the pH should be monitored; this is obviously not practical in village households, so monitoring is done by taste to ensure that the product is sufficiently sour. (This method is not completely reliable but may be the only practical option.)

Fig. 4 shows the steps in the preparation of a milk-water-sugar formula for feeding an infant. The critical control points are the boiling of the water used to dilute the concentrated milk, the cleaning and disinfection of the bottle, and the holding of the opened container of milk and the prepared formula. Temperature is "measured" by observing the boiling of the water used in the formula and to disinfect the bottles. The holding


**Analysing hazards and assessing severity and risks** 



Fig. 4. Food-flow diagram for preparation of infant formula from milk, water and sugar.

of the formula is a critical control point, and the time of holding is monitored.

## **Analysing measurements**

Plot temperature measurements against time on graph paper. Compare the temperatures recorded with the optimum temperatures for growth and multiplication of microorganisms of concern (see Table 3). For example, in interpreting heating curves, note the highest temperature reached and the combined time-temperature exposure, to determine whether the pathogens of concern could have survived the heating process. In interpreting cooling curves, note the time during which the temperature of the food is within a range that permits multiplication of the bacteria of concern (see Table 3).

Compare the temperatures attained during heat processing, cooking, and reheating to certain reference temperatures (e.g.,  $74^{\circ}$ C), or timetemperature values (e.g., 55 °C (130 °F) for 2 hours, 60 °C (140 °F) for 12 minutes) that are lethal for the microorganisms of concern. Mathematical techniques are available for calculating the probability of survival or destruction of the microorganisms expected to be present in the food being investigated. For examples of the use of these techniques, see Genigeorgis & Riemann, 1979, and Stumbo, 1973.

Compare the temperature,  $pH$  and  $a_w$  values measured with the ranges within which pathogens multiply or are killed. Where relevant and practicable, compare any conclusions with the results of microbial analyses.



#### **Table 3. Limiting conditions for multiplication of some common foodborne pathogenic bacteria**

<sup>a</sup> Group  $l=$  proteolytic: group  $ll=$  saccharolytic ("non-proteolytic").

#### **Examples**

Fig. 5 shows the time-temperature curves for various foods prepared in a village household. It can be seen that the temperatures reached by the moist foods were high enough ( $>7\oplus$ °C ( $1\oplus$ Sx°F)) to kill vegetative  $\mathscr{C}_{\mathcal{L}}$ pathogenic bacteria. Subsequently, the leftovers were held for approximately 12 hours within a temperature range  $(21-49 \degree C)$  that permits germination of bacterial spores and rapid multiplication of pathogenic bacteria. During reheating, temperatures sufficient to inactivate vegetative forms of bacteria (but not to destroy heat-stable toxins) were attained in all foods except the left-over rice. The left-overs were then kept at ambient temperature until lunchtime and were eaten without reheating. Left-over food from lunch remained at ambient temperature until suppertime. In these conditions, bacterial growth might be expected to occur.

Fig. 6 shows the time-temperature curve for foods during preparation and holding in an urban household. High temperatures were reached during cooking, but the food was then held for several hours at room temperature, during which time spores could germinate and the emerging vegetative forms multiply. Only one food was subsequently reheated. Left-overs remained at room temperature (near the optimum for growth of B. *cereus,* which is likely to be found in rice) for up to 12 hours. (For further information on interpreting time-temperature curves, see Bryan et al., 1981; Bryan & Bartleson, 1985.)

Use graphs and tables such as those shown in discussions with managers and supervisors of operations to emphasize hazards and point out the locations of critical control points. Such material can also be used in training sessions for professional staff or managers of food operations, and in public education programmes.



Fig. 5. Time-temperature exposure of foods prepared in a village household.





## **Selecting critical control points**

A critical control point, as defined on page 5, is a point in an operation at which control can be exercised to eliminate, prevent or minimize a hazard. Not every hazard requires a specific control measure: sometimes a control measure taken at one critical control point reduces the need for control measures at preceding points in the chain (e.g., irradiation of packaged poultry). At other times, a combination of control measures must be used at successive critical control points. In other operations (e.g., processing of raw meat and raw poultry), the hazard of contamination with salmonellae cannot be eliminated except by irradiation and other critical control points at best only reduce the risk of contamination. If a hazard cannot be eliminated, or if a critical control point cannot be monitored, particular attention must be given to other critical control points, before or after the operation, that can be effectively controlled and monitored.

Selection of critical control points depends on:

- *(a)* the likely hazards, their estimated severity and risk in relation to what constitutes unacceptable contamination of food, or survival or growth of microorganisms;
- (b) the operations to which the product is subjected during processing and preparation; and
- (c) subsequent use of the product.

Because incoming foods may contain pathogens, their purchase and receipt may be considered to be critical control points. One or more steps in the preparation (e.g., cooking) may eliminate or greatly reduce the hazard. If this is not the case, the food should be obtained from a safe source (e.g., shellfish from certified or non-polluted waters) or tested for contamination (e.g., dried eggs should be tested for salmonellae).

Formulation may also be a critical control point, particularly if the ingredients affect the pH or  $a_w$  of the formulated food, or if they are likely to contain pathogens. Thorough mixing is essential to ensure uniform distribution of ingredients that lower pH or  $a_w$ .

Certain aspects of processing may be critical control points. For example, heat processing inactivates many pathogenic microorganisms and others that cause spoilage. Cooling may be a critical control point for heatprocessed foods and for cold-stored products. Drying in itself does not kill pathogens, but the low  $a_w$  of the finished product may inhibit growth of microorganisms. Acidification may be a critical control point if the

final pH is sufficiently low. In cured products, the concentration of salt and nitrites and the resulting  $a_w$  must be specified and monitored to ensure safety. Specific conditions of temperature and humidity select and promote multiplication of particular microorganisms during fermentation. Control of these conditions and/or the use of starter cultures, or cultures from a previous batch, are essential for the safe production of fermented products. The resulting pH should be monitored, as should the  $a_{\rm w}$  if the products are dried. In other products, such as mayonnaise, the nature and concentration of acid should be controlled and monitored.

The environment is sometimes considered to be a critical control point, particularly when potentially hazardous foods are dried, blended, and packaged. The source and treatment of water used as an ingredient, or for cooling or cleaning, may be critical to the safety of a product. The cleaning of equipment used in the processing of foods, particularly equipment used for heated foods or for ready-to-eat meat products, is a critical control point. The handling of foods can also be considered to be a critical control point; training and education of food-handling personnel are thus essential preventive measures. If foods are to be packaged, the atmosphere in the package and thus the type of packaging material may be critical control points.

In food service operations and in homes, cooking is often a critical control point, although bacterial spores may survive. It should be noted, however, that the beneficial effects of cooking may be nullified by contamination of the cooked food. Critical control points for cooked foods include: handling, hot-holding, cooling, and reheating (see examples in Fig. 2–4).

Critical control points will depend on the food being prepared, the equipment available, and the cultural habits of the preparer. Nevertheless, critical control points for a particular system are usually the same wherever used (see Table 4). Further specific critical control points for various operations are listed in Annexes 4-6.

## **Specifying criteria**

Once the critical control points have been identified, applicable control measures should be implemented. These measures must be practicable and economically feasible, and must ensure food safety. For each point, criteria must be specified that will ensure the safety of the product. Examples of criteria are: end-point temperatures attained after heat processing; time-temperature exposure adequate to inactivate microorganisms of concern; the pH or  $a_w$  of the final product; temperatures during cooling or hot-holding; the concentration of chlorine in water used to cool cans. Each criterion must be expressed in a clear and unambiguous statement, with specification of acceptable tolerances.



## **Table 4. Common critical control points in food service systems**

 $a$  Sometimes a critical control point.

 $37$ 

## **Monitoring critical control points**

Monitoring of critical control points is essential to ensure that the specified criteria are being met. Foods can be monitored in many ways depending on the type of control point and the instruments and equipment available.

Monitoring should aim to detect any deviation from the established criteria. It usually depends on observations, or physical or chemical measurements (e.g., temperature, pH, concentration of salt). Results should be obtainable immediately so that the process can be quickly adjusted if necessary. Microbiological tests are therefore of limited usefulness, since they may not be available for several days. Some of these procedures can be applied in food service establishments and cottage industries; monitoring may also be done in homes but, in that case, simpler approaches are often chosen.

If the receipt of raw materials constitutes a critical control point, the quality of these materials should be monitored; using a statistically sound sampling plan, to determine whether they are within acceptable microbiological limits (ICMSF, 1986b). Spices, sugar, and starches, for example, may need to be tested for numbers of thermophilic spores before use in certain operations (e.g., in low-acid canned foods), since such spores survive retorting and can germinate under conditions of hightemperature storage. However, monitoring of spices and sugars is not necessary when they are to be used in carbonated beverages, because the pH of the product will prevent the germination of any bacterial spores present. The small amounts of spices and sugars used in family meals do not greatly affect the quality or safety of the foods, so monitoring in the home is unnecessary (WHO/ICMSF, 1982). Nuts should be examined for signs of mould or aflatoxin, and fish for honeycomb decomposition; any affected products should be immediately rejected. Dried, frozen, or liquid eggs may need to be monitored for salmonellae before use in formulated foods.

When formulation of acidified products is a critical control point, monitoring may be by measurement of pH. For example, the safety of salads that contain mayonnaise should be monitored by checking that the pH is below 4.6. Such monitoring is feasible in a processing plant, but not in a home. If monitoring of pH is not practicable, or if the pH exceeds 4.6, product safety can be evaluated by monitoring the time that the food is kept before being eaten or, if a refrigerator is available, the temperature of the ingredients before formulation, the temperature of the finished product, and the rate of temperature reduction during cooling.

Heating processes may be monitored in a number of ways. In food processing plants, heat treatment of foods is often monitored with indicating and recording thermometers. Flow-diversion valves may be used to ensure that fluids that are not at a sufficiently high temperature are recycled. In canning operations, temperature, pressure, and duration of heating should be monitored to ensure that the temperature-time exposure is sufficient to inactivate the spores of pathogens of concern. If the cooking process in a food service establishment is designated as a critical control point, the internal temperature of cooked foods should be monitored when they are removed from the cooking device, and after the post-cooking temperature rise. If a microwave heating unit is used, temperatures should be monitored at or near the surface of the food, as well as inside the food, immediately after it has been removed from the unit.

In homes in industrialized countries, the temperature of foods such as turkeys, casseroles or large cuts of meat should be monitored during cooking using bayonet-type meat thermometers. Simple but less precise monitoring procedures include: observation of changes in the texture or colour of foods (e.g. uncured pork turns white on cooking); observation of the flow and colour of juices; cooking at a prescribed oven temperature for a specific time per pound of product. In homes in developing countries, monitoring is often limited to observing whether a mixture that contains fluid boils and whether it is thoroughly mixed during the boiling process. It should be understood, however, that even though a fluid may bubble, the solid food in the mixture may not be thoroughly heated. No additional monitoring is required when foods are eaten promptly after thorough cooking.

If cooked foods are to be held hot for more than one hour, the temperature should be monitored at regular intervals (e.g. every 2 hours) to ensure that it does not fall to within the range in which pathogenic bacteria can multiply, or that it does so only for a short time. In food service establishments, the internal temperature of foods should be monitored; if food is held in a container without a lid or in a unit (e.g., steam table, bain-Marie) where heat comes from the bottom or the sides, then temperatures at or near the surface should be monitored, and observations made of the frequency and efficiency of stirring.

Cooked foods should be monitored to ascertain for how long they are left at room temperature. In homes and street markets, the only practical control measure is to ensure that foods are not held for more than *5* hours (preferably less) after cooking, unless they can be refrigerated, held hot, or reheated.

Handling of foods after cooking can be monitored in a number of ways. Observations can be made to determine whether cross-contamination could occur:

- from raw food to workers' hands to cooked food;
- from raw food to equipment to cooked food processed on or in the same equipment;

- from cloths used to wipe areas where raw and then cooked foods are handled; or
- as a result of dripping from raw foods that are stored above cooked foods.

By observation, one can determine whether cooked foods have been touched or whether improperly cleaned equipment has been used to handle or hold the cooked foods. Monitoring of the handling of cooked foods is not always practical in homes, but an understanding of hazards and personal and food hygiene, and supervision of family members by the homemaker can serve as a safeguard.

For some foods, cooling may be a critical control point, and monitoring of the cooling procedures is essential. This can be done either by measuring the volume (particularly the depth) of the food being cooled or by measuring temperature before cooling and at intervals during cooling. A single measurement of the temperature of a food being cooled provides information for only one moment and is thus of limited value. Additional monitoring may include observing whether lids or covers are used and ensuring that there is an air space above, below, and between items. Measurement of air temperature in the refrigerator is of limited value in measuring the cooling rates of cooked foods. In developing countries where refrigerators are not easily affordable, monitoring is often limited to time of holding at room or outside ambient temperature.

Reheating of cooked foods must be monitored in the same way as the initial cooking. Monitoring of foods at this stage is particularly important because poor storage practices may have allowed the proliferation of large numbers of microorganisms in the cooked food. In homes in developing countries, the only way of monitoring liquid foods may be to ensure that they are thoroughly mixed and that they are reheated at least to boiling point.

An alternative form of monitoring may be to collect and test samples of finished products for microorganisms of concern. This is acceptable only if the product remains with the processor until the results of testing are available. For example, infant formulae, dried milk and dried eggs are often tested for salmonellae, and only distributed if the results of the tests are acceptable. Whenever samples are collected, a statistically sound sampling plan is essential (ICMSF, 1986a). The sampling plan should be based on an assessment of the severity and risk of hazards and on the expected use and storage of the food after sampling. Record-keeping is essential in large processing plants and should be considered in certain other operations, but is not practical in homes.

## **Taking corrective action**

If monitoring indicates that a process is out of control, or that established criteria are not being met, immediate action must be taken. The specific action will depend on the process being monitored and may include reheating or reprocessing, increasing temperature, decreasing  $a_{\rm w}$ , decreasing pH, extending the processing time, adjusting the concentration of certain ingredients, adjusting the processing at a later stage, rejecting incoming lots, diverting the product to use as animal feed, or discarding the product. The decision will be based on the hazards, their severity, and the risks involved and on the expected use of the product.

One of the positive features of the HACCP approach is that unacceptable contamination, process failure, or the existence of conditions that would permit multiplication of undesirable microorganisms can be detected as it occurs or shortly afterwards, so that immediate corrective action can be taken.

## **Food-processing establishments**

Upon completion of the initial study, a **HACCP** system should be drawn up for the establishment, by either health personnel, quality control personnel, or outside consultants. This should then be carefully reviewed by technically qualified supervisors from the establishment and officials of the food safety programme, and if necessary, in consultation with specialists familiar with the processing and preparation of the foods concerned. The plan should include:

- a flow diagram of the various processes;
- a list of significant potential hazards;
- an indication of the critical control points;
- specification of the criteria for control;
- details of the monitoring procedures to be applied at each critical control point; and
- action to be taken when the operation is out of control.

Once the plan has been approved by all concerned, it should be returned to the manager of the establishment. **A** copy should be kept for review by quality-control and regulatory personnel before follow-up visits are made.

Routine monitoring of the critical control points of a food operation is the responsibility of the manager of the establishment, but food safety programme supervisors will need to verify the appropriateness of control criteria and critical control points, and inspectors will need to verify the extent and effectiveness of the monitoring. Verification may include:

- checking records of time-temperature readings;
- observing operations at critical control points;
- making measurements to confirm the accuracy of the monitoring;
- collecting samples;
- conducting special studies, e.g. inoculated pack or challenge test, with regard to the safety of products; and
- interviewing staff about the way they monitor critical control points.

Furthermore, the composition of food products and operational procedures should be reviewed to determine whether any changes have been made since the **HACCP** system was established. If so, it may be necessary to select different critical control points or modify the monitoring procedures.

People who conduct HACCP evaluations can make a significant contribution to improved health and welfare and to economic development, by providing leadership to the food industry and the public. They are also ideally placed to guide the development of educational programmes so that the food industry and the public are informed of significant risks associated with food processing and food preparation practices, and of practical and economical ways to prevent or eliminate hazards.

#### **Guiding health strategies**

Information obtained during HACCP evaluations should be used for planning and setting priorities for health programmes. Control measures will have to be chosen or devised to deal with the hazards identified. These should be pointed out during routine inspections of food establishments, and should be the basis for regulations adopted to cope with existing or potential problems in food safety. Cumulative data generated during hazard analyses and experience in monitoring critical control points should be used to train staff of the health department.

#### **Health education**

Once the major risks associated with the processing and preparation of foods have been identified, and the relevant cultural patterns and social structures understood, educational materials should be developed, and training and educational efforts implemented, to increase awareness of the risks and how they can be avoided. Appropriate measures may include:

- modification of curricula at universities;
- training of public health personnel;
- training of managers and other staff in the food industry;
- health education of the public during home visits by public health workers;
- provision of relevant information to mothers and low-income families when food is distributed;
- discussions with interested community groups, such as mothers' clubs and consumer groups;
- preparation of educational films, leaflets, posters, and announcements for radio and television;
- teaching of food safety in schools.

## **REFERENCES**

BRYAN, F.L. (1978) Factors that contribute to outbreaks of foodborne disease. Journal of food protection, 41: 816-827.

BRYAN, F.L. (1981) Hazard analysis of foodservice operations. Food technology,  $35(2)$ : 78-87.

BRYAN, F.L. (1982) Foodborne disease risk assessment of foodservice establishments in a community. Journal of food protection, 45: 93-100.

BRYAN, F.L. (1986) New approaches for the control of foodborne diseases. In: Proceedings of the Second World Congress on Foodborne Infections and Intoxications. Vol. 1. Berlin, Institute of Veterinary Medicine, pp. 70-8 1.

BRYAN, F.L. (1988) Risks of practices, procedures and processes that lead to outbreaks of foodborne diseases. Journal of food protection, 51: 663-673.

BRYAN, F.L. & BARTLESON, C.A. (1985) Mexican-style foodservice operations; hazard analyses, critical control points and monitoring. Journal of food protection, **48:** 509–524.

BRYAN, F.L. ET AL. (1981) Hazard analysis, in reference to *Bacillus cereus*, of boiled and fried rice in Cantonese-style restaurants, Journal of food protection, 44: 500-512.

BRYAN, F.L. ET AL. (1987) Procedures to investigate foodborne illness, 4th ed. Ames, IA, International Association of Milk, Food, and Environmental Sanitarians.

BRYAN, F.L. ET AL. (1988) Critical control points of street-vended foods. Journal of food protection, 51: 373-384.

DAVEY, G.R. (1985) Food poisoning in New South Wales: 1977-84. Food technology, Australia,  $37: 453-456$ .

FAO/WHO (1984) The role of food safety in health and development: report of a Joint FAO/WHO Expert Committee on Food Safety. Geneva, World Health Organization (WHO Technical Report Series, No. 705).

GENIGEORGIS, C. & RIEMANN, H.(1979) Food processing and hygiene. In: Riemann, H. & Bryan, F.L., ed., Foodborne infections and intoxications, 2nd ed. New York, Academic Press, pp. 613-713.

GREENSPAN, L. (1977) Humidity fixed points of binary saturated aqueous SIGUE CO. 1968, Academic Fress, pp. 013–713.<br>GREENSPAN, L. (1977) Humidity fixed points of binary saturated aqueous<br>solutions. *Journal of research of the National Bureau of Standards* - *A.*<br>*Physics and chamitty:* **21A:** Physics and chemistry, 81A: 89-96.

ICMSF (1978) Microorganisms in foods. 1. Their significance and methods of enumeration, 2nd ed. Toronto, University of Toronto Press.

ICMSF (1986a) Microorganisms in foods. 2. Sampling for microbiological analysis: principles and specific applications, 2nd ed. Toronto, University of Toronto Press.

ICMSF (1986b) Prevention and control of foodborne salmonellosis through application of the hazard analysis critical control point system. Unpublished WHO document WHO/CDS/VPH/86.65. Available on request from Veterinary Public Health, World Health Organization, 121 1 Geneva 27, Switzerland.

ICMSF (1988) Microorganisms in foods. 4. Application of the hazard analysis critical control point (HACCP) system to ensure microbiological safety and quality. Oxford, Blackwell Scientific Publications.

ROBERTS, D. (1982) Factors contributing to outbreaks of food poisoning in England and Wales 1970–1979. Journal of hygiene,  $89: 491-498$ .

SPECK, M.L., ed. (1984) Compendium of methods for the microbiological examination of foods, 2nd ed. Washington, DC, American Public Health Association.

STUMBO, C.R. (1973) Thermobacteriology in food processing, 2nd ed. New York, Academic Press.

Subcommittee on Microbiological Criteria for Foods, Committee on Food Protection, Food and Nutrition Board, National Research Council (1985) An evaluation of the role of microbiological criteria for foods and food ingredients. Washington, DC, National Academy Press.

TODD, E.C.D. (1983) Factors that contribute to foodborne disease in Canada, 1973-1977. Journal of food protection, 46: 737-747.

TROLLER, J.A. ET AL. (1984) Measurement of water activity. In: Speck, M.L., ed., Compendium of methods for the microbiological examination of foods, 2nd ed. Washington, DC, American Public Health Association, pp. 124-134.

WHO (1989) Health surveillance and management procedures for foodhandling personnel: report of a WHO Consultation. Geneva, World Health Organization (WHO Technical Report Series, No. 785).

WHO/ICMSF (1982) Report of WHO/ICMSF meeting on hazard analysis critical control point system in food hygiene. Unpublished WHO document, VPH/82.27. Available on request from Veterinary Public Health, World Health Organization, 1211 Geneva 27, Switzerland.

## **Food microbiology and foodborne diseases**

AYRES, J.C. ET AL. Microbiology of foods. San Francisco, Freeman, 1980.

BANWART, G.J. Basic food microbiology, 2nd ed. New York, Van Nostrand Reinhold (AVI), 1989.

DOYLE, M. Foodborne bacterial pathogens. New York, Dekker, 1989.

FRAZIER, W.C. & WESTHOFF, D.C. Food microbiology, 4th ed. New York, McGraw-Hill, 1988.

HOBBS, B.C. & ROBERTS, D. Food poisoning and food hygiene, 5th ed. Baltimore, Edward Arnold, 1987.

International Commission on Microbiological Specifications for Foods. Microbial ecology of foods. Vol. *1.* Factors aflecting life and death of microorganisms. New York, Academic Press, 1980.

International Commission on Microbiological Specifications for Foods. Microbial ecology of foods. Vol. 2. Food commodities. New York, Academic Press, 1980.

JAY, J.M. Modern food microbiology, 3rd ed. New York, Van Nostrand Reinhold, 1986.

RIEMANN, R. & BRYAN, F.L. Foodborne infections and intoxications, 2nd ed. New York, Academic Press, 1979.

## **The HACCP system**

BRYAN F.L. Hazard analysis critical control point. What the system is and what it is not. Journal of environmental health, 50: 400-401 (1988).

Committee on the Microbiological Safety of Foods. The microbiological safety of foods, Part 1. London, Her Majesty's Stationery Office, 1990.

SIMONSEN, B. ET AL. Report from the International Commission on Microbiological Specifications for Foods (ICMSF). Prevention and control of foodborne salmonellosis through application of hazard analysis critical control point (HACCP). International journal of food microbiology, 4: 227-247 (1987).

TOMPKIN, R.B. The use of HACCP in the production of meat and poultry products. Journal of food protection, 53: 795-803 (1990).

#### **Application of HACCP system to food-processing operations**

BAUMAN, H.E. The HACCP concept and microbiological hazard categories. Food technology, **28:** 30, 32, 34, 78 (1974).

BAUMAN, H.E. The hazard analysis critical control point concept. In: Felix, C.W., ed., Food protection technology, Chelsea, MI, Lewis Publishers, 1987, pp. 175-179.

HABERSTROH, C. ET AL. HACCP: making the system work. Food engineering, Aug: 70-80 (1988).

ITO, K. Microbiological criteria critical control points in canned foods. Food technology, **28:** 16-48 (1974).

PETERSON, A.C. & GUNNERSON, R.K. Microbiological critical control points in frozen foods. Food technology, **28:** 37-44 (1974).

SILLIKER, J.H. Principles and application of the HACCP approach for the food processing industry, In: Felix, C.W., ed., Food protection technology. Chelsea, MI, Lewis Publishers, 1980, pp. 81-89.

### **Application of HACCP system to food service operations**

BOBENG, B.J. & DAVID, B.D. HACCP models for quality control of entree production in hospital food service. 1. Development of hazard analysis critical control point models. Journal of the American Dietetic Association, **7:** 534-539 (1978).

BRYAN, F.L. Hazard analysis critical control point approach: epidemiologic rationale and application to foodservice operations. Journal of environmental health, 44: 7-14 (1981).

BRYAN, F.L. Application of HACCP to ready-to-eat chilled foods. Food technology,  $44(7)$ : 70-77 (1990).

BRYAN, F.L. & McKINLEY, T.W. Hazard analysis and control of roast beef preparation in foodservice establishments. Journal of food protection, **42:** 4-18 (1979).

BRYAN, F.L. ET AL. Time-temperature survey of a restaurant that specializes in barbecued food. Journal of food protection, **43:** 595–600 (1980).

BRYAN, F.L. ET AL. Time-temperature conditions of gyros. Journal of food protection, **43:** 346-353 (1980).

BRYAN, F.L. ET AL. Hazard analyses of fried, boiled, and steamed Cantonese-styled foods. Journal of food protection, **45:** 410-421 (1982).

CREMER, M.L. & CHIPLEY, J.R. Microbiological problems in the foodservice industry. Food technology, **34:** 59, 68, 84 (1980).

DAHL, C.A. ET AL. Cook/chill foodservice systems with a microwave oven: aerobic plate counts from beef loaf, potatoes, and frozen green beans. Journal of microwave power, 15: 95-105 (1980).

GUZEWICH, J.J. Practical procedures for using the HACCP approach in food service establishments by industry and regulatory agencies. In: Felix, C.W., ed., Food protection technology, Chelsea, MI, Lewis, 1987, pp. 91-100.

MATTHEWS, M.E. Monitoring the critical points in food service operations. In: Microbial safety of foods in feeding systems. Washington, DC, National Academy Press, 1982, pp. 158–168.

MUNCE, B. Hazard analysis critical control points and the food service industry. Food technology in Australia, **36:** 214-217, 222 (1984).

SNYDER, O.P. JR. Applying the hazard analysis and critical control points system in food service. Foodborne illness prevention. In: Proceedings of the Second World Congress on Foodborne Infections and Intoxications, Vol. II. Berlin, Institute for Veterinary Medicine, 1986, pp. 1018-1024.

SNYDER, O.P. Microbiological quality assurance in foodservice operations. Food technology, July: 122-130 (1986).

## **Application of HACCP system in homes**

BRYAN, F.L. Safety of ethnic foods through the application of the hazard analysis critical control point approach. Dairy and food sanitation, **8:** 654-660 (1988).

ZOTTOLA, E. & WOLF, I. Recipe hazard analysis  $-$  RHAS  $-$  A systematic approach to analyzing potential hazards in a recipe for food preparation/preservation. Journal of food protection, 44: 560-564 (1981).

## **Application of HACCP approach by health agencies**

BRYAN, F.L. Procedures for local health agencies to institute a hazard analysis critical control point program for food safety assurance in foodservice operations. Journal of environmental health, **47:** 241-245 (1985).

GUZEWICH, J.J. Statewide implementation of a HACCP food service regulatory program. Journal of environmental health, **49:** 148-152 (1986).

## **A, and its measurement**

BEUCHAT, L.R. Influence of water activity on growth, metabolic activities and survival of yeasts and molds. Journal of food protection, **46:** 135–141 (1983).

LABUZA, T.P. ET AL. Water activity determination: a collaborative study of different methods. Journal of food science, **41:** 910-917 (1976).

RODEL, W. ET AL. Measurement of water activity  $(a_w)$  value of meat and meat products. Fleischwirtschaft, 59: 849-851 (1979).

SPERBER, W.H. Influence of water activity on foodborne bacteria - a review. Journal of food protection, **46:** 142-150 (1983).

TROLLER, J.A. Water relations of foodborne bacterial pathogens  $-$  an updated review. Journal of food protection, **49:** 656-670 (1986).

TROLLER, J.A. & CHRISTIAN, J.H.B. Water activity and food. New York, Academic Press, 1978.

#### **Sampling and testing foods**

BRYAN, F.L. Procedures to use during outbreaks of foodborne illness. In: Lennette, E.H. et al., ed., Manual of clinical microbiology, 4th ed. Washington, DC, American Society for Microbiology, 1985.

CORRY, J.E.L. ET AL. Isolation and identification methods for food poisoning organisms. London, Academic Press, 1982.

GABIS, D.A. ET AL. Sampling plans, sample collection, shipment and preparation for analysis. In: Speck, M.L., ed., Compendium of methods for microbiological examination of foods, 2nd ed. Washington, DC, American Public Health Association, 1984.

SANDERS, A.C. ET AL. Foodborne illness — suggested approaches for the analysis of foods and specimens obtained in outbreaks. In: Speck, M.L., ed., Compendium of methods for the microbiological examination of foods, 2nd ed. Washington, DC, American Public Health Association, 1984.

SCHMIDT-LORENZ, W. Sammlung uon Vorschriften zur microbiologischen Untersuchung von Lebensmitteln. [Collection of methods for the microbiological examination of foods.] Weinheim, Verlag Chemie, 1983.

## COLLECTION OF WATER SAMPLES

Water samples can be collected in a number of ways, depending on the source.

#### **From a tap or pump**

Before taking a water sample from a tap, allow the water to run to waste (for 5-10 seconds for line samples and up to 5 minutes for source samples). Adjust the flow of water so that any sodium thiosulfate present in the sample bottle (to neutralize chlorine) will not be flushed out. Keep the sample container closed until just before collection. Hold the bottle near the base, fill without rinsing, and immediately replace the stopper or cap, and secure the hood, if attached. Leave an air gap of 2.5 cm to facilitate mixing.

If a plastic sample bag is used instead of a bottle, tear off the top, and open it by pulling the side tabs apart. Grasp the end wires and place the bag under the flowing water. Remove the bag before it is completely filled and squeeze out most of the air; fold over the top of the bag several times, and secure it by twisting the end wires.

#### **From a dug well**

Attach a stone or metal weight to a sampling bottle. Tie a clean piece of string to the bottle and lower the weighted bottle into the well. Immerse the bottle completely in the water and allow to fill. Once the bottle is full, pull it out of the well, discard the first 2-3 cm of water to provide an air space, and place a tight-fitting stopper or cap on the bottle.

#### **From a container**

Collect samples from buckets, jars, pans and other vessels either by pouring a portion into a sample container or by dipping a suitable sterile vessel into the water. Use a forward and upward motion, so that the hand remains behind the bottle. Then pour the water into the sample bottle or bag.

#### **From water bodies**

To collect samples from rivers, lakes, reservoirs, springs, shallow wells, step wells, and toilet tanks, hold the sample bottle or bag at the bottom and plunge it neck down to a depth of 15 cm below the surface. Turn the bottle the right way up and allow it to fill. Use a sweeping continuous, arc-shaped motion, against the flow of the stream. If possible, when taking samples from bodies of water avoid wading, because it often stirs up the bottom. Piers or other similar structures, or the front end of a drifting or slow-moving boat, are good sampling stations. If wading is unavoidable, wade upstream and keep moving forward until sample collection is completed.

#### **Concentration methods**

Concentration of microorganisms using swabs, filtration, or absorption is particularly important when waterborne pathogens are sought. Suspend Moore swabs or sponges, secured by strings or wires, overnight or for as long as possible (up to 5 days) in a water vessel, drum, stream, lake, sewer, latrine pit or drain. Bacteria can also be concentrated by filtering water through membrane filters, diatomaceous earth, or other filter media. For membrane filters, pass several litres of water through a sterile filter. Using aseptic techniques, transfer the filter to the surface of a selective enrichment medium held in an agar substrate in a saturated sterile absorbent pad, or suspend in a solution of enrichment broth, as used in the method of isolation.

More information on methods of sampling water can be found in Bryan et al.<sup> $a$ </sup> and Greenberg et al.<sup>b</sup>

<sup>&</sup>lt;sup>*a*</sup> BRYAN, F.L. ET AL. *Procedures to investigate waterborne illness*, Ames, IA, Asso**ciation of Milk, Food and Environmental Sanitarians, 1979.** 

**GREENBERG, A.E. ET AL.** *Standard methods for the examination of water and wastewater,* **15th ed. Washington, DC, American Public Health Association, 1981.** 

## COLLECTION OF CLINICAL SPECIMENS

If collecting a specimen from a person who is vomiting, instruct the person to vomit directly into a clean receptacle or lavatory. Transfer a spoonful of the vomit to a sterile specimen container or a small glass jar that has been thoroughly cleaned and boiled in water for approximately 15 minutes. Take the specimen directly to the laboratory, if practicable; if not, refrigerate it or add transport medium (see p. *53),* but do not freeze it.

If the person has diarrhoea or has had diarrhoea in the previous month, obtain either a stool specimen or a rectal swab. Rectal swabs should only be taken by a trained medical practitioner, nurse, technician, or microbiologist. If this is not practicable, provide the person with a stool specimen container and either a disposable plastic or wooden spoon or tongue depressor. A clean container (such as a jar or milk carton that can be sealed and later disinfected, burned, or otherwise disposed of in a sanitary manner), and a clean spoon or short stick can be used if laboratory supplies are not available.

If there are flush toilets, tell the person to collect the stool specimen by one of the following methods:

- 1. Put two sheets of newspaper under the toilet seat and push them down slightly in the centre, without letting them touch the water in the bowl. Defecate on to the newspaper; using a clean spoon or other utensil transfer a spoon-size portion of faeces into a specimen container, or a clean glass or plastic container.
- 2. Float a paper towel on the surface of the water in the toilet bowl. Defecate on to the towel; using a spoon, tongue depressor, or stick, collect a spoon-size specimen of the faeces from above the water line and transfer it to the specimen container.

If there are no flush toilets; use one of the following methods:

- 1. Tell the person to defecate directly into a specimen container or other dry container.
- 2. Give the person a swab and a tube containing transport medium. Tell the person to press the cotton-wrapped end of the swab into the top of the faeces, or on to faecally soiled toilet paper; a twisting motion should be used to pick up some excrement. The excrementcoated swab should then be broken off into the sample tube.
- **3.** If faecal specimens cannot be easily obtained otherwise, give the person a pad of paper tissues and a sterile specimen bottle containing liquid transport medium. Tell him or her to use the tissues or toilet paper to wipe the anus after defecation and then to put them into the specimen container.

To collect specimens from an infant, rub a sterile cotton or alginate tipped swab or sponge over the anal region after the infant has defecated. Use a disposable plastic glove or a piece of sterile paper to handle the sponge so as not to introduce contaminants. Alternatively, rub the sponge or a moistened sterile swab over the soiled portion of the infant's napkin (diaper). Put the sponge into a sterile jar; break the tip of the swab into a tube of enrichment broth or transport medium.

Collect samples from latrines, sewers, sewage-contaminated water courses, and overflow from toilets by inserting Moore swabs into the faecal matter or stream, secured with a string or wire. Transport the samples to the laboratory in plastic bags. These specimens will provide information about pathogens likely to infect people in a particular household or neighbourhood. The data can indicate which microorganisms should be tested for in food samples.

If you cannot deliver faecal specimens to the laboratory immediately, do one of the following:

- 1. Transfer a spoon-size portion of stool from the container to a specimen bottle containing transport medium.
- 2. Push a swab into the faecal matter and transfer it to a tube containing transport medium.
- **3.** Refrigerate the specimen at or below 4.4 "C. Transport media (e.g., Cary-Blair, Amies', or Stuart's transport medium, or buffered glycerol saline) preserve pathogens and prevent them from being overgrown by normal faecal flora.

If it appears that animals or their faeces may be sources of food contamination, collect specimens of droppings. If the droppings have a loose and liquid consistency insert a swab into one or more of them. If the dropping is dry, pick it up using a spoon, tong, tongue depressor or disposable plastic glove. Put the swabs directly into a tube of enrichment broth or transport medium. Put the dried faeces into a sterile jar or plastic bag.

For additional information on specimen collection, see Bryan et al. (1979, 1987)."

<sup>&</sup>quot; **BRYAN, F.L. ET AL.** *Procedures to investigate waterborne illness.* Ames, IA, Association of Milk, Food and Environmental Sanitarians, 1979; **BRYAN,** F.L. ET **AL.** *Procedures to investigate foodborne illness.* Ames, IA, International Association of Milk, Food and Environmental Sanitarians, 1987.

#### Annex 3

# TESTS THAT MIGHT BE USED DURING HAZARD ANALYSIS, MONITORING OR VERIFICATION<sup>a</sup>



 $a$  Other tests that might be considered during investigations of outbreaks of foodborne disease and the monitoring of critical control points have been reviewed by the Subcommittee on Microbiological Criteria for Foods of the National Research Council (An evaluation of the role of microbiological criteria for foods and food ingredients, Washington, DC, National Academy Press, 1985).





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## **Hazard analysis critical control point evaluations**





# HAZARDS, CRITICAL CONTROL POINTS AND MONITORING PROCEDURES FOR FOODS THAT MIGHT BE PREPARED IN HOMES, IN SMALL FOOD SHOPS AND BY STREET VENDORS

The table overleaf gives examples of hazards associated with the preparation of some common foods in homes and small food service establishments, together with appropriate control actions and monitoring procedures. The information is based on studies by Bryan et al. (1986, 1988a,b) and Michanie et al. (1987, 1988a,b). (CCP) indicates a control point at which a hazard can be reduced, but not eliminated.

## **References**

*BRYAN,* F.L. *ET AL.* (1986) *Phase II: Food handling. Hazard analysis critical control point evaluations of foods prepared in households in a rice-farming village in Thailand.* Rome, Food and Agriculture Organization of the United Nations.

*BRYAN,* F.L. *ET AL.* (1988a) Hazard analyses of foods prepared by inhabitants near Lake Titicaca in the Peruvian Sierra. *Journal of food protection,* **51:** 412-418.

BRYAN, F.L. *ET AL.* (1988b) Hazard analyses of foods prepared by migrants living in a new settlement at the outskirts in Lima, Peru. *Journal of food protection,* **51:** 314-323.

*MICHANIE,* S. *ET AL.* (1987) Critical control points for foods prepared in households in which babies had salmonellosis. *International journal of food microbiology, 5:* 337-354.

*MICHANIE,* S. *ET AL.* (1988a) Hazard analyses of foods prepared by inhabitants along the Amazon River. *Journal of food protection,* **51:**  293-302.

*MICHANIE,* S. *ET AL.* (1988b) Critical control points for foods prepared in households whose members had either alleged typhoid fever or diarrhea. *International journal of food microbiology, 7:* 123-134.



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Annex 4



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Hazard analysis critical control point evaluations


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## Annex 5

# COMMON CRITICAL CONTROL POINTS AND EXAMPLES OF MONITORING PROCEDURES FOR FOOD-PROCESSING OPERATIONS



#### **Annex 5**





### **Hazard analysis critical control point evaluations**



## **Hazard analysis critical control point evaluations**



# HAZARDS, CRITICAL CONTROL POINTS AND MONITORING PROCEDURES FOR COMMON FOOD SERVICE OPERATIONS

The table below gives examples of hazards associated with some common food service operations, together with appropriate control actions and monitoring procedures. The information is adapted from Bryan, F.L., Microbiological hazards of feeding systems. In: Microbiological safety of foods in feeding systems, Washington, DC, National Academy Press, 1982 (ABMPS Report No. 125), pp. 64-80.





#### **Hazard analysis critical control point evaluations**

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