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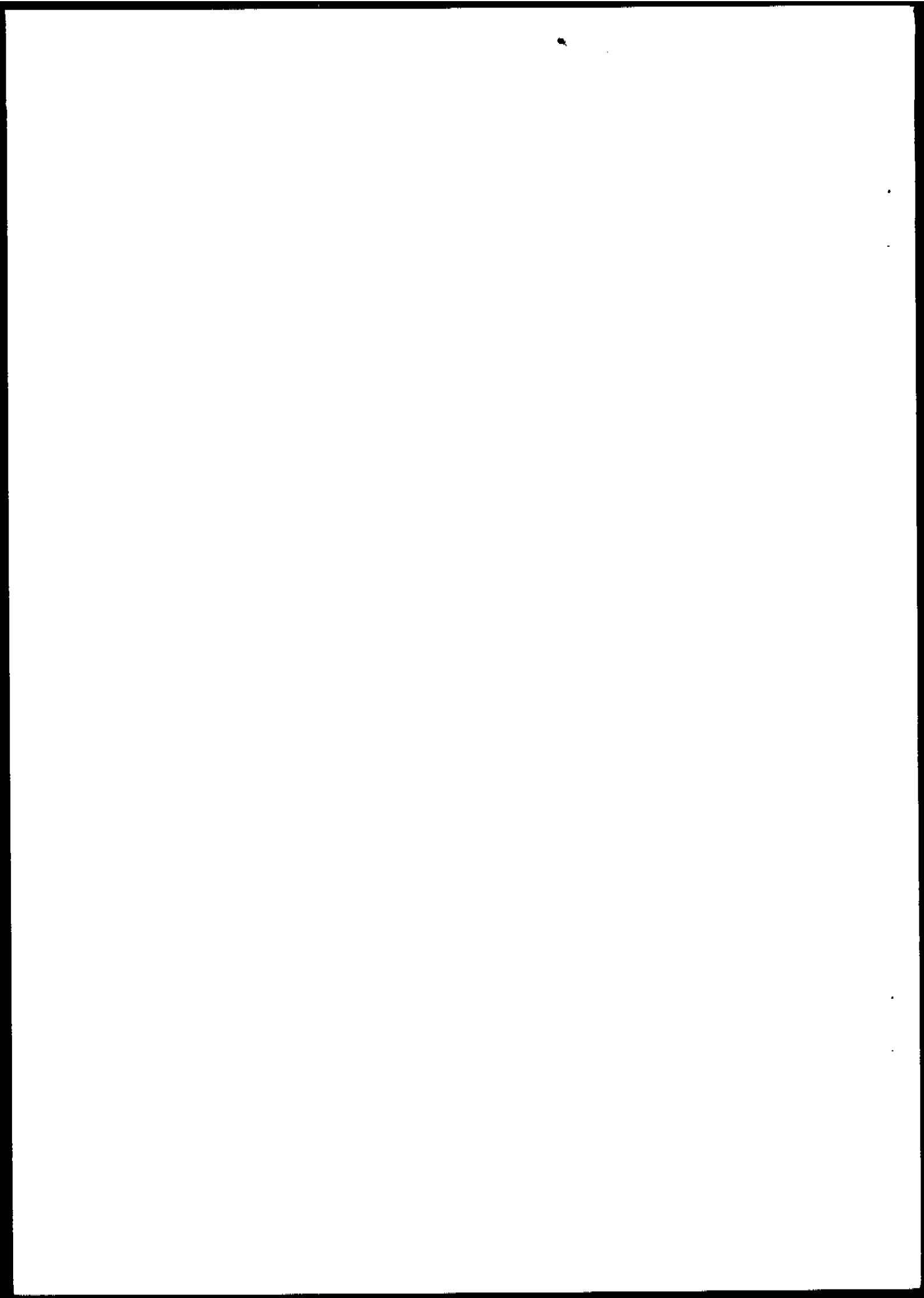
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1. Introduction

A Working Group was convened in Copenhagen from 21 to 25 November 1983 by the WHO Regional Office for Europe to discuss food inspection, with a view to producing suggestions for improved food inspection systems and the better use of available resources. As indicated in the meeting's scope and purpose document, the main purpose of food inspection was seen to be that of protecting the consumer against foodborne disease.

The Working Group comprised 17 temporary advisers from Member States of the European Region, and one representative each from the European Bureau of Consumers' Unions (BEUC), the European Food Law Association (EFLA), the Food and Agriculture Organization of the United Nations (FAO), the International Organization for Standardization (ISO), together with representatives from WHO headquarters and the Regional Office for Europe. The list of participants is given in Annex 2.

The meeting was opened by Mr J.I. Waddington, Director, Environmental Health Service, WHO Regional Office for Europe, who explained that each of the WHO regions had different priorities. Many activities of the Regional Office for Europe were related to areas other than communicable diseases. The three "epidemics" of major concern in the European Region were cancer, cardiovascular diseases and road traffic accidents. However, there had been some surprises in recent years, such as occurrence of legionnaires' disease and acquired immune deficiency syndrome (AIDS). Although foodborne infections should not be increasing in Europe, they were in fact doing so. The incidence of reported bacterial food poisoning was also rising. It was necessary to keep the debate on food inspection within the context of the total field of environmental health. In that connection, there was a need for a broad view of related functions; career development now made it possible for personnel to move from one discipline to another.

The control of food depended on good legislation, good scientific control and good inspection. The first two were useless without adequate inspectors. Many countries in Europe already had a large volume of food legislation, which, if not fully applied, could give a false sense of security.

Inspectors needed to be employed effectively and in a strategic manner; analysis was not necessarily the best way of using resources. Cost-effectiveness was a key concept: health services everywhere were under close financial scrutiny and it was necessary to quantify the resources devoted to food control.

Dr M. van Schothorst was elected Chairman and Dr G.K. Gheorghiev Vice-Chairman.

2. Scope and purpose

Presenting the scope and purpose of the meeting, Mrs B. Blomberg, Regional Officer, Food Safety Programme, said that the intention was to discuss the principles and philosophy of food inspection. Different concepts of food inspectors existed in different countries, ranging from highly qualified academic inspectors to basic inspectors with no academic training. Another problem was that the varying backgrounds of the Working Group's participants could lead to different interpretations being placed on the same terms. There were two aspects to a food control service: (1) inspection and (2) laboratories. It was important that inspectors should not be seen merely as sampling officers - they had many other important functions. The present meeting was a natural follow-up to an earlier conference^a on food control laboratories, held by the Regional Office in 1977. Many believed that there was a misuse of available resources, and one of the purposes of the Working Group was to formulate suggestions for utilizing these in a more effective way.

3. Food inspection systems

Two working papers were presented, describing food inspection systems in the Federal Republic of Germany and the United Kingdom. The Chairman, by way of introduction, said that it was difficult to justify sampling as being cost-effective; he questioned whether it helped to prevent foodborne disease. Like superfluous legislation, excessive sampling could lead to a false sense of security. The hazard analysis critical control point (HACCP) system was a way of identifying areas where the greatest inspection effort was needed. It was necessary to analyse the system and ask what would happen if individual elements were not carried out. An important task was to decide where to concentrate the effort in relation to types of business. Most foodborne disease outbreaks were caused by mishandling at the food preparation rather than at the food production level.

^a Food control laboratories: report on a Conference. Copenhagen, WHO Regional Office for Europe, 1978 (document ICP/FSP 003).

It was not the objective of the working papers to make recommendations: that was for the Working Group as a whole to do. He hoped that there would be a frank exchange of views, with participants being prepared to discuss the weaknesses as well as the strengths of their respective systems.

Introducing his working paper, Mr Kingcott pointed out that joint FAO/WHO guidelines^a described the food inspector as occupying a key position in the food control service. The paper took its lead from the scope and purpose document of the Working Group and concentrated on the system of food hygiene and safety inspection in England and Wales; composition and labelling were not dealt with fully. There were differences of detail, but not of principle, in the systems in Scotland and Northern Ireland.

The food inspection service in the United Kingdom was entirely a local authority function: central government did not exercise enforcement powers. Among the advantages of local enforcement was the local knowledge of inspectors in relation to food businesses. Potential disadvantages included the problem of achieving uniform standards of inspection and interpretation of the law among more than 400 local authorities. However, in practice that was not a major problem.

The inspectors were all qualified environmental health officers (EHOs), often supported by technical assistants, and worked in departments dealing with all aspects of environmental health. This imposed a discipline on the food control functions in terms of competition with other aspects of environmental health as far as resources were concerned. After briefly outlining the development and structure of the service, including a description of the laboratory support, which was usually independent of the local authorities, the paper emphasized the importance of well qualified inspectors. In the United Kingdom all inspectors were now educated to university degree level. There were six degree courses and two three-year diploma courses which reach the same standard as the university degree courses. They covered all aspects of environmental health, but food control formed a substantial part of the studies.

There were about 6000 EHOs in England and Wales (population about 50 million), about half of whom were engaged in food control work. The local authority departments in which they worked were headed by an EHO, who was a chief officer of the local authority. The career development this offered to EHOs encouraged the recruitment of well qualified student EHOs. Inspectors required a wide range of professional and scientific skills, and considerable resources were involved in ensuring compliance with food legislation.

The United Kingdom food hygiene law was drawn up with the stated purpose of protecting public health. Case law held that, in relation to risk of contamination, for example, it had to be shown that such contamination was prejudicial to health. It was therefore important that inspectors should be sufficiently well qualified to be able to make health judgements in relation to food hygiene without needing to seek advice from superiors.

Food hygiene education was an increasingly important function of EHOs, both in the course of inspections and in more formal teaching situations. In addition to the educational role, inspectors did institute legal proceedings for breaches of the regulations in the case of persistent offenders or particularly serious cases. However, there had been a sharp decline in the number of food hygiene prosecutions in recent years. That reflected the policy of achieving compliance through persuasion and education rather than prosecution.

In general, a good relationship existed between local government enforcement bodies, central government departments and industry. The dialogue thus established was mutually beneficial. The central government Department of Health and Social Security assisted field authorities with technical information and coordinated national and international activity in preventing or controlling foodborne infections and in resolving food hygiene problems.

With regard to sampling, the aim in the United Kingdom was to achieve food safety through good hygiene and safe production procedures rather than attempting to rely on end-product testing. Microbiological end-product sampling was of negligible value. Most microbiological sampling was performed in connection with the investigation of food poisoning and foodborne disease outbreaks. However, the situation was difficult in relation to imported food. A large number of samples of imported frozen cooked shrimps and prawns had been taken in recent years, but it was doubtful whether such sampling made any real contribution to public health. Where problems were identified in connection with imported food, the liaison system between local authorities and the central government health department was used. The central government department would contact the enforcement authorities in the country of origin if necessary and encourage them to enforce suitable standards at the factory in question or if necessary throughout the industry.

^a Guidelines for developing an effective national food control system. Rome, Food and Agriculture Organization of the United Nations/World Health Organization, 1976 (FAO Food Control Series, No. 1; WHO Food Control, No. 1).

In the discussion, it was confirmed that in the United Kingdom no distinction was made between food hygiene and meat and poultry hygiene. One participant believed that the existence of separate inspectors for health and food quality matters was too expensive for some countries; there should be a single inspector whose work would combine both aspects. It was confirmed that there were no special food courts in the United Kingdom. One participant expressed the opinion that the normal criminal courts were not equipped to deal with complex food cases and that special courts were preferable.

In his paper on inspection principles in the Federal Republic of Germany, Dr Teufel mentioned that interstate committees met several times a year to standardize the approach to food control, but there were still different approaches in different states. The organization of the information flow between the different levels was of the utmost importance. The provisions governing food control were contained in the Federal Food Law, which also covered tobacco, cosmetics and other commodities, e.g. cleaning materials, toys, food equipment and utensils. Food control included food hygiene and other safety aspects, as well as composition and labelling.

The main responsibility for food control lay with the field service whose tasks included responsibility for the registration and licensing of food plants where necessary, inspection, sampling, epidemiological investigations of foodborne diseases, consumer complaints, enforcement of food regulations and provision of advice. The food control laboratory and the field service were both necessary and complemented each other. It was stressed that effective food control was only possible where there was an effectively operating field service.

As a rule, the local medical officers or veterinary officers were responsible for food control in their own district or community. They should possess the necessary knowledge in the fields of food hygiene and food microbiology as well as in basic food chemistry and food technology and have experience in food control. They provided guidance to the food inspectors under their supervision. These food inspectors had not usually undergone academic training. In accordance with a federal regulation they were trained over a two-year period. The training was mainly carried out in the field, with intervening periods of lectures, laboratory courses and so on.

The seizure of unsound food usually required the expertise of the academically trained inspectors. In certain situations, collaboration with other bodies having enforcement functions, such as police or customs officials, was necessary. In Berlin (West), there were 44 academic inspectors, assisted by 53 non-academic inspectors. The state regulations specified the frequency of inspection for certain categories of food premises, but there were wide variations between states. In principle, establishments in which easily perishable foods were manufactured, processed or stored should be inspected more often than those dealing in nonperishable foods. Where inspection revealed failures in hygiene at particular premises, more frequent inspection should result.

Systematic sampling by food inspectors in the field service took place in close collaboration with the food control laboratory. This ensured rational use of the capacities of the laboratory and avoided overburdening the laboratory with samples it could not handle. The laboratory should be responsible for organizing sampling. Apart from sampling on grounds of suspicion or for import reasons, routine sampling was considered to be an integral part of preventive food control. As a rule, 5 food samples per 1000 inhabitants per year had to be taken.

In general, the inspection service was functioning quite well, but there was room for improvement. One approach would be voluntary control measures by commercial and industrial organizations and the development of mutual trust between the food inspection services and those organizations.

There were no referee laboratories in the event of disputes over samples. The sampling procedure involved taking two samples, one of which was handed to the owner of the food. Difficulties sometimes arose in court cases where there was a conflict of evidence between the official laboratory and the owner's laboratory.

In the discussion, Dr Teufel confirmed that the sampling of foods of animal origin was more frequent than that of other foods. The owner of the food from which a sample had been taken was not usually informed of the result unless there was something wrong. Food inspectors and laboratory personnel appeared quite frequently as expert witnesses in court.

On a general question concerning food of inferior quality but not unfit or dangerous to health, the Chairman confirmed that the Working Group was mainly concerned with discussing food safety, but quality could be considered if there was time. It was not always possible to separate those two aspects of food control.

Participants then proceeded to outline the food inspection systems in their own countries. There was general agreement that effective inspection was more important than end-product sampling. Sweden had a system of inspectors similar to that in the United Kingdom, but the systems in most other countries seemed to be closer to that followed in the Federal Republic of Germany. In some countries there were very few prosecutions relating to food, while in others there were many. Some countries empowered inspectors to make on-the-spot fines and also to collect them. Inspectors also had the power to destroy spoiled food on the spot. Some other countries empowered the inspection services to impose administrative penalties. In several cases there was overlapping between specialist inspectorates dealing with meat hygiene, fraud control and general food hygiene.

In most countries the lowest level of food inspector received little academic training. The inspection services were usually headed by a medical doctor, a veterinarian or a chemist. Most services were at local government level, with central government direction or advice being available.

In some countries it was admitted that too much sampling was being done without use being made of the results; it was agreed that this was wasteful of resources. In systems where the laboratory services were a main part of the inspection system it was felt that this was an advantage. In one country public pressure was leading to the former food laboratories having to spend more and more time examining environmental samples in connection with air pollution, odours, etc. It was suggested that computers could be used to produce more effective sampling programmes. Some countries had too much food legislation and it was not possible to enforce it all.

Mr Kermode (Chief, Food Quality and Standards Service, FAO) said that FAO and WHO had a clear policy to assist developing countries and strengthen their food control and inspection services. Most of the points raised in the discussion were also relevant to non-European countries. There was a lack of up-to-date food law in many countries and this frequently impeded the development and improvement of the food industry and export earnings. There tended to be a lack of status for personnel involved in food control, often coupled with poor remuneration. Rivalry between inspection services was frequently counterproductive. Rapid urbanization in certain areas was creating an urgent need to establish effective inspection services. Some developing countries were so anxious for technical aid to ensure the quality and safety of food supplies that they were often prepared to fund expert advice from other countries themselves rather than await the receipt of multilateral or bilateral aid.

Mr Davies (WHO headquarters) informed the Working Group that the report of the joint FAO/WHO Expert Committee on Food Safety was expected to be published by the spring of 1984. He emphasized the need for more education of the public in the safe and hygienic handling of food. Strongly supporting the HACCP approach, he indicated that work was being initiated to identify critical control points in domestic kitchens. Other activities currently being undertaken by WHO included the development of a teaching module on safe food, environmental and personal hygiene, and training guidelines for safe food handling in hospitals, restaurants and similar establishments. A provisional list of audiovisual aids was also expected to be available early in 1984.

4. Food inspection

Food inspection per se was seen by the Working Group to have two main aspects:

- (a) inspection of the food itself, including composition and labelling;
- (b) the inspection of all aspects of the handling, processing and storage of food, from production, processing and distribution to the point of sale to the consumer.

In approaching an inspection of premises, it was important for the inspector first of all to obtain an overall view of the operation; that would help to indicate the type of inspection necessary. The type of inspection involved in gathering evidence for a prosecution, for example, would be different from an inspection aimed at improving standards. Inspection of premises could fall under the following headings: people, pollution, plant (including equipment), premises (i.e. structure), processing and packaging.

A suggestion that detailed in-depth inspections should be paid for by the traders concerned was not generally accepted. Check-lists for inspectors were not generally favoured, although it was felt that they could be useful in certain circumstances. The danger was that such lists tended to discourage the inspector from taking an overview of the process and weighing up the critical control points for himself. Inspectors should have the power to act on the spot without always having to refer to higher authority on technical issues. It was useful for inspectors themselves to make simple tests.

There was general agreement that local inspectors would need some back-up from a central authority in relation to food technology. Food inspection was increasingly being recognized as a multidisciplinary function. A good standard of hygiene during manufacture was the best way of protecting the health of the consumer. One participant suggested that there was more danger from inadequate food technology in modern factories than from poor hygiene. In some cases, e.g. milk processing, the product was entirely contained within pipes and the traditional type of inspection was not appropriate.

The effective use of inspectors' time was important. The frequency of inspection of a given establishment should depend on the nature of the hazard. Some participants felt that inspections should be carried out on a "suspicion" basis rather than as a matter of routine. Microcomputers were useful for facilitating reference to records and for identifying problem areas.

Traders sometimes complained that they received inspection visits from a variety of central and local authority inspection services, e.g. food, fire prevention, etc. In Turkey, an attempt was being made to overcome the problem by organizing multidisciplinary inspection teams under the local authority. Another possibility was for the food inspector to take account of other matters not normally within his responsibility, such as price lists.

It was agreed that the food inspector should be involved in epidemiological studies. This was not the case in all administrations, at least not at the lower level of inspector.

Among the attributes required of a food inspector were flexibility and a reasonable attitude. It was not sufficient merely to follow check-lists slavishly. However, such lists could be useful for inspectors with minimal training. The inspector needed to be sufficiently knowledgeable to assess the hazards presented by any particular process. He had to have critical capacity. A good relationship with the laboratory services was emphasized, and it was also necessary for the inspector to collaborate closely with other inspection services, particularly where there were specialized inspection services, e.g. for meat hygiene. Inspectors should not be merely gatherers of samples. In some situations where they were used to take samples under the direction of the laboratory, the value of the sampling was considerably diminished if the inspector did not understand the purpose of it.

The question of using inspectors to monitor residue levels was raised. Some participants considered that inspectors were the wrong people to take samples of this kind or to participate in surveys; they were inclined to be somewhat biased in their sampling since they were trained to look for suspect or doubtful material in their normal work. It was clear that in some systems there was very little communication between inspectors and laboratories.

The food inspector needed to perceive his role within primary health care rather than to see himself purely as an enforcer of food law. He should not be concerned only with enforcing law, but should be prepared to identify areas where the law needed amending or where a new law was required. He should be able to judge the safety of unfamiliar foods, particularly imported foods. It was important for the food inspector to be realistic in the requirements that he imposed on the food trade and industry, and this enlightened approach was more likely to derive from a good education.

The desirability of involving the food industry in the training of inspectors was mentioned. At the University of Aston in Birmingham, United Kingdom, the course for academic food inspectors (EHOs) included lectures by representatives of industry and visits to industrial premises.

The advantages and disadvantages of using multidisciplinary inspectors were discussed. It was pointed out that some developing countries did not wish to establish systems in which the food inspector covered other non-food aspects of environmental health. However, one participant felt that in developing countries it was particularly important for the food inspector to be an EHO, because of the close connection between food inspection and epidemiology. Inspectors should be sufficiently well trained to interpret laboratory reports in relation to their inspection activities, without recourse to advice from academically qualified superiors of another profession. The EEC had a scheme for mutual recognition of qualifications in certain professions, and it might be of advantage if that scheme could apply to food inspectors.

The problem of defining a food inspector frequently arose. It was not possible to arrive at a universal definition owing to the diversity of systems represented. However, it was acknowledged that food inspection was not the exclusive preserve of one particular profession; it was necessary in each country to prescribe the educational requirements of inspectors and to endow them with the legal powers mentioned earlier.

In the countries represented at the Working Group, four categories of inspector were to be found:

(a) two types of academic inspector:

- the professions of medical officer and veterinarian;
- other academically qualified inspectors, e.g. EMOs (as in Sweden and the United Kingdom);

(b) two types of non-academic inspector:

- the inspector with some two years of training in service, supplemented by a certain amount of theoretical and laboratory training (as in the Federal Republic of Germany);
- lay inspectors, usually recruited from the food trade, or former policemen, with very little formal training.

Given these wide variations, it was difficult to make any specific recommendations as to the training requirements for inspectors. Clearly, the inspector had to be of high integrity and to have sufficient statutory powers, e.g. power to enter premises. In view of the increasing importance of the inspector's role in food hygiene education, his ability to communicate was emphasized. Some participants felt that basic inspectors without academic training, who had been recruited from the food trade, were better able to get their message across in the smaller retail premises. It was also suggested that administrations could not afford to use highly qualified academic inspectors at that level. It seemed that in most countries where academic inspectors were used, some form of technical assistance was available for the most basic work.

On the other hand, some participants believed that it was asking too much of a generalist food inspector to cope with modern automated factories; it was felt that this task called for a food technologist. However, a well-qualified generalist inspector could achieve much by asking the right questions, e.g. concerning the application of HACCP. It was generally agreed that the food inspection services required input from a variety of disciplines. Where the whole range of disciplines was not available within the local authority inspection service, help should be available from central authorities. It would be uneconomical to have a wide range of specialists within the local inspection service.

5. Use and abuse of microbiological specifications

The Working Group agreed that the emphasis should be on microbiological guidelines in preference to mandatory standards. Unfortunately, some countries tended to incorporate in their law microbiological specifications which were intended only as guidelines. In establishing microbiological criteria, there were a number of important factors to be considered.^a First, it had to be decided whether there was a need for a criterion or whether a requirement for inspection of processing would be more useful. It was important to consider cost-benefit, i.e. the calculation of the benefit derived in relation to the cost. It was very difficult to assess the cost of food poisoning, but it had been suggested that currently the cost of eradicating Salmonella from live animals would exceed the benefit gained from preventing Salmonella food poisoning. Consequently, in the case of poultry, for example, there was no point at the present time in requiring the absence of Salmonella in the raw meat.^b

Efficiency also had to be considered. Was the specification the most efficient and practical means of achieving the end? Attainability also needed to be taken into account. A specification should be attainable through adherence to good manufacturing practice. Action that had to be taken in the event of failing to meet a criterion should be considered. Food should not be needlessly destroyed merely because it exceeded the recommended limit. Relevant organisms had to be considered; only those of relevance should be included in the criterion. Methodology needed to be specified, and there had to be a sampling plan that was administratively and economically feasible. The limit values for end-products should be based on reliable data. The microbiology

^a General principles for the establishment and application of microbiological criteria for foods. Document ALINORM 81/13, Appendix II, Codex Alimentarius Commission, Fourteenth Session, 1981.

^b The eradication of Salmonella from food and feeding stuffs is discussed in: WHO/WAVFH Round Table Conference on the Present Status of the Salmonella Problem (Prevention and Control): report. Geneva, World Health Organization, 1981 (document VPH/81.27).

of the raw materials, as well as of the product at critical points in production, storage and distribution, should be taken into account. There was no point in establishing criteria which would require objectionable treatments of the product, e.g. those which might impair its nutritional quality.

The application of criteria for meals was difficult. Some countries had established criteria for precooked frozen meals and precooked chilled meals produced under defined conditions. Work was being carried out on the application of criteria to meals generally, but the task was difficult because of the wide range of conditions under which meals were produced.

It was agreed that a criterion could appear in international legislation on the basis that, if the limit values were exceeded, other action would be indicated in relation to production, but excluding the rejection or destruction of the food. The finding of levels in excess of the limits would indicate that something had gone wrong in processing; the criteria only caused problems in legislation if there was a penalty for exceeding the limits.

In some countries, there were standards related to the presence or absence of pathogens, and in that case there might be a penalty for contravening a standard. The danger with microbiological specifications was that it was sometimes easier to examine samples than to make a thorough food inspection. The example was cited of hospital food hygiene, where authorities in one country demanded microbiological specifications instead of a thorough inspection of the kitchens. It was suggested by one participant that inspection services headed by microbiologists tended to overemphasize the value of microbiological specifications.

It was agreed that microbiological specifications were justified where epidemiology had shown a need for them; in several countries standards had been elaborated on that basis for milk, ice cream and egg products, which historically had been associated with bacterial food poisoning and foodborne disease. However, in those cases the criteria were concerned mainly with establishing that the required heat treatment process had been applied.

One country was in the process of accepting criteria for 11 groups of foods. It was emphasized that those criteria were not intended to judge the fitness of the food, but rather to indicate the hygienic adequacy of the handling of the food. It was felt by some participants that food inspection laboratories should be integrated with the public health service. There was concern about the ability of inspectors in some countries to use correct methods for taking microbiological samples and transporting them to the laboratory without contaminating the sample. There was also criticism that in some systems inspectors failed to communicate to the laboratory the reasons for taking the sample.

In conclusion, it was agreed that microbiological examination should be used in support of the inspection system and not as an alternative. It could be used to improve hygienic practices in certain industries. Specifications could be used to ensure that certain processes had been applied. Where microbiological guidelines were established, this should be done in accordance with the principles elaborated by the Codex Alimentarius Commission.^a

The HACCP system^b

In food production, HACCP was a concept that could be applied at all stages and, if properly applied, would reduce the amount of time spent on inspection because records of the monitoring results should be available. Among its advantages was the stimulation of a better dialogue between the food inspector and the food industry, a more cost-effective approach to food inspection, and greater safety through concentration on the critical control points.

There were six essential steps in the establishment of a complete HACCP system in industry:

- (1) a description of the physicochemical characteristics of a finished product that influence the growth, death and survival of microorganisms, including storage conditions, pH, water activity, presence of preservatives, packaging and gas atmosphere, and anticipated consumer use or abuse;

^a General principles for the establishment and application of microbiological criteria for foods. Document ALINORM 81/13, Appendix II, Codex Alimentarius Commission, Fourteenth Session, 1981.

^b See Annex 1.

- (2) the production of a flow-sheet showing all steps in the manufacture of the product and detailing processes such as drying and pasteurization, storage tanks and other points where the product might be held, together with the holding temperature, and a prediction of what could happen at each point (hazard analysis); cleaning frequency and the equipment required should be specified;
- (3) a study of the microbial ecology of the product, including challenge tests involving inoculation studies, consideration of possible problems with the product during storage and an evaluation of the effect of processing;
- (4) identification of critical control points in the system;
- (5) monitoring of critical control points, including observation and regulation of equipment where necessary and the taking of corrective action.
- (6) recording of the results of monitoring, allowing trend analysis and review by food inspectors.

Finally, there should be feedback on any problems arising from the product, including feedback of epidemiological investigations. Setting up the system within industry required multidisciplinary consultation, which would include engineers, technologists, microbiologists, chemists and, if desired, food inspectors. The system was not only relevant to the food manufacturing industry; it could also be applicable to large food service establishments and even to farms. One of its greatest advantages was the dialogue and improved understanding it promoted.

The Working Group considered whether the system could be applied to the smaller catering establishments. It was acknowledged that this was difficult but by no means impossible. The application of HACCP required a certain amount of imagination in any system. It was difficult for a caterer to use the system without having the necessary technical experience. One participant suggested that the approach should be applied to national food hygiene regulations; this might result in a re-evaluation of some of the requirements and the removal of unnecessary regulations.

It was pointed out by one member of the Working Group that, in relation to catering, it was already known from recent studies which practices contributed to outbreaks of food poisoning. Another participant considered that HACCP was too scientific a system to be applied by food inspectors. There was general agreement that it was the responsibility of industry to set up the system in each particular establishment; although that was not the task of the food inspector himself, he should take a particular interest in monitoring the system.

The HACCP concept should be stimulated by the inspection service as a means of increasing the cost-effectiveness of its operations. Inspectors should encourage trade and industry associations to promote the system among their members. By involving themselves in this way, the inspection services could help to strengthen the essential dialogue with trade and industry.

7. Auto-control in the food industry

Continuing the theme of cost-effectiveness and reduction of inspection time, the Working Group considered systems already in operation in some countries where food manufacturers certified the compliance of their own products. That was not a complete alternative to inspection by authorities, but it could lead to economies in inspection time. Inspectors should examine the critical control points and laboratory records. The system was used both in relation to food exports and, in federal states, in interstate trade. It was necessary for the food inspector to be satisfied that the company laboratory was operating satisfactorily. Many of the smaller food processors would be unable to participate in the system through lack of the necessary laboratory expertise, but it was sometimes possible for them to utilize recognized trade and industry organizations. The amount of supervision of such schemes by inspection services should depend on the quality of the company's self-certification programme.

A participant from a country with experience of the system said that it should allow inspectors to concentrate their time on those plants not within the system which required more supervision. There was a possibility that the reduction in inspection time could increase the cost-effectiveness of the food inspection service. One of the benefits was that, where a company participated in the scheme, it was not necessary for the authorities to take samples from every batch of the product for export. Some participants questioned the validity of the claim that the scheme resulted in a financial saving. One said that the main advantage to the producer was in terms of his liability under the law; by demonstrating his involvement in the scheme and the controls adopted, he would be looked upon with favour by a court in the event of a prosecution.

Some participants were concerned that the system could imply that official control was less effective. It was pointed out that the system was in most cases largely a matter of improved quality rather than safety. One participant mentioned that in his country it was forbidden for food producers to quote official laboratory results in the promotion of their products.

Several participants acknowledged the advantages of using the results from industry as a means of avoiding duplication with official sampling. In one country it was the other way round, with the distribution trade pressurizing the enforcement services to take more samples of the products supplied. There was general agreement on the benefits in terms of reducing the workload of inspection agencies, but several participants were unhappy about the system enabling enhanced claims concerning product quality to appear on labels.

One participant asked whether, in the light of the foregoing discussion, full-time official meat inspection in slaughterhouses was not a waste of resources. It was pointed out that EEC directives requiring full-time inspection were based on Codex Alimentarius principles, which also required full-time inspection. There was a trend, however, towards moving the point of control in relation to zoonoses to the farm.

There was disagreement among participants on the acceptability of auto-control (self-regulation), and it was not possible to make an unqualified recommendation of the concept at this stage.

8. Imported food

Imported food presented special problems with regard to the monitoring of microbiological safety, because it was clearly not possible for inspection authorities in the importing country to have direct control over processing conditions. Participants were unanimous in condemning the practice of excessive sampling by port authorities. It was a form of end-product sampling and, that being so, it was impossible to devise sampling schemes which would provide any real assurance of safety. Some countries took one sample from each import batch and accepted or rejected consignments on the basis of the results of that sample.

The existence of strict liability legislation in some countries encouraged importers to protect themselves by having samples analysed by private laboratories, but the Working Group considered that a better assurance for the importer would be to require his overseas supplier to adopt the HACCP system. In some cases, that would require the importer to inspect the overseas plant.

There was concern over the ill feeling caused in some producing countries when receiving countries insisted upon inspecting plants, but until there was mutual recognition of the effectiveness of different inspection systems, such a situation seemed inevitable.

In one country, sampling of imported food was the responsibility of the customs authorities, who tended to take vast numbers of samples, but to little avail. It was admitted that some countries rejected batches of imported food and permitted them to be exported to other countries where it was known that the port authorities would be unlikely to reject the consignment. Reference was made to the Codex Alimentarius Commission's Code of Ethics for International Trade in Food^a and the GATT Agreement.^b Article 2.2 of GATT stipulated that, where technical regulations or standards were required and relevant international standards existed or their completion was imminent, parties were to use them or the relevant parts of them. Article 5.1.1 stated that imported products were to be accepted for testing under conditions no less favourable than those accorded to like domestic or imported products in the comparable situation, and Article 5.1.2 stated that the test methods and administrative procedures for imported products were to be no more complex and no less expeditious than the corresponding methods and procedures, in a comparable situation, for like products of national origin or originating in any other country.

9. Sanctions

The members of the Working Group were unanimous that inspection authorities should move away from a purely policing activity to education and persuasion. That called for food inspectors who were not only technically and scientifically competent but also good communicators. However, in

^a Code of ethics for international trade in food. Joint FAO/WHO Food Standards Programme, CAC/RCP 20-1979.

^b Agreement on technical barriers to trade. General Agreement on Tariffs and Trade, Geneva, 1979.

the case of serious offences, such as the sale of poisonous food, legal proceedings were justified, and one participant held the view that a prison sentence was the appropriate penalty in such cases. Some countries had provision for administrative sanctions by the food inspection services for less serious offences, e.g. on-the-spot fines. In some countries, the inspectors were also empowered to collect the fines.

Powers for inspectors to seize food were considered to be important. In some systems, the inspectors were also empowered to destroy food. In systems with inspectors of various levels of education, it was usual for the decision on seizure to be referred to the graduate inspectors. Seizure was not meant to be a punishment, but it was important to remove dangerous or hazardous food from the market-place. Another valuable form of sanction was the ability to close premises. In some systems, the administration had the power to do this for short periods of time, but in the event of repeated contraventions the court could close food premises permanently. In some administrations there were numerous prosecutions, while in others they were very rare.

Where prosecutions were made, the publicizing of these was an important additional "penalty" which could have a greater effect than the fine itself.

10. Education and training of food handlers and consumers

The educational role of food inspectors in their routine inspection work was a recurrent theme. In addition, it was agreed that inspectors should promote food hygiene education among food handlers at all levels. Reservations were expressed by a few participants about the ability of inspectors to do the educating, since they regarded that as the preserve of specialist educators. It seemed that only the academic inspectors were really suitable for formal teaching of that kind. The importance of ensuring that all levels of food handlers, from managers down to the lowest workers, received adequate food hygiene education was stressed. In one country, the food inspection service had made a point of checking the curricula for various courses undertaken by food handlers and, where necessary, had recommended that hygiene matters should receive more attention.

In one country, it was a requirement that owners of food businesses had to demonstrate that they had undertaken an approved food hygiene course before they could be licensed by the inspection service to run the food business.

The food hygiene education of consumers was discussed. Some participants were sceptical as to its value, and it was mentioned that in one country, although consumers considered themselves well versed in food hygiene, they were, in fact, only interested in more emotive issues, such as the question of additives. In principle, education of the public in this field was felt to be important, particularly in view of the known incidence of bacterial food poisoning in domestic kitchens. Such education should begin early in life.

11. The food inspector: a professional profile

The Working Group also reviewed the draft of a paper entitled "The food inspector: a professional profile", being prepared by WHO headquarters and intended to provide countries with a model of what the duties of a professional food inspector should be. The profile was also aimed at those countries where food inspection services were in an embryonic stage of development, and it contained information on the scope of food inspection services as well as outlining model training curricula at both undergraduate and postgraduate levels. The profile could also be of use to those countries which were considering restructuring or upgrading their existing food inspection services.

The draft document was, in the main, well received, and it was noted that its contents agreed in general with the Working Group's recommendations and conclusions.

12. Conclusions

(1) Food inspection has two main aspects:

(a) the inspection of the food itself, including composition and labelling;

(b) the inspection of all aspects of the handling, processing and storage of food (premises, etc.), from production, processing and distribution to the point of sale to the consumer.

(2) Safety and hygiene aspects can be more cost-effectively controlled by the inspection referred to in (1)(b) than end-product testing. However, end-product testing is still appropriate for the control of composition and labelling.

(3) The HACCP system is the most cost-effective means of ensuring the production of safe food. This concept embodies long-established principles that can be applied throughout the food chain. It is increasingly being adopted by trade, industry and inspection services.

(4) By ensuring that the HACCP system is being properly applied and is verifying the monitoring results and laboratory quality control programmes, food inspection can be made more cost-effective. Where an HACCP system has been successfully applied, it should be possible for the food inspection service to economize on inspection time.

In relation to food hygiene, the adoption of HACCP, wherever feasible, should permit the inspection services to concentrate their activities on those premises (e.g. catering premises) which have been shown by epidemiological evidence to be associated with foodborne disease outbreaks. The HACCP concept can equally be applied to other aspects of food safety, e.g. contaminants.

(5) HACCP creates ideal conditions for strengthening the dialogue between trade and industry and inspection agencies. Such a dialogue is of mutual benefit in achieving safety in a cost-effective way.

(6) Education and persuasion are preferred to penal sanctions as a means of achieving food safety.

(7) An important objective of inspection should be to advise and educate rather than exclusively to perform a policing function.

(8) Coordination between the inspection services in any country is essential in order to avoid overlapping and even neglect of certain areas of food inspection. This coordination is particularly critical in federal countries where each state has competence in matters of food control. It is important to establish mutual trust between inspection services, both within individual countries and internationally. The ultimate goal should be mutual trust between inspection services in different countries.

(9) The control of imported foods is, in general, dependent upon end-product testing. However, it is increasingly recognized that it is impracticable to devise, in relation to the microbiology of imported foods, sampling schemes capable of ensuring acceptable levels of public health protection. A more effective approach would be to encourage importers to require their suppliers to adopt the HACCP system. This may require special arrangements to be agreed between importers and exporters, e.g. recognition of export certificates or inspection. Wherever possible, food inspection services should accept test results, certificates or marks of conformity issued by the relevant inspection service in the exporting country. In accordance with the principles of the Codex Alimentarius, foods imported into a country should be treated no less favourably by the inspection services than foods of national origin. Food inspection of imported products should not create unnecessary obstacles to international trade.

(10) In general, the education and training of food handlers is one of the most effective means of improving hygienic practices, and the food inspector is called upon to play an important role in this.

(11) Food hygiene education of the consumer is necessary to reduce the incidence of domestically caused foodborne illness. The education on basic elements needs to be introduced as early as possible, as part of personal hygiene education, starting ideally in primary school.

(12) Current food inspection requires a wide range of expertise appropriate to the tasks of the service, supported by outside experts where necessary. However, the adequately trained food inspector will remain the core of the service. The level of training of inspectors will depend upon their level of responsibility within the service.

(13) Good laboratory support for inspection and good communication between inspectors and laboratories is essential for an effective inspection service.

13. Recommendations

(1) Food safety should be recognized as of paramount importance for the protection of the health of the community, and as one of the main components of primary health care and preventive medicine.

(2) Since safety and hygiene can be controlled more cost-effectively by food hygiene inspection than by end-product testing, food inspection services should place emphasis on inspection rather

than end-product testing. This inspection should include all aspects of the handling, processing and storage of food (premises, etc.), from production, processing and distribution to the point of sale to the consumer.

(3) The General Principles for the Establishment and Application of Microbiological Criteria for Foods,^a as elaborated by the Codex Alimentarius Commission, should be followed when setting up microbiological criteria for finished products in national or international legislation.

(4) When microbiological criteria are set, they should be used to identify non-compliance with hygiene rules and to correct bad manufacturing practice.

(5) The HACCP concept, already included in Codex Alimentarius Codes of Hygienic Practice, should also be used in national and international food legislation, so that special emphasis is placed on hazardous foods and the identification of critical control points.

(6) The application of HACCP should be considered as a means of improving the efficiency of the food inspection service. The food inspector should be provided with guidance on the monitoring of these points.

(7) The frequency and completeness of inspection of each food business should be related to the adequacy of its own quality control programmes.

(8) Inspection services should try to achieve mutual understanding with the food trade and industry. The involvement of the food inspection services in identifying critical control points and establishing monitoring procedures is one means of achieving this.

(9) Food importers should be encouraged to require their suppliers to adopt the HACCP system. This may require special arrangements to be agreed between importers and exporters, e.g. recognition of export certificates or inspection. Wherever possible, food inspection services should accept test results, certificates or marks of conformity issued by the relevant inspection service in the exporting country. In accordance with the principles of the Codex Alimentarius, foods imported into a country should be treated no less favourably by the inspection services than those of national origin. The inspection of imported food should not create unnecessary obstacles to international trade.

(10) The main emphasis in food inspection should be on advice and education rather than punitive sanctions. Sanctions should be reserved for deliberate violations of the law and for instances of serious negligence.

(11) The education of food handlers in food hygiene is one of the most effective means of improving hygienic practices and should be applied to all levels, from management to food handlers. It should be recognized as an essential element in all training courses for food handling and food management personnel. The food inspector should play an important role in this. Particular effort should be concentrated on those food handlers involved in situations known to be associated with outbreaks of foodborne infections and intoxications.

(12) The education of the consumer in food hygiene is necessary to reduce the incidence of domestically caused foodborne disease. Education on basic elements should be introduced as early as possible, as part of personal hygiene education, starting ideally in primary school. Food inspectors should actively promote and participate in such education at every possible opportunity. Application of modern techniques of communication should be considered.

(13) Coordination between food inspection services, both within and between countries, should be improved. The ultimate goal is mutual recognition of the effectiveness of different systems. International harmonization of requirements for foods and of inspection procedures would help to achieve this.

(14) In some countries, the training of food inspectors may need to be raised to a higher level. It would be appropriate for international bodies, such as FAO and WHO, to suggest suitable curricula, using the professional profile discussed in this report.

^a General principles for the establishment and application of microbiological criteria for foods. Document ALINORM 81/13, Appendix II, Codex Alimentarius Commission, Fourteenth Session, 1981.

Annex 1



WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

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ORIGINAL: ENGLISH

REPORT OF THE WHO/ICMSF¹ MEETING ON HAZARD ANALYSIS:
CRITICAL CONTROL POINT SYSTEM IN FOOD HYGIENE

Geneva, 9-10 June 1980

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¹ International Commission on Microbiological Specifications for Foods.

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PREFACE

In view of the emphasis given to the application of Hazard Analysis Critical Control Point (HACCP) by the WHO Expert Committee on Microbiological Aspects of Food Hygiene (1976),¹ the World Health Organization proposed that this be further studied and practical guidelines elaborated for its use in both developed and developing countries.

The purposes of this meeting were: (1) to review the literature relating to HACCP; (2) to collect information on the practical use of the system; (3) to assess its practical use in developing as well as in developed countries; and (4) to prepare a guide for this system, particularly for its potential use in developing countries.

I. INTRODUCTION

Microbiological hazards in food, which may result in either human illness or food spoilage, are well documented. In terms of human morbidity alone, the importance of microbiological hazards exceeds that of the other health hazards associated with foods, such as pesticide residues, food additives, chemical toxicants, and natural poisons or toxic substances. While incidence data are incomplete, available information provides considerable cause for concern (Todd, 1978; Vernon, 1977).

Numerous microbiological agents of food-borne disease have been identified (WHO, 1976; Speck, 1976; ICMSF, 1978), and factors that influence the occurrence, development and control of hazardous numbers or concentrations of these agents in foods have been described (ICMSF, 1980a,b). Although the epidemiology and control of many food-borne disease-causing agents have been described in considerable detail, the role of other agents is yet to be determined (Riemann & Bryan, 1979).

With regard to food spoilage, the literature is replete with studies dealing with the nature, causes and control of microbiological spoilage or deterioration of many food commodities (ICMSF, 1980b). As a consequence, specific spoilage problems have been identified, and the principles on which control programmes can be based have been established. Nevertheless, the economic losses continue to be enormous.

New and modified technologies may introduce additional opportunities for the entry of microbiological contaminants and for their survival or proliferation along the food chain, which may require new approaches to hazard control.

The places in the food chain where foods may be mishandled are numerous. Three such places are food processing or manufacturing plants, food service establishments (e.g., restaurants, cafeterias, and institutional kitchens), and homes. Available surveillance data indicate that the incidence of food-borne disease outbreaks caused by mishandling foods in food processing plants is very much lower than mishandling foods in food service establishments or in the home (Health and Welfare Canada, 1976-1979; United States Department of Health, Education, and Welfare, 1975-1979). However, whilst the number of outbreaks attributed to faulty processing is relatively few, the potential for involving large numbers of persons is high, particularly for foods distributed regionally, nationally or internationally. Therefore, rigorous and continuing application of control measures to prevent food-borne illness and food spoilage arising as a result of poor processing or manufacturing practice is necessary.

¹ WHO Technical Report Series, No. 598, 1976.

II. CONTROL OPTIONS

Traditionally, three principal means have been used by governmental agencies and commercial organizations to control microbiological hazards of foods. These are education and training (A), inspection of facilities and operations (B), and microbiological testing (C). Sophisticated programmes utilize combinations of all three approaches.

A. Education and training

Education and training programmes for the control of microbial hazards of foods are directed primarily towards developing an understanding of the causes of microbial contamination, including the survival and/or growth of the contaminants. An appreciation of personal hygiene, community sanitation and food hygiene should be acquired during primary and secondary education. The extent of training required depends upon the technical complexity of the food operations and the level of responsibility of the individuals involved. Broad in-depth training may be necessary for some, e.g., supervisory personnel; for others, training may relate only to some specific aspects of a food operation. Trained personnel should be able to select and apply control measures that are essential for providing safe products of acceptable quality.

B. Inspection of facilities and operations

Inspection of facilities and equipment and observations of hygienic practices of personnel which are often required by regulatory authorities are commonly used to check adherence to good food handling practices. Such practices may be those considered essential by the inspector, or they may be specified in various advisory or mandatory documents, such as Good Manufacturing Practice (GMP) guidelines, Codes of Hygienic Practice (such as those developed by the Codex Alimentarius Food Hygiene Committee), or food control laws, ordinances or regulations. Unfortunately, such documents often contain vague terms, such as "satisfactory", "adequate", "acceptable", "if necessary", "suitable", relative to some stated requirement, without specifying what is considered to be in compliance with the requirement. This lack of specificity, or some indication of the relative importance of the requirement, leaves the interpretation of compliance solely to the discretion of the inspector. Lack of discrimination between important and relatively unimportant requirements may result in over-emphasis upon unnecessary or relatively minor requirements and thus increase costs without significantly reducing hazards. Also, requirements that are critical to the safety of the product may be overlooked or underestimated.

C. Microbiological testing or examination

Samples of ingredients, materials obtained from selected points during the course of processing or handling, and the final product are sometimes examined for microorganisms. Such sampling and testing assist in determining adherence to good manufacturing, handling and distribution practices. In some instances, foods are examined for specific pathogens or their toxins (e.g., salmonellae or staphylococcal enterotoxins). More often, however, examinations are made to detect either organisms that are indicative of the possible presence of pathogens or spoilage or for specific spoilage organisms. Microbiological criteria (i.e., standards, specifications and guidelines) that state acceptable numerical limits for microorganisms in foods are useful to government and industry. Principles of sampling and the establishment and application of microbiological criteria have been proposed (FAO/WHO, 1979), and sampling plans, test procedures, and decision criteria (limits) for many foods have been suggested (ICMSF, 1974).

D. A modified approach

Whilst the above control options are widely applied, singly or in combination, there is little epidemiological evidence of their effectiveness, as the incidence of food-borne disease remains high even in the developed countries that apply these measures. Concern over apparent lack of success in this respect, as well as the need to reduce costs associated with assuring the safety and quality of foods, has led to the development of a more rational approach based

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on the Hazard Analysis Critical Control Point (HACCP) system. This HACCP concept, first presented at the 1971 National Conference on Food Protection (United States Department of Health, Education, and Welfare, 1972), was originally developed for use in food processing establishments (Kaufmann & Schaffner, 1974), but it has been extended more recently to food service establishments (Bobeng & David, 1977; Bryan & McKinley, 1979; Bryan, 1980), and to the home (Zottola & Wolf, 1980).

III. HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM

The Hazard Analysis Critical Control Point (HACCP) system consists of: (1) an assessment of hazards associated with growing, harvesting, processing/manufacturing, distribution, marketing, preparation and/or use of a given raw material or food product;¹ (2) determination of critical control points required to control any identified hazard(s);² and (3) establishment of procedures to monitor critical control points.³ Basically, the HACCP system provides a more specific and critical approach to the control of microbiological hazards than that achievable by traditional inspection and quality control procedures.

A. Hazard analysis

A hazard analysis consists of an evaluation of all procedures concerned with the production, distribution, and use of raw materials and food products: (1) to 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) to find sources and specific points of contamination by observing each step in the food chain; and (3) to determine the potential for microorganisms to survive or multiply during production, processing, distribution, storage, and preparation for consumption.

The participants did not deal with HACCP in growing and harvesting areas but thoroughly discussed the application of this system in processing plants, food service establishments and the home.

1. In food processing plants

A hazard analysis should be carried out on all existing products and on any new products that a processor intends to manufacture. Changes in raw materials used, product formulation, processing, packaging, distribution, or intended use of the product should indicate the need for re-analysis of hazards, because such changes could adversely affect safety or shelf life. Microbiological hazards will vary from one product to another, depending upon the raw materials, the processing procedures, the manner in which the finished product is marketed, and its ultimate use. They may vary from one food processing plant to another producing the same product and therefore must be determined by observations and investigations of the particular processing plant.

Hazards caused by microbiological contamination of raw materials must be evaluated. In some cases, microbiological safety and shelf life depend almost entirely on the selection of microbiologically suitable raw materials. For example, in the manufacture of dry blended products which are reconstituted without further heating, processing cannot be relied upon to eliminate contamination present in raw materials. Also, the stability of low-acid canned foods is dependent upon control of the level of thermophilic spore-forming bacteria in the ingredients.

¹ "Hazards" include contamination of food with unacceptable levels of food-borne disease-causing microorganisms and/or contamination with spoilage organisms to the extent that hazards occur within the expected shelf life or use of the product.

² "Critical control point" is a location or a process which, if not correctly controlled, could lead to contamination with food-borne pathogens or spoilage microorganisms or their survival or unacceptable growth.

³ "Monitoring" is the checking or verifying that the processing or handling procedure at the critical control point is properly carried out.

Food products manufactured from raw materials of animal origin should receive special attention because they are the main source of different food-borne diseases in man (salmonellosis, campylobacteriosis, yersiniosis). Other food products that can be assumed to be contaminated with pathogenic microorganisms are of vegetable origin. Such ingredients must be carefully considered in a hazard assessment of processes that utilize them.

Many of the processes used in food manufacture, such as heat treatment, acidulation, fermentation, and salting, will destroy or inhibit the growth of harmful microorganisms. However, other procedures, such as cooling of cooked products, boning of cooked meats, chilling of cans after sterilization in retorts, and slicing of processed meats, may add harmful microorganisms. Hazards associated with these procedures must be evaluated, and the consequences of failure of processing steps designed to destroy or inhibit harmful microorganisms must be understood. For example, the failure of a starter culture to initiate acid production promptly may permit the growth of staphylococci and enterotoxin production during the manufacture of cheese or fermented meats. Failure to allow for the equilibration of pH in an acidified canned food during pasteurization could result in growth of Clostridium botulinum spores. Similarly, failure to "vent" a retort properly prior to heat processing could result in cold spots, thus leading to under-processing and failure to destroy C. botulinum.

The physicochemical characteristics of a finished product that influence growth, death, or survival of microorganisms should be identified. These include such factors as water activity, pH, the presence of preservatives, the packaging system, and the gaseous environment within it. If interactions between various physical and chemical agents are relied on for safety, e.g., a_w and pH, pH and preservatives, packaging and gas atmosphere, fermentation and pH reduction, then these factors must be defined in terms of their influence on the microbial flora during processing, distribution, storage, and use by the consumer.

Hazard analysis should include an evaluation of the potential of the food processing plant environment as a source of contamination to the finished product. For example:

To what extent is there opportunity for cross-contamination between contaminated raw materials and finished goods?

Is air movement away from finished goods and toward raw materials?

Are there steps, such as the manual handling of products that are eaten without further cooking, where employees could contaminate the finished product with pathogenic microorganisms?

Is the cooling water of satisfactory microbiological quality?

2. In food service establishments

Each phase of food preparation operations - from taking delivery of foods to serving - should be examined step by step for sources or means of contamination, possibilities of the contaminants surviving heating processes, and likelihood of microbial growth. Particular attention should be given to foods and food preparation procedures that are known from epidemiological studies to be a hazard (Bryan, 1978; ICMSF, 1980b). A few examples are as follows:

Raw meat, poultry, eggs, fish and rice are frequently contaminated with food-borne pathogens when they reach food service establishments. For example, poultry frequently harbours salmonellae which may be spread to surfaces of equipment, to the hands of workers and to other materials. The possibility of cross-contamination to cooked foods must be checked during hazard analyses. For products eaten raw, such as certain fish (common in Japan), oysters, clams, etc., hazard analyses must concentrate on chilling practices before and after these products arrive at the establishment.

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If frozen turkeys are not completely thawed before cooking, salmonellae may survive the cooking process. Also, the interiors of rolled roasts, meat loaves and various ground meat products may contain food-borne pathogens. The significance of such contamination must be considered in any hazard analysis of a food service operation which offers these products. Therefore the thoroughness of cooking these products must be evaluated.

Food handlers constitute a hazard. Cooked ingredients in potato salad, for instance, can be contaminated by persons during peeling, slicing, chopping or mixing operations in its preparation. Hazard analysis should therefore include observations of food handling and hand-washing practices of the kitchen staff.

Epidemiological information indicates that the most important factors contributing to the occurrence of food-borne disease outbreaks are related to operations that follow cooking. For instance, rice becomes hazardous after cooking when it is left unrefrigerated for several hours or stored in large masses in large pots overnight. These conditions may permit growth of *Bacillus cereus* and formation of heat-stable toxin. Hazards intensify as the time between preparation and serving of food lengthens. Hazard analyses must assess conditions after cooking, while keeping food hot, cooling and cold storage, and reheating practices.

3. In the home

Homemakers can examine their kitchen environments for hazards only if they are aware of these hazards. Such awareness can result only from education, i.e., at home during childhood, in school, in special courses on homemaking, from publications from various sources and through experience.

B. Critical control points

A critical control point is a location or a process which, if not correctly controlled, could lead to unacceptable contamination, survival, or growth of food-borne pathogens or spoilage microorganisms.

1. Determination at food processing plants

Incoming raw materials may constitute critical control points, depending upon their origin and use. If one or more steps in a process can be depended upon to eliminate harmful microorganisms in a particular raw material, that raw material does not constitute a critical control point. For example, the testing, for *Salmonella*, of eggs used in the manufacture of mayonnaise is not usually a critical control point because most countries require mayonnaise to be so formulated that its content of acetic acid and pH will kill these organisms. Also, if the consumers' use of the product destroys contamination, for example, as in the cooking of raw pork sausage, then inspection of the incoming raw pork does not constitute a critical control point. Microbiological examination of such raw materials only provides an indirect means of evaluating general microbial quality. Organoleptic evaluation will often provide more useful information.

If, on the other hand, neither processing techniques nor consumer use can be depended upon to eliminate harmful microorganisms from raw materials, then these constitute critical control points. Particularly important in this respect are sensitive raw materials, e.g., dried eggs and milk which may contain salmonellae, and nut meats which may be contaminated with mycotoxins. If raw materials are not controlled at this point, the harmful microorganisms or toxins they may contain are likely to contaminate finished products, such as chocolate confectionary and beverages that are not heated before consumption.

Raw spices may be heavily contaminated with spore-forming organisms which may lead to a significant loss of expected shelf life of cooked sausages; Thus, the examination of such spices for spore-forming microorganisms constitutes a critical control point. However, spore-forming microorganisms in spices used, for instance, in small amounts at meal time to flavour food are not a critical control point, because they have no relevance to quality or safety.

Processing time-temperature combinations are frequently the most critical control points. For example, if a heat process is depended upon to destroy microorganisms, then the required combinations of processing time and temperature must be carefully established and followed. Similarly, the temperatures at which products are held prior to and during cooling and freezing and the length of time they are held are frequently critical control points.

Amongst other factors that can adversely affect safety and quality is improper sanitation in the plant, and packaging materials. If poor sanitation in a particular process step is likely to affect adversely safety of the finished product this would constitute a critical control point. Products may be subjected to environmental contamination from such sources as air, water, insects, rodents and personnel. Incoming packaging materials do not usually constitute a critical control point, except in the case of containers used for canned foods, where lack of integrity of the finished package may affect the safety or quality of the end product.

The critical control points in the manufacture of a number of different types of food products have been described (Corlett, 1973, 1978, 1979; Peterson & Gunnerson, 1974; Ito, 1974).

2. Determination in food service establishments and homes

Much of the discussion in the previous section is applicable in principle to food service operations and to homes. Places or points in food service operations or in homes where foods are handled or stored after cooking are particularly important critical control points. These points include the handling of cooked foods, keeping hot, cooling, cold storage and reheating (Bryan, 1978, 1979, 1980).

C. Monitoring

After analysing the hazards presented by a particular product and identifying critical control points, it is necessary to establish monitoring systems to ensure that these points are under control. Such monitoring may involve only visual inspection - for example, the pre-operational inspection of a temperature recorder to determine that the chart has been properly installed. Similarly, since the safety of boned cooked chicken may be affected by handling by employees, hand-washing procedures should be observed. Although such observations do not involve measurements, they should be recorded on suitable check lists. More commonly, chemical, physical or microbiological tests are used for monitoring.

For each critical control point the appropriate monitoring test must be determined, the procedures documented and the frequency of testing specified. Applicable statistically sound sampling plans must be employed. For example, for critical control points involved in canning operations, evaluation and sampling procedures are available (FDA, 1973a; FPI, 1975). Similar sampling plans have been recommended for the microbiological examination of other foods (National Academy of Sciences, 1969; ICMSF, 1974).

1. At food processing plants

In no phase of food processing is monitoring of critical control points so essential to the safety of the finished products as in the manufacture of low-acid canned foods. Indeed, in the United States, such monitoring is subject to federal regulations (FDA, 1973a,b; FPI, 1975). The extent of such monitoring has been reviewed by Ito (1974). Safety of low-acid canned foods is based upon the establishment of heat processes capable of destroying microorganisms of public health significance and of spoilage types likely to grow at normal ambient temperatures. Physical and chemical tests are performed during production to ensure that all factors necessary to the application of the established safe processes have been adequately controlled. Numerous checks and tests are made at various critical control points, including the adequacy of ingredient blending, determination of consistency, ratio between solids and liquids, weight of product placed in the container, amount of head space, adequacy of the double-seam, time and temperature during sterilization in retorts, quality of cooling water, and post-processing handling of cooled cans. There is no intent, here, to indicate all of the points that are monitored. Rather, the object is to emphasize the importance of checking each critical control point to ensure that the established procedures have been properly

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carried out. This necessitates specifying the method for measuring each parameter, the determination of satisfactory limits for each test and the determination of the frequency with which the tests and checks will be employed. The results of these tests must be recorded. If a defect is observed, remedial action should be taken and documented.

Monitoring systems for nonsterilized foods are also often complex and detailed and may involve microbiological examinations, for example, the production of non-fat dried milk or dried egg solids. The prime hazard presented by both products is the danger of post-processing contamination with Salmonella. Such products should therefore meet microbiological criteria recommended by the National Academy of Sciences (1969) and ICMSF (1974), and those often required by regulatory agencies. Assuming monitoring of the pasteurization process indicates proper time and temperature relationships, the most likely source of contamination of the finished product would be the environment. It has been repeatedly shown that when potential for such environmental contamination exists, a continuing environmental sampling programme is more likely to detect a problem than is finished product analysis. Accordingly, in such operations well-selected points in the environment that constitute critical control points should be constantly monitored. If Salmonellae are detected in samples from such points, negative results of tests on finished products should be interpreted with extreme care. An analogous situation would be presented by a dry-blended product composed of multiple ingredients, each of which had been pre-tested and found negative for Salmonella. Here, raw materials, the environment and the finished product are critical control points which must be subject to constant monitoring.

2. In food service establishments

Many of the measures for monitoring critical control points described in the previous section are applicable to food service establishments. Visual inspection, however, is the usual approach. Inspection forms developed for the purpose of hazard analysis, which are useful to record information observed during monitoring, include those related to the inspection of incoming foods, storage conditions and each step of preparation of potentially hazardous foods. Certain foods - milk and milk products, canned foods, meat, poultry, shellfish - should come from known safe sources that have been subjected to previous monitoring. These and other foods should be checked when received for integrity of can or other packaging, signs of spoilage, and perhaps temperature. Thermometers in cold storage rooms should be checked.

Particular attention during inspection should be given to: temperatures of food, hygienic practices and techniques of handling foods by workers, whether employees are ill or have infections likely to be transmitted by food, and opportunities for cross-contamination from raw foods to cooked foods.

If the cleanliness of equipment is a critical control point, managers should establish a hygiene maintenance schedule that specifies what should be cleaned, how it should be cleaned, when it should be cleaned, and who should clean it. Daily checks should be made to determine whether the schedule is being followed. The capability of cleaning equipment and the effectiveness of the procedures can be evaluated by checking temperatures, length of washing and rinsing cycles, water pressures, and concentrations of detergents or disinfectants. Furthermore, microbiological monitoring can be done on surfaces of equipment to evaluate the efficiency of cleaning. Physical and chemical evaluations of cleaning and disinfection processes, however, are usually of more value.

Measuring the temperatures of foods during preparation and storage is probably the most useful monitoring technique for critical control points in food service operations. Temperatures of certain potentially hazardous foods, such as poultry and pork products, should be measured at the completion of cooking and reheating, or a short time thereafter (during the period of post-heating temperature rise) to determine whether the interior has reached a temperature at which vegetative cells of food-borne pathogens would be killed. Particular attention should be given to the monitoring of temperatures of cooked foods while kept hot or cooling.

Several temperature measurements taken at intervals are necessary to evaluate time-temperature conditions (Bryan & McKinley, 1979).

Microbiological sampling and testing of foods at various steps of processing or of finished products provide additional means of monitoring critical control points. Interpretation of these, however, must be based upon ingredients and all of the previous steps of preparation, heating and storage.

3. In homes

Monitoring in homes includes: observing that certain foods in their preparation actually come to a boil, checking pressures (temperatures) and times during heating of low-acid canned foods, inserting a thermometer into meat and poultry during cooking, checking that shallow containers are used to store cooked foods in refrigerators, that foods are not left at room temperature for several hours, and that in the case of heat-and-serve items the manufacturer's instructions with regard to storage and preparation of the food are followed.

IV. APPLICATION OF HACCP SYSTEM

A. Approaches to hazard analysis

When considering hazard analysis both food poisoning and spoilage microorganisms are of concern. Knowledge that a food is hazardous may derive from one of two sources: (1) Epidemiological information indicating that a product is potentially a health hazard or is microbiologically unstable may derive from effective surveillance programmes that collect data on the incidence of food-borne disease and assess significance. Feedback from marketing sources of a particular product may indicate hazards relating to stability or, on occasion, food poisoning hazards. From the viewpoint of hazard analysis, epidemiological marketing information is most desirable, as the assessment is based on factual information. (2) Technical information may indicate that the product poses a health hazard or is subject to spoilage. Here, reaching a decision with respect to hazard is far more difficult than in the first situation. While accurate data concerning product composition and the influence of processing can be obtained at the processing level, it is often difficult to relate this information to the subsequent effects of storage, distribution and actual use of the product. This lack of information necessitates additional safeguards in analyses, which frequently lead to over-control.

If an existing product or a new product concept is to be subjected to hazard analysis, a food microbiologist¹ with extensive knowledge of the requirements for the type of product under evaluation should be consulted. For example, the following questions should be considered:

1. What are the conditions of intended distribution and use?

Is the product to be distributed under ambient or cold storage temperatures?

What is the expected shelf life both during distribution and storage and in the hands of the person who will ultimately use the product?

How will the product be prepared for consumption?

Is it likely to be cooked and then held for a period of time before consumption?

What mishandling of the product is likely to occur in the hands of the consumer or during marketing?

¹ The participants particularly dealt with microbiological aspects of the subject matter. Other specialists should be consulted when pathogenic agents, e.g., chemicals, are involved.

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2. What is the product formulation?

What is the pH?

What is the water activity?

Are preservatives used?

What packaging is used, and is this integral to product stability, e.g., the vacuum packaging of fresh meats?

3. What is the intended process?

Consideration should be given to those steps that lead to the destruction, inhibition, or growth of food-borne disease or spoilage microorganisms.

Based on answers to the above, and other available information, the expert food microbiologist is able to give a preliminary assessment of the potential hazard(s) involved in the manufacture, distribution and use of the product. However, it is desirable and in many cases necessary to check the assessment by inoculation of the product with appropriate food-borne pathogens and potential spoilage organisms. The inoculated food must be packaged under intended marketing conditions and then be subjected to tests under expected storage, distribution and consumer use conditions. Such tests should include evaluation of the effects of mishandling on product safety and stability. The test protocols, including the nature and size of the inoculum as well as other details, should be under the direction of an expert food microbiologist.

B. Approaches to critical control point determination

Sometimes critical control points are obvious from the hazard analysis. Epidemiological data collected during investigations of outbreaks that occurred in similar places can also be used as a guide. At other times, more extensive research on the food or the process, including microbiological investigations, may be necessary to establish appropriate control points. Of particular value is a determination of temperatures and times at which the product is held during processing or preparation for consumption at an establishment.

Microbiological investigations usually form a vital part of the procedure of selecting critical control points, and should include in-depth investigations of raw materials to establish types and numbers that may be a hazard in a final product, as well as collection of samples of products and/or materials from the surfaces of equipment coming in contact with the food at various stages during the manufacture or preparation for consumption. Statistically valid sampling procedures should be used and repeated on a number of occasions to obtain a realistic picture of the status at different operations, in order to identify stages in processing and the environment where unrestricted microbial growth may occur. Generally, these can be detected by simple aerobic plate count determinations.

C. Approaches to the establishment of monitoring system

The type of monitoring system depends upon the nature of the critical control point under consideration.

1. If a raw material is a critical control point, a specification should be set for that raw material detailing the microbiological tests, sampling plans and limits to be employed. Ideally, the supplier will perform the required tests and ensure that the materials comply with the specifications before the product is delivered to the user. However, it may be advisable for the user to check the consignment upon receipt, particularly if it is from a new supplier. Raw material storage conditions should be monitored to ensure that the satisfactory quality of the material is maintained until it is used.

2. Monitoring of process critical control points may involve microbiological tests but may be best achieved by physical and chemical tests, because the results of these are more rapidly available. There are, however, situations where in-process microbiological monitoring is necessary as, for example, in the production of highly sensitive foods for infants, children or malnourished persons. It may also be necessary to monitor the effectiveness of sanitation measures by the use of microbiological tests. In situations where a heat-stable toxin is a potential hazard, the product should be examined prior to a heat process for numbers of the toxicogenic organisms to assess the likelihood of the hazard.

3. Visual observation, although it may appear to be a mundane activity, is often the key means of monitoring critical control points. Personnel responsible for such monitoring require considerable training and expertise.

4. End product monitoring by microbiological testing is generally very limited. More often, determination of product attributes, such as pH, water activity, preservative level and salt content will give far more information about safety and stability. There are situations where microbiological examination of the finished product is mandatory, e.g., the examination of certain high-risk foods for Salmonella. For this purpose, the sampling plans and analytical procedure recommended by ICMSF should be followed (ICMSF, 1974, 1978).

Check lists should be employed for monitoring critical control points. These should show details of the location of the points, the monitoring procedures, the frequency of monitoring and satisfactory compliance criteria.

V. CONCLUSIONS AND PROPOSED STRATEGY

The above considerations have been mainly concerned with the application of the HACCP system by food manufacturers and food service establishments in developed countries. The participants of the meeting concluded that:

- the HACCP concept is a desirable alternative to more traditional control options. It can be applied at a better cost/benefit ratio in comparison with other approaches, as it is based upon a more systematic and logical approach to the avoidance of food hazards;
- application of the HACCP concept would likewise be very useful to food industries in developing countries. They recognized, however, that introduction of this approach to control would require the same degree of scientific sophistication as is necessary to its successful use in developed countries, since conducting hazard analyses and determining critical control points requires the input of trained specialists who are supported by adequate laboratory services;
- outside experts, supported by adequate laboratory facilities, could conduct hazard analyses and determine critical control points in specific food processing operations in developing countries, leading to the establishment of appropriate monitoring systems that could be administered by personnel in these countries. This would require the establishment of adequate laboratory facilities and the training of personnel;
- were such programmes undertaken, it would be necessary for outside experts periodically to carry out on-the-spot reviews of results and progress.

It was therefore proposed that WHO consider implementing the application of the HACCP system to food production in developing countries. The proposed strategy to achieve this would be:

A. WHO should select a food produced in a developing country or countries. The food selected should be one which has been identified as a health hazard or has been frequently rejected by importing countries.

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- B. WHO should convene an expert consultation to consider the application of the HACCP system to the selected food. This consultation should be composed of experts in the technology and microbiology of that particular food, including some with an extensive knowledge of the technologies used in different developing countries for the production of that particular food. Prior to convening the consultation, data such as those outlined in the previous section on application of the HACCP system should be available for review. If the application of the HACCP system is considered appropriate, the consultation should identify the probable hazard(s) associated with the food, consider the likely critical control points and suggest potentially applicable monitoring procedures.
- C. WHO should select a country and food processing plant(s) within that country in which the system could be tested.
- D. Outside experts designated by WHO should, with the appropriate national authorities of that particular country, conduct a thorough hazard analysis of the country's manufacturing plants for the selected food, and by means of the system indicated in this report identify the critical control points.
- E. Procedures necessary to monitor the critical control points should then be established. In cases where the necessary monitoring capabilities are not available at the outset of the programme, it is proposed that WHO offer the necessary assistance to provide these. This may require the establishment and operation of laboratories, and the training of personnel.
- F. Experience has shown that the HACCP system will be effective only if it is regularly reviewed. In order to ensure an optimal system it is suggested that the manufacturers and the national authorities in the developing countries regularly evaluate the progress of the programme, and if necessary make improvements. To assist in this WHO should supply the participating country or countries with outside experts.
- G. If the programme is successful in one developing country, it should be extended to other countries.
- H. WHO should convene other consultations to consider the extension of the HACCP system to other foods, if the results of the initial programme are sufficiently encouraging.

VI. RECOMMENDATIONS

The participants concluded that the Hazard Analysis Critical Control Point (HACCP) system is an effective and economical approach to ensuring the safety and quality of foods produced in developed countries and can be similarly applied in developing countries. In order to implement the HACCP system in developing countries, they recommended that WHO, in cooperation with other appropriate bodies, pursue the following activities:

1. That a food be selected which, on the basis of firm epidemiological evidence, is a hazard in national or international trade and for which a developing country can be identified in which a pilot programme can be established.
2. That a pilot programme for application of the HACCP system to the selected product be initiated and a protocol developed for application of the system in the pilot programme. The protocol should be based on the best information available concerning the most likely hazards, critical control points and applicable monitoring procedures.
3. That appropriate experts be recruited to work directly with relevant industry and government personnel in the selected country, in whatever manner is necessary, to:
 - (a) conduct hazard analysis of the operation;
 - (b) identify the critical control points pertinent to the hazards identified;

- (c) specify systems to monitor the critical control points and to assist in the application of the monitoring procedures;
- (d) conduct periodical reviews of the processing plants' use of the established HACCP system, including records of the results of monitoring checks of critical control points.
4. That any necessary assistance be given to provide adequate monitoring facilities.
 5. That, if the pilot programme is successful, WHO extend this activity to other countries that produce the same product.
 6. That when review of the pilot programme or other considerations justify it, appropriate consultation(s) be held to consider implementation of additional programmes for application of the HACCP system.
 7. That encouragement be given to the incorporation into Codex Alimentarius Codes of Hygienic Practice of the identification of critical control points appropriate to the commodity concerned and, as far as possible, the respective monitoring techniques required be specified.
 8. That encouragement be given to the establishment of food-borne disease surveillance programmes to collect epidemiological data on foods produced in developing countries and to identify the hazards and faulty processing operations that contribute to food-borne disease outbreaks.
 9. That encouragement be given to research on quantitative approaches to risk analysis and on the development of rapid and practical microbiological test procedures for monitoring critical control points.
 10. That discussion of the HACCP system be incorporated into appropriate WHO training programmes.

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