

Module 04 - lecture 02

The role of governments

Role of government authorities

As facilitators :

**Clarify the goals and scope of HACCP,
provide expertise when requested**

As enforcers :

**Assess correct application and
implementation of the HACCP principles**

As trainers :

Assist in or provide training programmes

Responsibilities of governments

Strategic

effective implementation of HACCP

Operative

**effective and on-going assessment
of HACCP**

Strategic responsibilities

- **Development of an overall strategy**
- **Providing leadership**
- **Providing the necessary infrastructure (expertise, legislation, training, etc.)**
- **Formulating an overall programme to assess HACCP systems**

Operative responsibilities

- ◆ **Enforcing relevant legislation and regulations**
- ◆ **Applying sanctions in case of non-compliance**
- ◆ **Engaging in international relations**
- ◆ **Conducting research, risk assessment**
- ◆ **Publicizing requirements**
- ◆ **Providing technical assistance**
- ◆ **Training (governmental and industrial people)**
- ◆ **Regulatory assessment**

Inspection

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 verify that they conform to requirements

Codex 1997

Regulatory assessment

Regulatory assessment (definition)

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

Prerequisites to 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 Practices.

Purpose of regulatory assessment

The purpose of assessment 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

Regulatory assessment should determine

- **whether all required elements of HACCP are present in the plan and that they are addressed adequately**
- **whether the system will satisfactorily maintain food safety**
- **whether the actual events comply with the documented procedures described in the plan**

Regulatory assessment should determine in addition

- **adequacy of prerequisites to HACCP**
- **compliance with other regulatory requirements**

Competencies of assessors (1)

- **Knowledge of and experience with HACCP and its application**
- **Knowledge and experience in assessing prerequisites to HACCP**
- **Ability to assess the effectiveness of methodologies for controlling hazards and of HACCP plan verification**

Competencies of assessors (2)

- **Knowledge of auditing methodologies**
- **Knowledge of relevant industrial processes**
- **Knowledge of relevant industrial codes of practice, legal requirements, guidelines and standards**
- **Recognized qualifications in food science or equivalent disciplines are desirable for the assessor or the assessing team**

Elements of regulatory assessment

Assessed should be:

- ◆ HACCP management
- ◆ HACCP plan development
- ◆ Hazard Analysis
- ◆ control measures
- ◆ verification procedures
- ◆ documentation
- ◆ implementation

Assessing the HACCP management

an indication of management's commitment to food safety can be obtained by checking:

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

Assessing the HACCP plan development

This involves an evaluation of

- ◆ accuracy of the product and process description
- ◆ accuracy of the flow diagram
- ◆ expertise used in the HACCP plan development
- ◆ adequacy of the prerequisites to HACCP

Assessing the Hazard Analysis

Adequacy of the hazard analysis

- ◆ all significant hazards have been identified
- ◆ hazard analysis has been undertaken for all products and processes to which the assessment is directed

Assessors may require access to supporting evidence

- ◆ 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

- **Adequacy of Critical Control Points (CCPs)**
- **Appropriateness of critical limits**
 - ◆ are they realistic, do they ensure the required safety level?
 - ◆ how were they determined and validated?
- **Adequacy of monitoring methods and frequency**
- **Adequacy of corrective actions to restore control and to prevent that deviating product reaches the consumer**

Assessing the verification procedures

First should be assessed what was verified, how, when and by whom, and whether these activities are adequate and effective

Then the adequacy of actions taken as a result of

- **new emerging hazards**
- **changes or deficiencies in the HACCP plan or prerequisites to HACCP**
- **other non-conformities**

should be assessed

Assessing the documentation

The following documents should be assessed

- ◆ description of the product and its intended use
- ◆ flow diagram, location of CCPs and important parameters
- ◆ HACCP worksheet
- ◆ list of verification activities
- ◆ results of monitoring and verification
- ◆ records necessary to demonstrate the adequacy of prerequisites to HACCP

Assessing the implementation

This means checking whether

- ◆ the HACCP plan and prerequisites have been adequately implemented
- ◆ the plan is adequately maintained and functioning correctly
- ◆ operators are sufficiently trained
- ◆ records are in order (monitoring and verification executed as planned and corrective actions, if any, taken)

Frequency of assessment

- **Classification scheme**
 - ◆ **potential hazards associated with the product or process**
 - ◆ **history of previous compliance**
 - ◆ **food safety management system**
- **Food safety incident**
- **Other factors**

Assessment in practice

*An assessment
includes the following
stages*

- ◆ **Planning**
- ◆ **On-site assessment**
- ◆ **Evaluation**

Planning

Information required for planning includes

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

On-site assessment

**The purpose of on-site assessment is to confirm,
based on observations,
interviews and record reviews,
that the HACCP plan and its prerequisites are,
according to the assessor's expertise, acceptable**

Checklist (1)

- **A list that contains points / elements that may be considered during assessment.**
- **A checklist is an assessment tool for the entire HACCP application including prerequisites, design, implementation, maintenance of the plan**

Checklist (2)

Advantages

- ◆ **aide-memoir**
- ◆ **helps to maintain focus and objectivity**
- ◆ **helps to ensure completeness of assessment**
- ◆ **acts as a record of assessment**
- ◆ **helps to evaluate comparability of different assessments, companies or assessors**
- ◆ **ensures transparency of the assessment process**

Checklist (3)

Potential problems

If improperly designed and / or used

- ◆ **it may contain irrelevant or unnecessary items but critical ones may have been overlooked**
- ◆ **restricts the initiative and judgment of the assessor and discourages critical evaluation**

Evaluation

- **Analyse information and evaluate deficiencies**
 - ◆ **impact of deficiencies on food safety**
 - ◆ **regulatory compliance**
 - ◆ **trade concerns**
- **Formulate proposals for improvements or remedial actions**
- **Discuss findings and proposals with management and agree on follow-up**

Key messages

- **Regulatory assessment may become increasingly important as a consequence of the WTO requirements**
- **The scope and purpose of an assessment should be well defined**
- **Assessors should have the necessary skills**
- **Assessors should determine the correct application and implementation of the seven HACCP principles and prerequisites to HACCP**
- **The evaluation of results of the assessment should be discussed with the responsible management**