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1. Introduction

The acronym HACCP, which stands for Hazard Analysis and Critical Control Point, is one which evokes 'food safety'. One cannot write about the HACCP system, however, without giving credit to those who conceived it, i.e. the Pillsbury Company, together with the National Aeronautics and Space Administration (NASA) and the U.S. Army Laboratories at Natick, who developed this system to ensure the safety of astronauts' food. In the thirty years since then, the HACCP system has become the internationally-recognized and accepted method for food safety assurance. While it was originally developed to ensure microbiological safety of foodstuffs, it has been further broadened to include chemical and physical hazards in foods. The recent growing worldwide concern about food safety by public health authorities, consumers and other concerned parties, to a great extent due to WHO's advocacy in this field, and the continuous reports of foodborne outbreaks have been a major impetus in the application of the HACCP system.

2. The need for an effective food safety assurance method

Food safety has been of concern to humankind since the dawn of history, and many of the problems encountered in our food supply go back to the earliest recorded years. Many rules and recommendations advocated in religious or historical texts are evidence of the concern to protect people against foodborne diseases and food adulteration. However, in recent decades this concern has grown. There are many reasons for this:

- # Foodborne diseases remain one of the most widespread public health problems in the contemporary world, and an important cause of reduced economic productivity, despite progress in food science and technologies. The *World Declaration on Nutrition*, adopted by the FAO/WHO International Conference on Nutrition (Rome, December 1992), emphasizes that hundreds of millions of people suffer from communicable and noncommunicable diseases caused by contaminated food and water.
- # The increasing incidence of many foodborne diseases, e.g. salmonellosis and campylobacteriosis, in many regions of the world.
- # Increased knowledge and awareness of the serious and chronic health effects of foodborne pathogens.
- # The possibility of detecting minute amounts of contaminants in food, due to advances in scientific and analytical methods.
- # Emerging foodborne pathogens, e.g. *Listeria monocytogenes*, verocytotoxin producing *E. coli*, *Campylobacter spp*, foodborne trematodes, etc.
- # An increase in the number of vulnerable people, such as the elderly, immunocompromised individuals, the undernourished, and individuals with other underlying health problems.
- # Increased awareness of the economic consequences of foodborne diseases.

- # Industrialization and increased mass production, leading to: i) increased risks of food contamination; and ii) the considerably larger numbers of people affected in foodborne disease outbreaks as a result.
- # Urbanization, leading to a more complex food chain, and thus greater possibilities for food contamination.
- # New food technologies and processing methods, causing concern either about the safety of the products themselves or the eventual consequences due to inappropriate handling during preparation in households or food service/catering establishments.
- # Changing lifestyles, depicted by an increasing number of people eating outside the home, in food service or catering establishments, at street food stalls, or in fast-food restaurants. Responsibility for food preparation shared between family members who are not always aware of food safety rules.
- # Increased worldwide tourism and international trade in foodstuffs, leading to a greater exposure to foodborne hazards from other areas.
- # Increased contamination of the environment.
- # Increased consumer awareness of food safety.
- # Lack of or decreasing resources for food safety.

It is this climate of increasing concern about food safety, the lack of sufficient resources, and the recognition of the limitations of traditional approaches to food safety assurance which have accentuated the need for a cost-effective food safety assurance method. The HACCP system has proven to be such a system.

3. The HACCP system and its benefits

The HACCP system is a scientific, rational and systematic approach to identification, assessment and control of hazards during production, processing, manufacturing, preparation and use of food to ensure that food is safe when consumed (i.e. it does not present an unacceptable risk to health). With the HACCP system, food safety control is integrated into the design of the process rather than the present ineffective system of end-product testing. Therefore, the HACCP system provides a preventive and thus a cost-effective approach to food safety. In 1993, the Codex Alimentarius Commission endorsed the HACCP system as the most cost-effective approach devised to date for ensuring the safety of food. Experiences gained in some countries indicate that application of HACCP systems leads to more efficient prevention of foodborne diseases.

The HACCP system can be applied throughout the food chain, from the primary producer to final consumer. Its implementation should be guided by scientific evidence of risks to human health. The

successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a multidisciplinary approach. This multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary science/medicine, production, microbiology, public health, food technology, environmental health, chemistry, and engineering, according to the particular study.

The HACCP principles can be applied in a variety of ways:

- The HACCP system is a system used as a method of food safety assurance in food production, processing, manufacturing and preparation.
- The HACCP system is amenable to effective food control. It allows for more efficient inspection of food operations, as the role of food inspectors is centred on the assessment of the HACCP plan and confirmation that it is properly designed and operating effectively.
- The HACCP concept can also be used to study food preparation practices, and to identify and assess hazardous behaviour, which should be the focus of health education interventions.
- The HACCP concept can also be used in the management of overall food safety programmes to identify those problems all along the food chain which are of greatest risk to public health, and in order to prioritize interventions.

The additional benefits of the HACCP system can be summarized as follows:

- ! The HACCP system overcomes many of the limitations of the traditional approaches to food safety control (generally based on 'snap-shot' inspection and end-product testing), including
 - a) the difficulty of collecting and examining sufficient samples to obtain meaningful, representative information, in a timely manner and without the high cost of end-product analysis
 - b) reducing the potential for product recall
 - c) identification of problems without understanding the causes
 - d) limitations of 'snap-shot' inspection techniques in predicting potential food safety problems
- ! The HACCP system allows for the identification of conceivable, reasonably-expected hazards, even where failures have not previously been experienced. It is therefore particularly useful for new operations.
- ! The HACCP system is sufficiently flexible to accommodate changes introduced, such as progress in equipment design, improvements in processing procedures and technological developments related to the product.

- ! The HACCP system will help target/direct resources to the most critical part of the food operation.
- ! With the HACCP system one can expect an improvement in the relationship between a) food processors and food inspectors, and b) food processors and consumers. The HACCP system provides a scientifically-sound basis for demonstrating that all reasonable precautions have been taken to prevent a hazard from reaching the consumer. In this way, it encourages confidence in the safety of food products and thus promotes both confidence in the food industry and stability of food businesses.
- ! Data collected facilitates the work of food inspectors for auditing purposes.
- ! The HACCP system is applicable to the whole food chain, from the raw material to the end-product, i.e. growing, harvesting, processing or manufacturing, transport and distribution, preparation and consumption.
- ! The application of HACCP systems can promote international trade by increasing confidence in food safety.
- ! The HACCP system can be readily integrated into quality management systems, e.g. Total Quality Management, ISO 9000, etc.

4. International status of the HACCP system and recent developments in its concept

The World Health Organization has recognized the importance of the HACCP system for prevention of foodborne diseases for over 20 years and has played an important role its development, harmonization and implementation. One of the highlights in the history of the HACCP system was in 1993 when the *Codex Guidelines for the Application of the HACCP system* were adopted by the FAO/WHO Codex Alimentarius Commission. The *Codex Code on General Principles of Food Hygiene* has also been revised and presently it includes recommendations for the application of the Codex HACCP Guidelines. In due course, all relevant codes of hygienic practice will need to be revised to include the HACCP system.

The work of Codex, i.e. through its standards, guidelines and recommendations (including the *Guidelines for the Application of the Hazard Analysis Critical Control Point system*), has played an important role in facilitating international trade and has influenced national health legislation for the protection of consumers. However, since the successful conclusion of the GATT Uruguay Round of Multilateral Trade Negotiations in April 1994, and the establishment of the World Trade Organization (WTO) in 1995, the work of Codex plays an even greater role in matters related to health and trade.

The reason is that in the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures, the

work of Codex is recognized as the reference or 'yard stick' for national requirements in food safety. This implies that Members of the WTO involved in food trade need to take the work of the Codex Alimentarius into consideration, and adapt their national legislation to the provisions provided by the Codex Alimentarius. In future, they could be required to furnish justification for food import restrictions based on national legislation that are stricter than Codex standards, guidelines and recommendations.

The Codex Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) system published in 1993 have been revised¹ and the revised text entitled *Hazard Analysis and Critical Control Point (HACCP) system and Guidelines for its Application* was adopted by the Codex Alimentarius Commission in June 1997.² The revised Codex text on the HACCP system is reproduced in the Annex.

¹ Some of the major changes are:

Definitions and terminology: Some of the definitions and terminologies have been changed or new definitions are provided for terms such as audit, deviation, validation, to enhance comprehension of the text and avoid misunderstanding in interpretation of the principles. The term Hazard Analysis Critical Control Point has been changed to Hazard Analysis and Critical Control Point to facilitate its translation into other languages.

Separation of the HACCP system Principles from the Guidelines. This change has been introduced to underline the fact that the principles of the HACCP system set the basis for the minimum requirements for mandatory application of the HACCP system, while the Guidelines are general guidance, adherence to which is voluntary, considering that details in the application may vary depending on the circumstances of the food operation. This separation provides greater flexibility in the use of the document, and facilitates the integration of the HACCP principles in the regulatory structure.

Good Hygienic Practice and Good Manufacturing Practice. The proposed revision also highlights the importance of the GHP and GMP as the foundation for food safety, which is a prerequisite for an effective HACCP programme.

Principle 1: Hazard Analysis: Additional guidance is provided regarding the application of this Principle taking into consideration issues related to risk assessment.

Management commitment. Greater emphasis is put on the commitment of management, without which the implementation and maintenance of a HACCP programme would not be successful.

Decision tree. It is made clear that the decision tree provided in the Codex Guidelines may not be applicable to all situations and that it is given as an example only.

² Codex Alimentarius Commission. Report of the Twenty-Second Session of the Codex Alimentarius Commission, Geneva, June 1997.

5. Considerations for the implementation of HACCP: a guide for industry and government agencies ³

The successful implementation of a HACCP programme requires consideration of the following points:

The need for HACCP

To successfully implement HACCP in the food supply system, authorities responsible for food safety must first be aware of the need to move to a system such as HACCP. Until this need is acknowledged, it is unlikely that a commitment at any level can be expected.

Motivations for adopting HACCP may include the need to:

- reduce the incidence of foodborne disease
- ensure a safe food supply for the population
- promote (facilitate) trade in food products
- promote tourism

Responsibility for HACCP implementation

The main responsibility for the implementation of a HACCP-based approach to food safety lies with:

- industries involved in all stages of the food chain
- policy makers and planners who have the mandate to facilitate the adoption of HACCP systems
- government authorities, including legislators, regulatory food control officials and health education bodies

In addition, the following groups also have an important contributory role to play in the successful introduction of HACCP systems:

- academia, training and research institutes
- nongovernmental organizations
- consumers

³ Excerpt from *Hazard Analysis Critical Control Point System: Concept and Application*. Report of a WHO Consultation with the participation of FAO (29-31 May 1995). Unpublished WHO document WHO/FNU/FOS/95.7.

Role of those responsible for implementation of HACCP systems

Industries 'own' the HACCP systems, and it is vital that all the key players recognize this fact and tailor their involvement accordingly. Specifically, the roles for industry and government are:

Industry considerations

- The need to take ownership of the HACCP system
- The need to have a clear understanding of the principles of the HACCP system
- The need for commitment on the part of both management and staff towards the implementation and maintenance of the HACCP system
- The need to allocate the resources necessary for HACCP implementation
- The need to provide sufficient resources for training
- The need to share experiences with other sectors to ensure that adequate provision is made for food safety

Government considerations

- The need to provide leadership based on understanding and commitment
- The need to provide appropriate legislation and policies that promote and enhance the adoption and implementation of HACCP principles
- The need to define and establish nationally-acceptable levels of food safety risks
- The need to ensure that, when HACCP is implemented, regulatory food control officials are able to confirm that the system is correctly designed and conducted
- The need to provide sufficient resources to train regulatory food control officials
- The need to enforce any legislative requirements that have been adopted
- The need to develop appropriate strategies to implement and monitor the progress of HACCP
- The need to liaise with representatives from all sectors of the food chain, including consumers, on issues of food safety, appropriate control mechanisms and HACCP in general
- The need to liaise internationally on all aspects of HACCP for its harmonization and development

Development of implementation strategies

Once the decision has been made to implement HACCP, countries ought to develop strategies which reflect perceived needs. These strategies should be resource realistic and designed to ultimately achieve the desired objectives. They should be determined and agreed upon by the "key players" and the governmental agencies should work in conjunction with the industry sectors, wherever possible, to identify and promote the best option available for the development of the HACCP initiative. Where possible, the implementation strategies should facilitate a phased move towards HACCP to better manage the transition. Factors to be taken into consideration when determining priorities should include epidemiological information on foodborne diseases, high-risk foods or processes, and the economic importance of the sectors under consideration.

The plan for implementation of HACCP should be developed within the constraints of the available resources and achievable time-scales. The availability of training resources needs to be taken into consideration during the developmental stage. Care should be taken to ensure that costs are kept to a minimum and that a maximum benefit is obtained.

Implementation of the HACCP system should be integrated into national food policies. It should be considered an important component of any country's National Plan of Action for Nutrition,⁴ or National Plan of Action for Environment and Development.⁵ Progress and status reports on the implementation of HACCP systems should be considered a permanent item for national food safety coordinating committees or equivalent organizational bodies.

Approaches and programmes should be harmonized by the different regulatory agencies involved, should these exist.

Through consultation between regulatory and industry personnel, specific HACCP implementation strategies can be developed relevant to specific industries. Appropriate auditing programmes can be developed in the same way.

A first priority when implementing the HACCP system in the food safety programme should be to sensitize and raise the awareness of all people responsible in all sectors of the food industry and regulatory agencies. This should be done by using the skills of personnel who are knowledgeable in the HACCP system and who can respond effectively to the concerns expressed about proposed changes.

As far as possible, the integration of HACCP into food regulations should be delayed until the mechanisms have been set up to train food inspectors and food safety assurance personnel in industries.

Food industry associations, as well as regulatory agencies, should consider creating an advisory body for HACCP implementation in small and medium-size enterprises. It is likely that these enterprises will constitute the largest proportion of the food industry in any country. Their resources will be limited. Practical assistance in making the transition should aid the change process.

⁴ National Plan of Action developed as a follow-up to the FAO/WHO International Conference on Nutrition (Rome, December 1992).

⁵ National Plan of Action developed as a follow-up to the United Nations Conference on Environment and Development (Rio de Janeiro, June 1992).

Intercountry trade agreements can be a strong motivating force and should be used as a mechanism for the promotion of the HACCP system.

Time-scale

As the adoption of HACCP systems constitutes a major reform, the transition from an existing traditional food hygiene control system to a HACCP approach should be considered within a realistic time-scale, especially where a regulatory approach is taken.

The time-scale should be adapted to each country's individual situation, taking into account the resources available and allowing enough time and opportunities for training. Where regulations are enacted, sufficient time for training and implementation should be given before enforcement action is taken.

Resource assessment and capacity building

HACCP implementation allows for enforcement resources to be more effectively utilized. However, in the initial stages, the implementation of the HACCP system requires additional resources encompassing qualified personnel, technical support facilities and financial inputs. Governmental agencies and the various sectors of the food chain are likely to have different needs. Training requirements, resource inputs (both human and material) and access to specific expertise from a variety of sources all need to be taken into consideration. These may be available from within the government, international organizations, industry sectors and sectors of the academia already familiar with HACCP principles. Both the private sector and government should contribute to mobilizing the necessary resources. Developing countries facing difficulties in mobilizing the necessary resources may have to seek assistance from donor agencies and international organizations.

Regulatory considerations

Any consideration of the necessity to adopt a regulatory approach to HACCP will depend upon the strategy chosen to secure food safety in the relevant industry sectors. Legislative or regulatory objectives should concentrate on what is to be achieved and not how they should be achieved. The latter issue rests firmly in the domain of the food industry and their HACCP systems.

A voluntary HACCP approach can be effective in securing improvements in the safety of the food chain. In many cases, industry sectors have introduced the principles of HACCP without a regulatory requirement. In such voluntary programmes, training initiatives on a pan-industry or a more targeted basis may prove the most effective mechanism for the successful implementation of HACCP.

There are numerous benefits with the implementation of HACCP as a regulatory tool for food safety control. Key benefits include:

- each country being able to ensure that sufficient attention is given to the safety of the food supply for its population
- common understanding as regards HACCP design and application
- confidence in the safety of food products, thus promoting confidence in food trade and stability of food businesses
- incorporation of HACCP and food safety issues into the design and construction of newly-established food industry facilities and equipment

- focusing of food sector and regulatory resources and activities on HACCP-based interventions

Priority for regulatory attention should be directed at high-risk food or high-risk food processes based on epidemiological data, when available. The economic importance of the food process should also be considered but care must be exercised to ensure that the domestic and export markets are not differentiated.

The form that mandatory rules may take include:

- regulations which require the application of the principles of HACCP to high-risk or key food industries
- regulations which require the application of the principles of HACCP to all industries

The application of mandatory requirements may vary from one food sector to another.

The use of regulatory, pre-determined Critical Control Points does not eliminate the requirement for industry to develop HACCP plans. If they are to be used, care must be taken to ensure that they are appropriate for the product and process, and that they do not preclude the use of more cost-effective critical control points or control measures.

Assessment of HACCP systems

Following the implementation of a HACCP system, an ongoing assessment is essential. This can be achieved at two levels:

- internal assessments/audits⁶ carried out by those responsible for the system
- independent external assessments/audits

The assessor/auditor must be a person of integrity, skilled in audit and inspection processes, skilled in the process that is being undertaken, and able to communicate effectively on any questionable issue. It is recommended that the assessor/auditor has a demonstrable independence that facilitates an ability to report objectively and directly to the person responsible for the system.

a) Internal assessment/audits

Once a HACCP system is in place, it is essential that the person responsible ensures that the system is working effectively. This will involve daily checks to determine if the system is being adhered to and that all necessary measures are in place. The details of the checking process must be included in the HACCP plan. Depending on the nature and size of the industries, these checks may be quite complex, or if it is a small street-vending enterprise, a few quite basic actions only are required. Reliable records will demonstrate that the system is working and that adequate actions are being carried out.

b) Independent assessments/audits

⁶ For the purpose of this Report, the terms 'assessment' and 'audit' are considered to be equivalent.

There is widespread acceptance that for HACCP to be effective an independent assessment/audit is needed to provide an objective assessment. Owners and official agents having jurisdiction need the assurance that the HACCP system is effective and the activities are appropriate to the assurance of the provision of safe food.

Independent assessments/audits may be carried out by:

Regulatory agencies:

As a country moves towards the adoption of HACCP, regulators will be faced with their food industry carrying out its business in a new way. The traditional role of food inspectors based on enforcing prescriptive food hygiene regulations will change to assessment of HACCP systems in food industries, and confirmation that the system is correctly designed and conducted.

Third party assessments and/or certifications:

These may be considered as one approach to increase assurance that food safety regulations are being met.

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