

**GUIDANCE ON REGULATORY ASSESSMENT OF HACCP**

**REPORT OF A JOINT FAO/WHO CONSULTATION ON  
THE ROLE OF GOVERNMENT AGENCIES IN ASSESSING  
HACCP**

**GENEVA, 2-6 JUNE 1998**

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## **ABBREVIATIONS**

CAC	Codex Alimentarius Commission
CCP	Critical Control Point
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CM	Control Measures
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agriculture/Aquaculture Practice
GHP	Good Hygienic Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point System
ISO	International Organization for Standardization
PFD	Process flow diagram
QMS	Quality Management Systems
SPS	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TQM	Total Quality Management
WHO	World Health Organization
WTO	World Trade Organization
UNIDO	United Nations Industrial Development Organization

## I. Introduction

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) convened a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing the Hazard Analysis and Critical Control Point (HACCP) system, in Geneva, Switzerland from 2 to 6 June 1998. The list of participants is presented in *Annex 1*.

The Consultation was opened by Dr F. S. Antezana, Deputy Director General *a.i.* of the World Health Organization, on behalf of the Directors General of FAO and WHO. In welcoming the participants, Dr Antezana noted that for many years public health and food control authorities worldwide, as well as international organizations such as FAO, WHO and UNIDO have promoted the application of the HACCP system. He pointed out that the FAO/WHO Codex Alimentarius Commission (CAC) adopted at its 20th Session (1993), the Guidelines for the Application of the Hazard Analysis Critical Control Point System (CAC/GL 18-1993)<sup>1</sup>. Dr Antezana emphasized that the work of Codex has increased in importance with the establishment of the World Trade Organization (WTO) and the coming into force of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). According to this Agreement, Codex standards, guidelines and recommendations relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice have been recognized as the reference for international food safety requirements and thus as a benchmark for national requirements.

As the implementation of the HACCP system is making headway in food safety management systems of food industries, the traditional role of food safety control agencies, including that of food inspectors, is also changing, particularly in countries where the application of the HACCP system is mandatory. In addition to the inspection of food industries for compliance with good manufacturing practices (GMPs) and other regulatory requirements, government officials have to assume new responsibilities and these include the assessment of industry-designed and implemented HACCP system.

Dr Antezana stated that in view of the above it is important to provide government agencies with guidance on their roles and responsibilities regarding HACCP assessment, including essential activities that they need to carry out, and to give advice on how to perform these adequately. Dr Antezana informed the Consultation that FAO as well as WHO (jointly with the Industry Council for Development) have developed manuals for HACCP training and the outcome of this Consultation will be an important supplement to these manuals.

Dr Antezana thanked all participants and representatives for having accepted the invitation of FAO and WHO. He also expressed gratitude to those governments, institutes and organizations that have contributed financially and those supporting the attendance of the participants.

The Consultation elected Mr Richard Souness as Chairperson, Ms Doris Hernandez as Vice-Chairperson, and Mr John Barnes agreed to serve as Rapporteur. The deliberation of the Consultation were based on a number of background papers (listed in *Annex 2*) and the work

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<sup>1</sup> The Codex Guidelines were subsequently revised by the Codex Committee on Food Hygiene; the revised version, adopted at the 22nd Session of the Codex Alimentarius Commission (Geneva, 1997) and entitled "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application" were annexed to the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev, 3 (1997)).

carried out by working groups led by Prof. Michiel van Schothorst, Dr Judi Lee, and Prof. Alex von Holy.

In closing, Dr Motarjemi emphasized that the subject of the meeting was important and complex, and acknowledged the difficulty of covering all aspects of the subject and reaching consensus within the course of one meeting. Dr Motarjemi recognized that more work was needed in the field of implementing and assessing HACCP in small businesses and the primary production sector. However, the subject was an evolving one, and the Consultation represented a first attempt to examine the role of government agencies in assessing HACCP. In the light of the experience gained in assessing HACCP, the guidance provided in this report may need to be revised. Dr Motarjemi invited the participants of the Consultation as well as government officials and other readers of the report to share their experiences with FAO and WHO.

## **2. Background and objectives**

At a previous WHO Consultation on the *Hazard Analysis Critical Control Point System: Concept and Application* (Geneva, June 1995)<sup>2</sup>, organized with the participation of FAO, it was concluded that ongoing assessments are essential once a HACCP system has been implemented and that such assessments may be carried out at two levels as:

- internal assessments carried out by industry; and
- independent assessments carried out by either
  - (i) regulatory agencies, or
  - (ii) third parties.

The Consultation also noted the shift in the role of government agencies from traditional inspection methods towards assessment of HACCP systems and recommended the development of guidelines for regulatory assessment. Such guidelines were found to be essential for defining the role of inspectors and ensuring that food/health inspectors assess HACCP systems in a consistent manner.

At the WHO Workshop on Training in HACCP<sup>3</sup> that was subsequently convened in June 1995 with the participation of FAO, it was recommended that, in addition to training in the HACCP system itself, government officials should also receive training in regulatory assessment.

The *objectives* of the present Consultation were to follow up the recommendations of the previous WHO Consultation and Workshop and to provide government agencies with guidance on regulatory assessment, focusing specifically on:

- a. government agencies' role and responsibilities with regard to the assessment of HACCP;
- b. essential activities which need to be carried out when assessing HACCP; and
- c. how to perform these adequately.

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<sup>2</sup> WHO. *Hazard Analysis Critical Control Point System: Concept and Application*. Report of a WHO Consultation with the participation of FAO, Geneva, 29-31 May 1995. WHO document WHO/FNU/FOS/95.7.

<sup>3</sup> WHO. *Training Aspects of the Hazard Analysis Critical Control Point System*. Report of a WHO Workshop on Training in HACCP with the participation of FAO, Geneva, 1-2 June 1995. WHO document WHO/FNU/FOS/96.3.

A description of the type of internal assessment that a food business may carry out is given in *Annex 3* for information purposes only.

### **3. Definition and purpose of regulatory assessment**

Regulatory assessment refers to a governmental activity carried out with the objective of obtaining evidence that the seven HACCP principles have been effectively applied; the HACCP plan and prerequisites are correctly implemented; and, that the system has been maintained.

The primary reason for assessing HACCP is to establish whether the food business has the ability to consistently manufacture and/or distribute safe food, i.e. to ascertain that the HACCP system is effective. However, the assessment of HACCP systems by government agencies might also be undertaken for a variety of other reasons and these may differ, depending on mandatory or voluntary applications.

Where the application of HACCP systems is mandatory, the reasons for assessing HACCP systems, apart from ensuring food safety, may be to:<sup>4</sup>

- enforce relevant legislation and regulations;
- publicize requirements;
- assess food industry compliance;
- apply sanctions in case of non-compliances;
- engage in international relations (leading to government-to-government certification and assurances and providing feedback to industry);
- provide technical assistance and training for food control officials and food industry; and
- conduct research to improve decision-making capabilities.

Where HACCP is being implemented within a voluntary scheme, the purpose of the assessment may be geared to activities other than regulatory compliance. Such activities might include:

- establishing operating frameworks for voluntary programmes;
- advising on where HACCP may integrate with government programmes, such as certification;
- encouraging understanding and adoption of HACCP for improving food safety;
- providing technical assistance and training;
- providing relevant information;
- encouraging stakeholder ownership; and
- testing pilot HACCP systems and implementing modifications.

Under both schemes, these activities may be carried out by different sections of government agencies to avoid conflict of interest and improve effectiveness.

An assessment of the HACCP plan will need to determine whether:

- all required elements are present in the plan and addressed adequately;
- the system will satisfactorily maintain food safety; and

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<sup>4</sup> In no order of priority.

- the actual events comply with the documented procedures described in the plan.

In addition to the above, prerequisites for HACCP and compliance with other regulatory should also be assessed.

#### **4. Government agencies' role and responsibilities**

Government agencies have both a strategic role in the implementation of HACCP as well as an operative role in organizing the effective and ongoing assessment of HACCP systems of the food industry.

A key role of government agencies will be to show leadership by promoting and facilitating the implementation of HACCP. The type of activities that government agencies need to consider have been described in other FAO and WHO documents.<sup>5,6</sup> In summary, these could include:

- facilitating training programmes for industry and government personnel;
- providing the necessary infrastructure in terms of guidance, expertise and where appropriate, legislation;
- encouraging the necessary support and development of training material for industry, government officials and other interested parties; and
- formulating an overall programme to assess HACCP systems.

In addition, government agencies have a duty to clearly communicate all health and safety standards, regulations, guidelines, and other requirements. Government agencies should provide the necessary infrastructure that is conducive to the implementation of HACCP systems by industry, including regulations, training, assessment of compliances, industry guidelines, and coordination among governmental agencies and other institutions when dealing with industry.

With regard to the actual assessment of HACCP, government agencies also play an important role in providing guidance on the assessment process needed to be developed and provided to officials for its uniform and acceptable application. This guidance should be developed by government agencies in collaboration with, when possible, food control officials and industry.

A number of different government agencies (national, state, local) may be involved in food safety assessment in a country. If this is the case, it is essential to harmonize and define their approaches and procedures to the extent possible. In some cases, government agencies may choose to use appropriately competent third parties to undertake food safety control as agents for the government. The key competencies described in this document may contribute to this judgement (see Section 8). However, governments should always remain accountable for food safety.

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<sup>5</sup> WHO. *HACCP: Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. Geneva, World Health Organization, 1997 (based on the Report of the WHO Consultation on *Hazard Analysis Critical Control Point System: Concept and Application*, with the participation of FAO, Geneva, 29-31 May 1995. WHO document WHO/FNU/FOS/95.7).

<sup>6</sup> FAO. *The use of hazard analysis critical control point (HACCP) principles in food control*. Report of an FAO Expert Technical Meeting, Vancouver, Canada, 12-16 December 1994. FAO Food and Nutrition Paper 58. Rome, Food and Agriculture Organization of the United Nations, 1995.

## **5. Essential elements/principal activities in regulatory assessment**

The government agencies or their agents responsible for assessing HACCP need to obtain evidence that the seven principles of HACCP have been effectively applied, the prerequisites for HACCP are adequate and the HACCP plan has been correctly implemented and maintained.

Some of the following elements should be taken into account as part of regulatory assessment.

### *Assessing the HACCP management*

Confidence in the management's ability to implement and maintain HACCP may not always be easy to measure. However, the following elements may give an indication of the level of commitment of the management to ensuring food safety and compliance with HACCP:

- the compliance history of the business;
- the level of food hygiene training and its application;
- the technical knowledge within or available to the company; and
- the existence of satisfactory documented procedures and food safety management systems.

### *Assessing development of the HACCP plan*

Assessing the basis for the development of the HACCP plan will include an evaluation of the accuracy of the product and process description, including information and consideration of the intended use of the product. A flow diagram of the process under assessment should also be provided and consideration should be given to its accuracy, and when, how and by whom it was confirmed. The assessor should consider the expertise used and how this has been utilized in the development of the HACCP plan. In evaluating the basis for the development of the HACCP plan, consideration should also be given to the adequacy of the prerequisites for HACCP.

### *Assessing the hazard analysis*

The assessor should consider the adequacy of the hazard analysis, in particular whether all significant hazards have been identified, ensuring that this has been undertaken for all products and processes to which the assessment is directed. In assessing the analysis of hazards, assessors may require access to supporting evidence in the form of, for example, records of validation, sample results, history of the safety of the product, generic plans, relevant and appropriate predictive models.

### *Assessing the effectiveness of control measures*

The assessor should consider whether control measures eliminate or reduce identified significant hazards to acceptable levels. The assessor should ensure that all Critical Control Points (CCPs) have been identified, that appropriate critical limits have been determined and that, where relevant, these are at least operating within applicable legislative parameters. An assessment should be made of the critical limits in relation to how realistic these are, their measurability and their relevance. Evidence should be obtained as to how these were determined including the expertise used, and any supporting documentation to validate these.

Evidence should be obtained that the monitoring of critical limits indicates adequate control of the hazards. The adequacy of training in relation to personnel working at CCPs and engaged in monitoring should also be considered, as should whether suitable instructions

have been given to such personnel, and their role in relation to appropriate and timely actions.

An assessment should also be made as to whether the corrective actions would adequately restore control and are adequate to prevent an unsafe product from reaching the consumer.

#### *Assessing the verification procedures*

The assessor should consider what, how, when and by whom the verification procedures have been undertaken, and whether these are adequate and effective. This may be indicated by an assessment of the validation data, sampling results, internal and external audit documentation as well as the frequency and thoroughness of all verification activities. The assessor should also consider whether changes, deficiencies in the HACCP plan, new emerging hazards, etc., are adequately provided for. Assessors should consider what actions are taken as a result of inadequacies in the HACCP plan or its prerequisites, or any other non-conformities.

#### *Assessing the documentation*

The following documents should be assessed:

- the description of the product and its intended use;
- the process flow diagram with the location of CCP and related parameters;
- the HACCP worksheet on which are mentioned the hazards, the control measures, the CCPs, the critical limits, the monitoring procedures and the corrective actions;<sup>7</sup>
- the list of verification activities;
- the results of monitoring and verification according to the HACCP plan; and
- appropriate records necessary to assure the adequacy of prerequisites for HACCP.

#### *Assessing the implementation*

The assessors should assess the adequacy of the implementation, i.e. whether the HACCP plan and the prerequisites for HACCP have actually been implemented in the food business, maintained and are functioning correctly. Assessors should consider whether records were in order, i.e. whether recordings of monitoring and verification results were as described in the HACCP plan.

## **6. Organization and planning**

#### *Scope and frequency of assessment*

The scope and frequency of any assessment will depend on a number of factors. Ideally, an assessment programme should be in place at either national or local level. It is beneficial for this programme to be based on some form of risk classification scheme.

Classification schemes enable resources to be targeted effectively and provide a better focus by having more frequent inspections at higher risk premises and associated operations. At an initial stage in the implementation cycle it is unlikely that any classification scheme could be based solely on an accurate assessment of the risk presented by an establishment. However, a scheme might be supported by a system which evaluated information relative to the following aspects:

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<sup>7</sup> FAO/WHO Codex Alimentarius Commission. *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*. In: Food Hygiene Basic Texts. Rome, Food and Agriculture Organization, 1997.

- the potential hazards known to be associated with the product and or process;
- the history or previous compliance performance details on Good Manufacturing Practices or other regulatory controls, where these exist;
- food safety management systems; and
- other considerations such as processing methods, intended use and population at risk.

Subsequent frequencies for assessment could be considered in the light of the findings, particularly relating to the efficacy of operation of the HACCP plan in place. Assessments might also be triggered by an adverse occurrence or food safety incident. This will also affect the scope of the assessment. Additionally, government agencies may wish to conduct random assessments as part of an overall programme.

Within a mandatory regulatory framework, other factors that might influence the time and frequency of assessment include:

- initial assessment;
- level of compliance;
- reassessment when the system has changed (process, formulation, etc.);
- risk and performance; and
- market access requirements.

Under a voluntary scheme, factors that might influence the time and frequency of assessment include:

- the operating framework of voluntary programmes;
- when requested or needed;
- risk and performance; and
- market access requirements.

The following will influence the scope of an assessment:

- whether it is an initial assessment or follow-up;
- size of operation, e.g. number of employees, volume of production, turnover;
- type of products and processes;
- complexity of operation;
- level of in-house expertise;
- amount of available resources;
- presence of management systems, e.g. ISO quality management systems, TQM;
- results of previous assessments; and
- population at risk.

Whether a full or partial assessment is carried out will depend on the original purpose of assessment. For example, a partial assessment might be appropriate where it is related to a particular incident and is for investigatory purposes, closing out non-compliances or where a previous assessment has demonstrated that a sound system is in place.

#### *Other administrative arrangements*

In order to support the role of government assessors, the necessary infrastructure and administrative procedures need to be in place. These may include:

- advice, guidelines, generic models, codes, check-lists, etc. for competent and consistent assessments;
- support services;
- collection, analysis and dissemination of relevant scientific and technical data;

- a government programme to evaluate assessments;
- appeals procedures;
- government-to-government negotiation procedures;
- ongoing training schemes;
- provision of assessment reference manuals to guide assessors in the use of checklists;
- requirements for record-keeping procedures;
- participation in international HACCP-related fora, such as CAC; and
- coordination of government agencies having a role in assessing HACCP.

## **7. Assessment process**

The assessment process will need to include the following stages:

- (i) a planning process to focus and direct the assessment;
- (ii) an on-site assessment to gather relevant information; and
- (iii) an evaluation process to analyse findings, determine compliance and decide follow-up actions.

### *The planning process*

Initial planning is important to help clarify the scope of the assessment and the approach that will be taken on-site. It helps to ensure that assessors have the necessary information and tools to complete an effective assessment. Information, which will help in this planning process, will include:

- relevant company documentation;
- previous file records, data on premises and products; and
- results from previous visits or assessments.

A review of company documentation available to government authorities could be carried out off-site, although in some instances there may be some constraints which make this difficult or impractical, for example where the assessment is of an urgent investigatory nature or where it is intended to be unannounced. However, even where this can only take place on site, it is important to review and make use of relevant documentation prior to a further physical examination of the site premises, processes and procedures. A review of the flow diagram or site plan, for example, will provide information on the nature and scale of activities carried out. This will help to target the assessment, particularly the further scrutiny necessary of records, equipment and processes.

The information obtained at this planning stage will also help determine the focus of the assessment and the skills which might be necessary, particularly where assessment would be carried out by a team. It also provides an opportunity to refine any checklist and protocols that might be used and, where appropriate, communicate arrangements of the visits to the establishment. It is also during this stage that standardization of the assessment team may take place, if necessary.

### *On-site assessment*

The purpose of on-site assessment is to confirm that procedures and practices described in the HACCP plan and the prerequisites for HACCP are implemented and are adequate to ensure food safety. The on-site assessment will normally involve an initial meeting with relevant personnel to explain the nature and extent of the review and to promote cooperation during the assessment. At this stage any additional documentation required for an on-site review could also be requested and examined.

The scope of the assessment should have been decided during the planning stage. However, it could change depending on the findings of the on-site review of information, particularly if an off-site review (pre-assessment) was not undertaken and the on-site assessment represents the first examination of the material. The scope of the assessment should also be changed during the assessment if serious non-compliance/deficiencies are seen.

The on-site assessment will consist of a combination of activities. It should commence with a review of the relevant documentation relating to the HACCP plan and the prerequisites for HACCP and assessment of their adequacy and accuracy. It will then move on to a physical examination of the processes, practices and records, by observation, measurement or interview to assess whether the actual operation in practice complies with the documented procedures.

Activities may include:

- confirmation of the accuracy of the process flow diagram(s);
- scrutiny of the hazard analysis to check adequacy;
- confirmation of the suitability of CCPs, critical limits and corrective actions and that monitoring schedules are established and operating correctly;
- confirmation that persons responsible at CCPs perform activities correctly;
- establishing whether effective verification procedures are carried out;
- confirmation of the correct application of prerequisites for HACCP; and
- obtaining sufficient information and data to evaluate food safety status.

During these activities, the assessor will need to keep sufficiently detailed records and collect supporting evidence to enable conclusions to be made. Use of checklists (see Annex 4) together with a narrative, notebooks or, where appropriate, tape recorders will assist this process. Depending on the judgement of the assessor, checks might be made on items of equipment, on-site measurements may be carried out, or samples may be taken for subsequent laboratory analysis.

### *Evaluation process*

Where the assessment is being carried out by a team and a range of skills are being utilized, the evaluation and conclusions drawn will need to be agreed in advance of any final meeting with the site representatives.

The assessor (or the team) will need to identify and analyse all information obtained during the assessment in order to draw up preliminary conclusions of deficiencies found, if any, and their effect on food safety, regulatory compliance or other trade-related concerns. Assessors should use the findings of their investigations to evaluate the effect any deficiencies have on food safety and the speed with which they would need to be rectified.

The assessor(s) should evaluate deficiencies based on objective evidence drawn from qualitative or quantitative information, records, statements, observations, measurements or tests which demonstrate that the prerequisites for HACCP or the HACCP system in place would not ensure food safety. Information and records gathered should be organized into a format that would support and justify the presentation of findings. It is beneficial to provide feedback on any positive findings of the assessment, where appropriate.

At the exit meeting, the assessor will need to discuss and agree on the expected remedial actions. The approach taken at this stage will depend on the purpose of the assessment, for example when the assessment had been triggered off by a serious food safety problem or where the assessment was to exclude previously identified deficiencies. However, in all

circumstances, it is preferable to present any findings in a methodical manner specifically highlighting critical non-compliance or deficiencies.

The assessor should then discuss non-compliances/deficiencies found with the company. The company should be given the opportunity to put forward its own solutions for acceptance. At the conclusion of any assessment, the company should be clear on any immediate remedial action required. The remedial action should be communicated to the site representatives with the appropriate responsibility. In some cases, written assessment reports might only follow more detailed off-site evaluation of the findings by the assessor or other competent authorities. However, in all cases, it is necessary for the regulatory authority to engage in follow-up activities to ensure that reported non-conformance is rectified.

#### *Acceptance or regulatory approval*

The actions taken by government agencies where deficiencies are noted will depend on whether the assessment is carried out within a voluntary or mandatory scheme. The necessary actions will vary according to whether the identified deficiency, be it non-conformance or non-compliance, in either the HACCP plan (deficiencies in key elements, including the 7 principles) or relevant prerequisites, has an adverse effect on food safety. Some deficiencies will not have a direct impact on food safety. Assessors will need to have sufficient skills and competencies to evaluate the effect of deficiencies. Other factors which will influence the action taken will include evidence of a repetitive pattern suggesting insufficient control that could lead to an adverse food safety problem. When assessment is conducted within a mandatory regulatory framework, government agencies will retain responsibility for the acceptance or regulatory approval of the system and/or for imposition of other legal sanctions when non-compliances or other deficiencies in the system are found.

## **8. Competencies of assessors and other related specific considerations**

A range of competencies are required to enable this assessment to be undertaken effectively. These competencies may be available in a single individual or a team depending on the nature of the food or the process under consideration.

The following key competencies are the minimum competencies required to assess an HACCP plan, and the associated prerequisites for HACCP. The scope of the competencies will vary according to the risk to public health and technical complexity of the food operation(s) to be assessed. The competencies, especially for high-risk and more complex food operations, may be contained within a team of people, but in most cases a single person with appropriate experience and knowledge will undertake the assessment.

Key competencies for the assessment of HACCP are:

- a) Knowledge of and experience with HACCP systems and their application, including the ability to identify and assess potential hazards which may occur during food production, handling, preparation, storage and transportation including:
  - biological hazards
  - chemical hazards
  - physical hazards
- b) Knowledge and experience in assessing prerequisites for HACCP;
- c) The ability to assess the effectiveness of control measures and of HACCP plan verification;
- d) Knowledge of, and experience in, auditing methodologies;
- e) Knowledge of relevant industry processes;

- f) Knowledge of relevant industry codes of practice, legal requirements, other guidelines or standards.

Furthermore, recognized qualifications in food science or a similar discipline are desirable for the assessor or the assessing team.

At the moment, in some countries, the assessors may be able to assess the suitability and adequacy of prerequisites for HACCP. It is recognized, however, that some assessors may not currently have all the key competencies necessary to assess the effectiveness of the HACCP plans and therefore should have a role in the assessment process limited to their key competencies, either as an individual or a member of a team. Appropriate checklists may be used by regulatory assessors to overcome a deficiency in competencies.

Independent assessors may have a role in regulatory assessment, although regulatory assessors who are authorized under relevant food legislation will have additional legislative responsibilities. It is therefore desirable that public and independent regulatory assessors should satisfy the same key competencies.

An important consideration for any assessor relates to the issue of conflict of interest in relation to assessment activities. To avoid the possibility of conflict of interest, assessors should not assess any HACCP system in which they were involved in the design or implementation. In general, all assessors must avoid any activity that conflicts with their independence of judgement and integrity in relation to their assessment activities.

## **9. Potential problems in regulatory assessment**

When assessing HACCP systems, government agencies may encounter a number of potential problems. Many of the problems may not be obvious during a HACCP assessment. Some of these problems are discussed below.

### **9.1 People**

*Attitude of people towards resistance to change* - Assessing HACCP requires a shift in attitude from traditional inspection methods to an HACCP-based inspection using auditing techniques. Identifying benefits of such change to both the individual assessors as well as to the government agencies might help motivate the switch to the necessary new approach to inspection.

*Lack of knowledge, language and cultural difficulties* - Another problem might be a lack of knowledge in general food safety issues and/or specific issues related to the product or operation being assessed. Appropriate training targeted on identified gaps in knowledge is the best way to overcome this obstacle. Differences in language and culture can also provide barriers to the use of HACCP assessment by government agencies. For instance, in some cultures the respective roles of employers and employees might make assessment difficult as the employer may be reluctant to replying to questions which may jeopardize the position of the employee. It is therefore important to provide training and technical materials that have been translated into the appropriate language and take cultural norms into account. It is equally important to ensure that assessors have the general educational background sufficient for them to understand the technical and/or any other issues identified as gaps in knowledge during the planning of the training.

*Personal judgement* - Regulatory assessments differ from prescriptive inspections by introducing an element of flexibility and personal judgement. As a result there are likely to be problems with uniform competence and consistent assessments between assessors. This can be dealt with by the development and use of a standardized approach to assessment, including

the use of checklists (see *Annex 4*), and implementation of a quality assurance system in assessment as part of the management review of assessor performance.

## 9.2 Legal

A potential problem could be the liability of government agencies or their assessors due to their having imposed various requirements on industry, such as generic plans or critical limits. Further difficulties might arise where an assessor has provided assistance or given approval to HACCP plans developed by industry. In these cases, it is vital that specific HACCP plans are developed and evaluated by the industry to meet the guidelines established by the government agencies

A potential barrier is that not all countries might have the legal authority to move to an HACCP-based inspection system (i.e. regulatory assessment of HACCP). Some countries might not have an appropriate legal framework in place to permit this approach. These issues need to be resolved by the government agencies involved, but would be greatly assisted if those countries that had the experience of trying to set down a legislative HACCP-based inspection system shared their experiences with them. In particular, there is a need for countries to share their information and experiences when a mandatory approach to HACCP has failed to achieve its expected legal outcome.

Another potential problem yet to be addressed is what a government agency should do if its domestic industry challenges the need for a HACCP-based inspection system on the basis that the industry feels that existing “GMP/GHP” controls provide a suitable assurance for food safety. A similar problem can arise between countries. This issue needs to be explored further and raises a number of questions which further strengthen the need for harmonization and implementation of provisions of existing international agreements calling for application of equivalence, such as the SPS Agreement.

## 9.3 Cost/investments

Any new system brings with it associated costs. Regulatory assessments are no different and any costs can be considered as investments. With proper planning, costs can be minimized. Costs to government agencies can be associated with:

- retraining of assessors to use the new inspection system;
- equipment, such as thermometers or pH metres, to be used by assessors;
- developing new tools, e.g. predictive modelling programmes;
- in some circumstances, increased end-product testing for an initial period before confidence in the HACCP plan is gained;
- the longer time required to carry out this type of assessment compared to the prescriptive type food inspection and associated administrative expenses;
- increased need for technical assistance;
- new research<sup>8</sup>;
- increased human resources since regulatory assessment might require a team of assessors;
- the provision of a Hot Line for assessment problems; and

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<sup>8</sup> Examples of the types of research required are listed in the Report of an FAO Expert Technical Meeting (Vancouver, Canada, 12-16 December 1994) entitled: *The Use of hazard analysis critical control point (HACCP) principles in food control*. FAO Food and Nutrition Paper 58. Food and Agriculture Organization of the United Nations, Rome, 1995.

- open public consultations held in some countries to generate consumer confidence in the new system.

Any discussion about costs should ideally be balanced with a discussion on associated benefits. The need for regulatory assessment is a logical and inevitable consequence of the application of HACCP systems in food industry . Although specific benefits of regulatory assessment have not been elaborated by the present Consultation, its benefits are closely linked with those of HACCP application itself. These have been extensively described in other fora.<sup>9</sup>

#### **9.4 Infrastructure and availability/access to technical expertise**

Experience from both industrialized countries and developing countries point to problems related to infrastructure and availability or access to technical expertise. More specifically, these may be:

- absence of infrastructure suitable for the assessment of food safety situations in general and regulatory assessment of HACCP in particular;
- restricted access to technical information: this can be general technical information, but can also cover technical information specific to that country, e.g. specific hazards associated with that country’s raw materials and appropriate control measures;
- access to facilities, e.g. laboratories, equipment, and calibration facilities needed for validation;
- lack of pressure from consumers to change to “safer” food systems like HACCP-based systems; and
- restriction of HACCP assessment to food exports in some countries.

#### **9.5 Conflict of interests**

Sometimes, where failure to comply with food safety requirements were found by an assessor, depending on who paid for the regulatory assessment, conflict of interests may arise. There may for example be a real conflict of interest where the assessor is employed by a government agency, but is acting as a paid consultant to the company. A further conflict of interest may arise where the HACCP assessor provides advice on how to implement HACCP and subsequently has to assess the HACCP plan. These conflicts should be avoided as far as possible (see also Section 8).

### **10. Future considerations and recommendations**

1. The consultation recommended that the appropriate Codex Committee undertake work to clarify the terms food safety objective, significant hazard and officially recognized bodies. It also recommended that the relationship between risk assessment, food safety objectives and HACCP be addressed.<sup>10</sup>
2. The Consultation recommended the need for the development of internationally accepted criteria for certification of HACCP assessors.

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<sup>9</sup> WHO. *HACCP: Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

<sup>10</sup> During the consultation, work would have been enhanced if there had been an agreed understanding on certain terms, such as *food safety objectives*, *significant hazard* and *officially recognized bodies*, thereby allowing these terms to be used. It was recognized that elaboration of the concept of significant hazards in advance may require information and scientific evidence.

3. Proper assessment of HACCP requires competency which should be addressed through adequate training, including in-plant practical training. This training needs to address the items in GMPs or codes of practices which are essential for food safety and which, therefore, should be considered as prerequisites for HACCP. Such differentiation of GMPs will vary depending on the nature of the products. The Consultation recommended FAO and WHO to consider work which may facilitate such training and further clarify the constituencies of prerequisites for HACCP.
4. The Consultation noted the difficulties in translating technical documents into other languages and the confusion which arises from faulty translations. The Consultation recommended FAO and WHO to undertake work towards development of equivalencies for the essential terms used in the area of HACCP and food safety into other languages.
5. The Consultation stressed the need for sharing technical information on the HACCP application internationally. Such exchange of information enhances the common understanding of the subject and can be facilitated by the use of communication media such as the Internet.

## Annex I

### List of participants

1. Prof. Lahsen Ababouch, Food Microbiology and Quality Control, Institut Agronomique et Vétérinaire Hassan II, Morocco
2. Mr John Barnes, Principal, Joint Food Safety and Standards Group, Department of Health, United Kingdom
3. Dr Enrique Bertullo, Director, Institute of Fisheries Research, Veterinary Faculty, University of Uruguay, Uruguay
4. Dr Michael Dillon, Director, Midway Technology Ltd. and M.D. Associates Ltd., United Kingdom
5. Mr Bertrand Gagnon, Inspection Strategies Division, Planning, Policy and Coordination Directorate, Canadian Food Inspection Agency, Canada
6. Mr E. Spencer Garrett, Director, National Seafood Inspection Laboratory, National Marine Fisheries Service, USA
7. Ms Doris Hernandez Torres, Director of Quality Assurance, Directorate of the Ministry of the Fishery Industry, Cuba
8. Mr Le Dinh Hung, Director, Branch IV, National Fisheries Inspection and Quality Assurance Center (NAFIQACEN), Vietnam
9. Dr Jaap Jansen, Inspection for Health Protection, Ministry of Health, Welfare, and Sport, The Netherlands
10. Dr John Kvenberg, Strategic Manager for HACCP Policy, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, USA
11. Dr Hector J. Lazaneo, Meat Safety Division, Ministry of Livestock, Agriculture and Fisheries, Uruguay
12. Mrs Susan Leaper, Training Manger, Campden & Chorleywood Food Research Association, United Kingdom
13. Dr Judi Lee, National Advisor (HACCP), Ministry of Agriculture and Forestry (Meat and Seafood), New Zealand
14. Mr Tony Mayes, Senior Microbiologist, Unilever Colworth Laboratory, United Kingdom
15. Ms Sara Mortimore, Director of Quality, Pillsbury Europe, United Kingdom
16. Prof. Michiel van Schothorst, Vice President, Food Safety Affairs, Nestlé, Switzerland
17. Mr Richard Souness, Program Manager, Food Hygiene, Australia New Zealand Food Authority, Australia
18. Dr Dorothy Stringfellow, Program Manager, Regulations & Inspection, U.S. Department of Agriculture (USDA), USA
19. Miss Sirilak Suwanrangsi, Chief, Fish Inspection Center (Bangkok), Department of Fisheries, Kasetart University Campus, Thailand
20. Dr Anneke Toorop-Bouma, Head, Quality Management Department, TNO Nutrition and Food Research Institute, Netherlands

21. Prof. Alexander von Holy, Department of Microbiology, University of the Witwatersrand, South Africa

### ***Representatives of other organizations***

22. *European Commission*: Ms Michaela Christine Majewski, Administrator, DG III: Industry - Foodstuffs, legal, scientific and technical aspects, Belgium
23. *Industry Council for Development*: Dr Anthony Mayes, Senior Microbiologist, Unilever Research, Colworth Laboratory, United Kingdom
24. *International Commission of Microbiological Specification for Foods*: Dr Zahara Merican, Principal Research Officer, Technical Services Centre, Malaysian Agriculture Research and Development Institute (MARDI), Malaysia
25. *International Life Sciences Institute*: Prof. Michiel van Schothorst, Vice President, Food Safety Affairs, Nestlé, Switzerland
26. *International Union of Food Science and Technology*: (unable to attend)
27. *National Food Processors Association*: Mr Dane Bernard, Vice-President, Food Safety Programs, National Food Processors Association, USA
28. *NSF International*: Mr Bob Tanner, Vice President and European Managing Director, Belgium
29. *United Nations Industrial Development Organization*: Dr Ahmidou Ouaouich, Industrial Development Officer, Austria

### ***Observer***

30. *European Commission*: Mr E. Caparis, Consultant Coordinator of EU-South Asia Industrial Cooperation Programme, Directorate General IB/C/5, Belgium

### ***FAO secretariat***

31. Mr Peter Karim Ben Embarek, Fishery Industries Officer, Fish Utilization and Marketing Service (FIU), Fisheries Department, FAO
32. Mr Carlos A. Lima dos Santos, Senior Fishery Industries Officer, Fish Utilization and Marketing Service (FIU), Fisheries Department, FAO
33. Dr Hector Lupin, Project Manager, FAO/DANIDA Training Programme on Fish Technology and Quality Assurance (FII), FAO
34. Ing. Oscar Do Porto, Private Consultant, France (*FAO Temporary Adviser*)
35. Mr Anthony Whitehead, Senior Officer, Food and Nutrition Division (ESN), FAO

### ***WHO secretariat***

36. Dr F.S. Antezana, Deputy Director General a.i., WHO
37. Dr Primo Arambulo III, Coordinator, Veterinary Public Health Program, Pan American Health Organization/World Health Organization, Washington, USA
38. Dr Jaime Estupinan A., Director, Pan American Institute for Food Protection and Zoonoses (INPPAZ), Pan American Health Organization/World Health Organization, Argentina
39. Dr Marco Jermini, Food Safety Regional Adviser, Regional Office for Europe of the World Health Organization, European Centre for Environment and Health, Rome

Division

40. Dr F.K. Käferstein, Director, Food Safety and Food Aid Program, WHO
41. Dr Robert T. Mitchell, Head, Environmental Surveillance Unit, Communicable Disease Surveillance Centre, Public Health Laboratory Service, United Kingdom (*WHO Temporary Adviser*)
42. Dr Yasmine Motarjemi, Food Safety Unit, Programme of Food Safety and Food Aid, WHO (*Secretary*)
43. Dr Gerald Moy, Food Safety Unit, Programme of Food Safety and Food Aid, WHO
44. Mr Alan Reilly, Food Safety Unit, Programme of Food Safety and Food Aid, WHO



## Annex 2

### List of background papers

*Definitions concerning assessment of HACCP.* M. van Schothorst, Food Safety Affairs, Nestlé, Switzerland

*Hazard Analysis and Critical Control Point (HACCP) as a part of an overall quality assurance system.* G. Orriss and A.J. Whitehead, Food and Nutrition Division (ESN), FAO

*Procedures used by industry to assess HACCP.* T. Mayes and M. van Schothorst on behalf of Industry Council for Development (ICD)

*The role of governmental agencies from an industry's perspective.* T. Mayes and M. van Schothorst on behalf of Industry Council for Development (ICD)

*An example of some procedures used to assess HACCP systems within the food manufacturing industry.* S. Mortimore, Pillsbury Europe, United Kingdom

*An industry perspective on assessment of HACCP in the U.S.* D. Bernard *et al.*, National Food Processors Association, USA

*Independent assessment by third-party certification bodies: NSF International.* B. Tanner, NSF International, Belgium

*The role of government agencies in assessing HACCP - Australia.* Mr Richard Souness, Food Hygiene, Australia New Zealand Food Authority, Australia

*The role of government agencies in assessing HACCP - Canada.* B. Gagnon *et al.*, Canadian Food Inspection Agency, Canada

*The role of government in HACCP audit - Cuba.* D. Hernandez Torres, Directorate of the Ministry of the Fishery Industry, Cuba

*The role of government agencies in assessing HACCP systems - New Zealand.* J. Lee and S.C. Hathaway, Ministry of Agriculture and Forestry (Meat and Seafood), New Zealand

*The role of government agencies in HACCP audit - Thailand.* S. Suwanrangsi, Fish Inspection Center (Bangkok), Department of Fisheries, Kasetart University Campus, Thailand

*The role of government agencies in assessing HACCP - UK procedures.* J. Barnes, Joint Food Safety and Standards Group, Department of Health, and R.T. Mitchell, Communicable Disease Surveillance Centre, Public Health Laboratory Service, United Kingdom

*Overview of HACCP development and regulatory assessment in the United States of America.* J. Kvenberg, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, P. Stolfa and D. Stringfellow, U.S. Department of Agriculture (USDA), and E. Spencer Garrett, National Seafood Inspection Laboratory, National Marine Fisheries Service, USA.

*Enforcement of regulatory requirements in establishments subject to the HACCP system regulations.* J. Kvenberg, Center for Food Safety and Applied Nutrition, U.S. Food and Drug

Administration, P. Stolfa and D. Stringfellow, U.S. Department of Agriculture (USDA), and E. Spencer Garrett, National Seafood Inspection Laboratory, National Marine Fisheries Service, USA.

*FSIS Directive on inspection system activities* J. Kvenberg, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, P. Stolfa and D. Stringfellow, U.S. Department of Agriculture (USDA), and E. Spencer Garrett, National Seafood Inspection Laboratory, National Marine Fisheries Service, USA.

*Pathogen Reduction / HACCP Training modules.* J. Kvenberg, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, P. Stolfa and D. Stringfellow, U.S. Department of Agriculture (USDA), and E. Spencer Garrett, National Seafood Inspection Laboratory, National Marine Fisheries Service, USA.

*A viewpoint on the role of government agencies in assessing HACCP - Morocco.* L. Ababouch, Food Microbiology and Quality Control, Institut Agronomique et Vétérinaire Hassan II, Morocco

*The role of government agencies in assessing HACCP - Malaysian procedures.* International Commission of Microbiological Specification for Foods: Z. Merican, Technical Services Centre, Malaysian Agriculture Research and Development Institute (MARDI), Malaysia

## **Annex 3**

### **Internal assessment as carried out by industry**

#### **Introduction**

The following text is a straightforward and practical description of the approach to the HACCP assessment systems taken within the food manufacturing industry. It is based on a background document prepared for the FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP. The document reflects primarily the experience gained in some large food manufacturing industries. However, the principles outlined here are also applicable to small or medium-sized industries. The guidance provided here is not intended to be definitive and the scope and approach taken may vary between smaller and larger firms, food sectors, and countries, depending also on the purpose of the assessment and the resources available. It is provided for information only and is not designed as a blueprint for model assessment of HACCP systems. However, it does raise certain issues, such as assessment procedures and skills required of assessors, which might be useful in the context of assessing HACCP systems by government agencies.

#### **Purpose and scope of assessing HACCP within the food manufacturing industry**

Whereas the purpose of carrying out internal assessments of HACCP systems by industry will vary, the principal reason will be to establish whether the food business has the ability to consistently manufacture and distribute safe food. The scope and approach taken will reflect the specific purpose(s) of the assessment, some of which could be to:

- comply with the company policy regarding food safety control and/or with national legislative requirements or industry requirements;
- verify that a sound HACCP system has been implemented. This may include some validation that (or confirmation that validation of ) the hazard analysis has been carried out satisfactorily, determining whether control measures will be effective in addressing identified hazards and whether the business has developed monitoring, record-keeping and verification activities that facilitate adequate control of the identified hazards on an ongoing basis;
- verify that the design of the products and process specifications are appropriate and are being consistently achieved;
- assess the knowledge / attitude / competence of the people implementing and maintaining the HACCP system.

There may be other specific reasons for carrying out an assessment, as for example to:

- carry out a gap analysis, i.e. to evaluate the company standards of today against the desired future standards in order to identify improvement requirements (where are we now and where do we want to go);
- look at problems (investigative audits initiated for example as a result of recurring CCP-related complaints);
- raise the standards in general across the organization by sharing expertise, e.g. sister audits;
- reinforce HACCP training;
- assess the supplier's Quality Assurance (by assessing supplier's HACCP system);
- communicate and benchmark the site status to management and gather data (feedback system);

- demonstrate competence to third party (clients, regulatory or certification bodies, industry associations/sectors); and
- carry out a partial assessment in response to for example previous non-compliance /non-conformance issues.

In common with regulatory assessments of HACCP, the primary concern of industry is consumer protection through product safety assurance. However, HACCP assessment also ensures protection of the brand/company reputation.

Typically the food industry will have other reference documents or standards, such as Good Manufacturing Practice (GMP), or Industry Codes of Hygienic Practice based on the Codex Code of Practice on General Principles of Food Hygiene<sup>11</sup>, outlining the basic requirements for hygienic processing and manufacturing of foods. The guidance provided in such documents is regarded as an essential basis (or prerequisite) for the application of HACCP and will therefore be included as part of the assessment process. The way in which these prerequisites for HACCP may be incorporated within an operating system is likely to vary. Sometimes the prerequisites for HACCP may be covered in separate documented systems and sometimes as CCPs within the HACCP plan. The degree to which prerequisite programmes need to be assessed will depend on the objective of the assessment. Changes in a product or process specification may not necessarily require a re-evaluation of the GMP.

## **Methodology**

The assessment process is a formal procedure which is agreed by both parties and carried out in accordance with a set format although the format may vary. Assessors should ensure that they plan the process properly, i.e. that:

- sufficient time is allocated;
- the required skills are available within the assessment team (in accordance with resources available);
- arrangements are agreed upon with the site being assessed.

There are typically two stages of assessing a HACCP system. The first stage consists of the initial review of documentation which may be carried out on or off-site. Although it is possible to carry out an assessment without a pre-assessment or document review, experience shows that a review of the documents prior visiting the site leads to a more focussed, thorough and informed assessment. The second stage is the on-site determination of whether the seven principles have been applied in practice.

It is helpful to prepare an agenda for the audit programme to ensure that relevant personnel are available during the assessment and may assist in the on-site discussion.

## **An example of an assessment programme**

### **I. Pre-assessment document review**

This initial stage is, in fact, more than a document review. It is a "desktop assessment" of the HACCP system. Ideally, prior to an on-site assessment, all documentation relating to the scope of the assessment should be reviewed by the assessor. This is an important activity since it may enable the drawing up of an initial assessment checklist. Even a quick scan may

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<sup>11</sup> FAO/WHO Codex Alimentarius Commission. *Recommended International Code of Practice. General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)), Rome, FAO, 1997.

allow the assessor to get an idea of the standards presented and the assessor may become familiar with the site products and processes. It will give an opportunity for the assessor to carry out some research to build up knowledge of the product technology, legislative control measures, and /or industry standards.

Typically, the documents reviewed might include:

- a site layout plan (may give an idea of the flow of products through the site, the scale of the operation, and the products produced);
- a process flow diagram and specifications relating to it whereby any inconsistencies may be noted); and
- a HACCP plan.

When assessing a HACCP plan for the first time, an important part of the assessment will be to gauge the competency of the people responsible for the study. One method of doing this is for the assessor to take sections of the process flow diagram, preferably a high-risk section and, without reference to the HACCP control chart, carry out own desktop hazard analyses using own expert knowledge and reference material. At this stage the assessor may also consider:

- whether only significant food safety hazards have been included or whether quality and legal "hazards" have been identified;
- whether the hazards and control measures have been precisely defined or are vague and general;
- whether there is a control measure for each specific hazard;
- whether the hazard analysis has been carried out in an organized manner; and
- whether corrective measures have been identified, are realistic and likely to be effective.

Based on the above, the assessor may be able to judge how the CCPs have been established and may check whether records have been kept of the decision-making process and review these on arrival at the site.

The pre-assessment documentation review may help the assessor identify the personnel required for detailed discussions, the specific questions to be asked, and which areas to focus on when carrying out the on-site assessment activities.

If the assessor finds on the other hand that the document review has indicated obvious inadequacies, the assessor may decide to stop the assessment at this point instead of proceeding to the on-site assessment. Based on the findings, the assessor may decide for example to ask the company to review its HACCP system in the light of the preliminary findings or suggest further training requirements.

## **2. Assessment protocol**

### *On-site initial meeting*

It is helpful to have a brief opening meeting which is used to confirm, with the key people being assessed, the assessment scope, timetable, facilities and personnel required. The time and location of the closing meeting could be confirmed and any additional documentation required for the on-site document review could be requested.

### *Activities*

It is important to determine the accuracy of the process flow diagram (for all operating conditions) at an early stage during the assessment. This is facilitated by an initial walk

through the site. The assessor will subsequently need to engage in a range of questioning and investigative activities to assess the efficacy of the HACCP system.

Often a form of aide-memoire or checklist may be used to focus these activities. Some of the questions that might be appropriate to ask are provided in a checklist later in this annex. The questions have been arranged according to the seven HACCP principles though they would in practice be used by an assessor in the order set out in the scope and purpose of the assessment. An assessor needs to adapt any supplementary questions/activities to the scope and purpose of the assessment.

The assessor should use a range of acknowledged questioning and auditing techniques (e.g. determination of audit trails) to obtain the information required to be able to judge the capabilities or actions necessary to achieve the assessment objectives.

It is important to keep sufficiently detailed records during an assessment in order that the assessor may be able to support the recommendations. Such records could typically include:

- personnel interviewed;
- records examined;
- equipment examined;
- product / process details;
- non-compliances identified; and
- areas not included within the assessment.

### *Assessors*

Assessments in industry are typically carried out by teams because a range of skills are usually necessary. In some smaller businesses or where either the scope of the assessment or the assessment resources are limited, an individual assessor is often used. However, certain principles always apply:

- assessors should be independent even if taken from the same organization; and
- assessors should be sufficiently skilled for the activity in question (e.g. proven auditing skills, knowledge of HACCP in practice, and experience of the technology under consideration and relevant GMP/prerequisites).

### *Outcome and follow-up*

A closing meeting to discuss and agree on initial findings and to identify any necessary corrective actions is usually held with the responsible site personnel. It is useful to agree on time scales for completion of key non-compliance issues. At a later date, it should be verified that areas of non-compliances are adequately addressed.

Assessors should use the response to any checklist, or the findings of their investigations, to evaluate the likely impact of any non-compliance/non-conformance with the seven HACCP principles and/or relevant prerequisites for HACCP. Any deficiencies that adversely affects product safety should be highlighted immediately and corrective measures may be required as a matter of urgency. Deficiencies that do not adversely affect product safety directly could be addressed by means of a planned improvement programme. Assessors should therefore be capable of making sound judgements with regard to the categorization of critical versus non-critical deficiencies.

In industry, follow-up actions might require for example:

- capital expenditure;

- recruitment of new personnel;
- retraining of personnel; and
- recommendations to or changes of supplier.

### **3. Reporting**

The format of assessor reports varies according to company policy. However, it is essential that the results of the assessment are communicated to all relevant persons within the organization (i.e. with responsibility for safety) in a timely manner.

#### **Frequency and duration of assessment**

This will depend on the objective of the assessment and its scope. In general, assessments are often triggered by:

- regulatory requirements;
- changes to products/process/formulation, etc.;
- follow-up to HACCP training (preparation of a first HACCP plan);
- company and/or third party approval requirements;
- poor performance during previous assessments;
- pattern of non-compliance/non-conformance, indicating a systematic failure of management control; and
- it is good practice to have a minimum baseline frequency for assessment regardless of other factors.

The duration of the assessment will vary according to the scope and purpose of the assessment as well as the size of the establishment under consideration. Typically, a period of one day to one week may be required. However, within industry, the assessment of a HACCP plan may take up only part of the total time spent on-site, depending on the scope of the assessment, e.g. whether assessments of the prerequisites and Quality Management Systems are carried in addition to assessment of HACCP. In organizations who are using ISO9001 to manage their systems, it is often the case that regular maintenance assessments are incorporated into the QMS audits.

#### **Core HACCP assessment checklist**

The checklist on the following pages represents a compilation of commonly used questions. It does not represent a comprehensive checklist or a checklist which is currently in use. It intends to show how a list may look and the sort of questions and activities which may lead to an effective assessment.

HACCP Principle	Checklist
<p><b>Preparation</b></p>	<p>What evidence is there of management commitment to HACCP use?</p> <p><i>HACCP Team</i></p> <ul style="list-style-type: none"> <li>- Who was on the team?</li> <li>- Are all appropriate disciplines represented?</li> <li>- What is the likely knowledge level of the individuals? (Evidence of training, qualifications, experience etc.)</li> <li>- Has external expertise been sought where necessary?</li> <li>- What is the decision making leverage of the HACCP team leader?</li> </ul> <p><i>HACCP System</i></p> <ul style="list-style-type: none"> <li>- How does the system fit with the overall food safety control programme?</li> <li>- Does the company have a food safety policy?</li> <li>- Has the scope been clearly defined?</li> <li>- How is the system structured?</li> </ul>
<p><b>Principle 1</b> <i>"Conduct a hazard analysis "</i></p>	<p>Has the product been properly described?</p> <ul style="list-style-type: none"> <li>- Are intrinsic control measures identified?</li> </ul> <p>Is the process flow diagramme (PFD) comprehensive?</p> <ul style="list-style-type: none"> <li>- How was the PFD verified for accuracy and by whom?</li> <li>- Are all raw materials and process/storage activities included in the flow diagramme? (Rework can be included as an ingredient.)</li> <li>- Have all activities been included?</li> <li>- Is the PFD correct?</li> <li>- Have changes been made since the PFD was drawn up?</li> <li>- How does the HACCP Team get notified of changes to the process or product parameters?</li> <li>- How were the changes recorded and approved?</li> <li>- Were any changes discussed with HACCP Team before implementation?</li> <li>- Are there rework opportunities and have they been included?</li> </ul> <p>How was the hazard analysis conducted?</p> <ul style="list-style-type: none"> <li>- Were only significant hazards identified?</li> <li>- Have all raw materials (including rework) been included?</li> <li>- Have all process steps been considered?</li> <li>- Have the hazards been specifically identified by type/source or have they been generalized?</li> <li>- How did the team assess the likelihood of occurrence?</li> <li>- What information sources were utilized?</li> </ul> <p>Have appropriate control measures (CMs) been identified for each hazard?</p> <ul style="list-style-type: none"> <li>- Will the CMs control the hazards and how was this validated?</li> <li>- Are all the CMs in place at the plant level?</li> </ul>

<p><b>Principle 2</b> <i>"Determine the Critical Control Points (CCPs)"</i></p>	<p>How were the CCPs identified?</p> <ul style="list-style-type: none"> <li>- By expert judgement?</li> <li>- By the use of a decision tree? (has the decision tree been used correctly?)</li> <li>- By the use of consultants?</li> </ul> <p>- Have all necessary CCPs been identified?</p> <p>Did each identified hazard undergo a systematic consideration?</p> <p>How are the hazards which are not controlled by CCPs addressed?</p>
<p><b>Principle 3</b> <i>"Establish critical limits"</i></p>	<p>How were the critical limits established?</p> <ul style="list-style-type: none"> <li>- Is there evidence (experimental data, literature references etc.)?</li> <li>- What validation exists to confirm that the critical limits control the identified hazards?</li> <li>- Have critical limits been established for each CCP?</li> </ul> <p>How do they differ from operational limits?</p>
<p><b>Principle 4</b> <i>"Establish a system to monitor the control of the CCP"</i></p>	<p>Have realistic monitoring schedules been established?</p> <ul style="list-style-type: none"> <li>- Do they cover all CCPs?</li> <li>- Has the reliability of monitoring procedures been assessed where appropriate?</li> <li>- What is the status of monitoring equipment?</li> <li>- Is it evidenced as being in place and calibrated appropriately?</li> <li>- Are the CCP log sheets being used at all CCPs?</li> <li>- Have CCP log sheets been filled out correctly?</li> <li>- Is there any evidence that procedures are not being followed consistently?</li> <li>- Does the frequency of monitoring adequately confirm control?</li> <li>- Are the sampling plans statistically valid?</li> <li>- Are statistical process control records being used to demonstrate that the process is in control on a day-to-day basis?</li> <li>- Check that records agree with stated activities.</li> </ul> <p>Are monitoring personnel and their deputies properly identified and trained?</p> <ul style="list-style-type: none"> <li>- How was the training undertaken?</li> <li>- Are the monitoring records being reviewed by designated appropriate reviewers?</li> </ul>
<p><b>Principle 5</b> <i>"Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control"</i></p>	<p>Have the corrective actions been properly defined such that control is regained?</p> <ul style="list-style-type: none"> <li>- What evidence is there to demonstrate that this is being done in the event of a CCP deviation?</li> <li>- Has corrective action been recorded and how is the effectiveness being verified?</li> </ul> <p>How has the authority for corrective action been assigned?</p> <p>How is non-conforming product controlled and is this clearly recorded?</p> <p>Are there clear disposition actions listed?</p>

<p><b>Principle 6</b>  <i>"Establish procedures for verification to confirm that the HACCP system is working effectively"</i></p>	<p>Have verification procedures been clearly and appropriately established?</p> <ul style="list-style-type: none"> <li>- How are these procedures communicated through the business?</li> <li>- Have responsibilities for verification procedures been allocated?</li> <li>- Are they being carried out effectively?</li> <li>- Are all CCPs covered by the verification programme?</li> <li>- Is the information on the HACCP Control Chart up to date?</li> <li>- Is there a formal system to trigger amendments?</li> <li>- Are control parameters being achieved?</li> </ul> <p>Have process capability studies been carried out?</p> <p>How is the data from HACCP being used to improve the system?</p> <p>How is consumer complaint data being used within the verification system?</p> <p>Is there a regular review of CCP failure and product dispositions?</p> <p>Are prerequisite support systems included within the verification programme?</p>
<p><b>Principle 7</b>  <i>"Establish documentation concerning all procedures and records appropriate to these Principles and their application"</i></p>	<p>What format is being used to document the system?</p> <ul style="list-style-type: none"> <li>- Does the documentation cover all of the HACCP system operation?</li> <li>- How is the documentation controlled with regard to update and issue etc.?</li> <li>- Are the records accessible?</li> <li>- Are the HACCP records clearly identified by unique reference numbers?</li> <li>- Are all documents accurate and current?</li> <li>- Are verification procedures documented?</li> <li>- How is change control managed?</li> </ul>

## Annex 4

### The development and use of a checklist

For the purposes of this report, a checklist refers to a list that contains points that may be considered during the assessment and which may be used as a tool for assessing the application of the HACCP system, including the prerequisites for HACCP and the design, implementation and maintenance of the HACCP plan.

#### *Advantages and potential problems*

A checklist is a useful tool for the assessment of HACCP provided that it does not limit the freedom of the assessor to pursue additional avenues of inquiry that may be judged necessary to bring the assessment to a logical conclusion.

Some of the advantages of a check list are that it may:

- function as an aide-memoire;
- help maintain the focus and objectivity of the assessment;
- act as a record of the assessment itself;
- help ensure the completeness of the assessment;
- be a particularly useful tool in ensuring consistency of approach between different assessors;
- help, together with associated reference manuals, evaluate the comparability of different assessments, different companies, or different assessors;
- ensure transparency of the assessment process; and
- engender confidence in the assessment process by all concerned, including government, industry and consumers.

However, there are also a number of concerns regarding potential misuse of checklists. Some of the potential problems are that:

- a checklist may be improperly designed so that it may include unnecessary or irrelevant items, or may omit critical items;
- if designed or used improperly, it may restrict the initiative and judgment of the assessor and discourage critical evaluation; and
- it is important that the use of a checklist does not evolve into a simple “tick-a-box” approach where there is no critical evaluation.

#### *Design of a checklist*

The design of a checklist should address the generic aspects of prerequisites for HACCP, including GMP and provisions given in the Codex General Principles of Food Hygiene<sup>12</sup>, as they apply horizontally to most industries as well as the implementation of the principles of HACCP. A checklist should be designed for each specific sector of the food chain.

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<sup>12</sup> FAO/WHO Codex Alimentarius Commission. *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev, 3 (1997), Rome, FAO, 1997.

A checklist should be designed in such a way that it lists *at least* the minimum requirements referred to in regulatory criteria. To facilitate their application, checklists should be supported by an assessment reference manual to guide the assessor in their correct and consistent application.

A checklist should be designed so that a quantitative or qualitative measure of the evaluation can be recorded. An example of qualitative evaluation would be the use of the terms: “excellent, good, medium, and poor”. Space should also be provided for written comments and objective evidence to be recorded next to each heading.

To facilitate consistency, government agencies should coordinate the design and use of checklists used for regulatory assessments of HACCP.

### *Content of a checklist*

The content of a checklist will depend upon the purpose of the specific assessment being undertaken. For example, regulatory assessors will seek answers to questions about issues such as:

- the implementation of prerequisites for HACCP;
- product description and specification;
- production flow diagram;
- the hazard analysis process;
- the identification of CCPs;
- the establishment of critical limits and monitoring procedures;
- the development and implementation of corrective actions;
- appropriateness of documentation and records; and
- the effectiveness of validation and verification activities.

## **Annex 5**

### **Glossary**

This glossary provides a list of definitions of terms used in the report. The glossary should not be used in lieu of the official definitions of the Codex Alimentarius Commission.

#### **Accreditation**<sup>13</sup>

This is the procedure by which a governmental agency having jurisdiction formally recognizes the competence of an inspection and/or certification services.

#### **Acceptance**

No deficiencies that can lead to a loss of food safety control have been identified.

#### **Regulatory approval**

Official confirmation that the regulatory requirements are complied with.

#### **Regulatory assessment**

A governmental activity to obtain evidence that the seven HACCP principles have been effectively applied and the HACCP plan and prerequisites correctly implemented and that the system has been maintained.

#### **Certification**<sup>13</sup>

Procedure by which official certification bodies or officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements.

#### **Checklist**

A list that contains points/elements that may be considered during assessment. It is used as an aide-memoire to promote uniformity in assessment.

#### **Compliance**

Compliance means the HACCP plan and prerequisites and their implementation meet regulatory requirements.

#### **Conformity**

Conformity means that activities are carried out according to the established procedures, e.g. HACCP plan and prerequisites.

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<sup>13</sup> Adapted from WHO/FAO Codex Alimentarius Commission ALINORM 97/30, Appendix 3. Food and Agriculture Organization, Rome, 1997.

## **Generic HACCP plans<sup>14</sup>**

These are examples of HACCP plans developed for a food commodity or process that may be used as guidance for business operators producing such commodities or using such processes. Generic plans are not appropriate for use until customized for a specific food and food process.

## **HACCP plan<sup>15</sup>**

A document describing the activities developed in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the product under consideration and its intended use.

## **Implementation of the HACCP plan**

The ongoing execution and maintenance of the HACCP plan.

## **Inspection<sup>13</sup>**

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution including in-process and finished product testing, in order to provide assurance that they comply with requirements.

## **Prerequisites for HACCP**

Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in Codex Alimentarius Commission's General Principles of Food Hygiene and other Codes of Practice.

## **Third party**

An independent assessor be it a person or an organization with competence to assess HACCP.

## **Validation<sup>15</sup>**

Obtaining evidence that the elements of the HACCP plan are effective.

It is the responsibility of the industry and should be undertaken initially and as needed thereafter.

## **Verification<sup>15</sup>**

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine conformity with the HACCP plan. This is primarily an industry responsibility however some verification activities can also be undertaken during regulatory assessments.

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<sup>14</sup> Adapted from WHO. *Training Aspects of the Hazard Analysis Critical Control Point System*. Report of a WHO Workshop on Training in HACCP with the participation of FAO, Geneva, 1-2 June 1995. WHO document WHO/FNU/FOS/96.3.

<sup>15</sup> From the WHO/FAO Codex Alimentarius Commission ALINORM 97/13A, Appendix II. Food and Agriculture Organization, Rome, 1997.