



# **Better Training for Safer Food BTSF**

## **Section 7 The Practical Application of the Principles of Auditing HACCP**

# Summary of Relevant Legislation

Regulation EC No 178/2002 laying down the requirements of food & feed law

Regulation EC No 854/2004 on official controls for products of animal origin

Regulation EC No 882/2004 on official controls to verify compliance with food & feed law

# Regulation EC No 882/2004 Definitions

Official control – means any form of control that the competent authority performs for the verification of compliance with feed and food law

Official controls include:

- Audit
- Inspection
- Verification
- Monitoring
- Surveillance
- Sampling

# Regulation EC 882/2004: Definition

## Audit

“Means a **systematic** and **independent examination** to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives”

# Regulation EC 882/2004: Definition

## Inspection

“Means the **examination** of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with legal requirements of feed and food law and animal health and animal welfare rules”

# Audit v Inspection

## Audit

Focus - Past/Present/Future

Audit against FSMS and Regulations?

Documentation heavy?

More time consuming?

FBO may carry out own validation/verification?

## Inspection

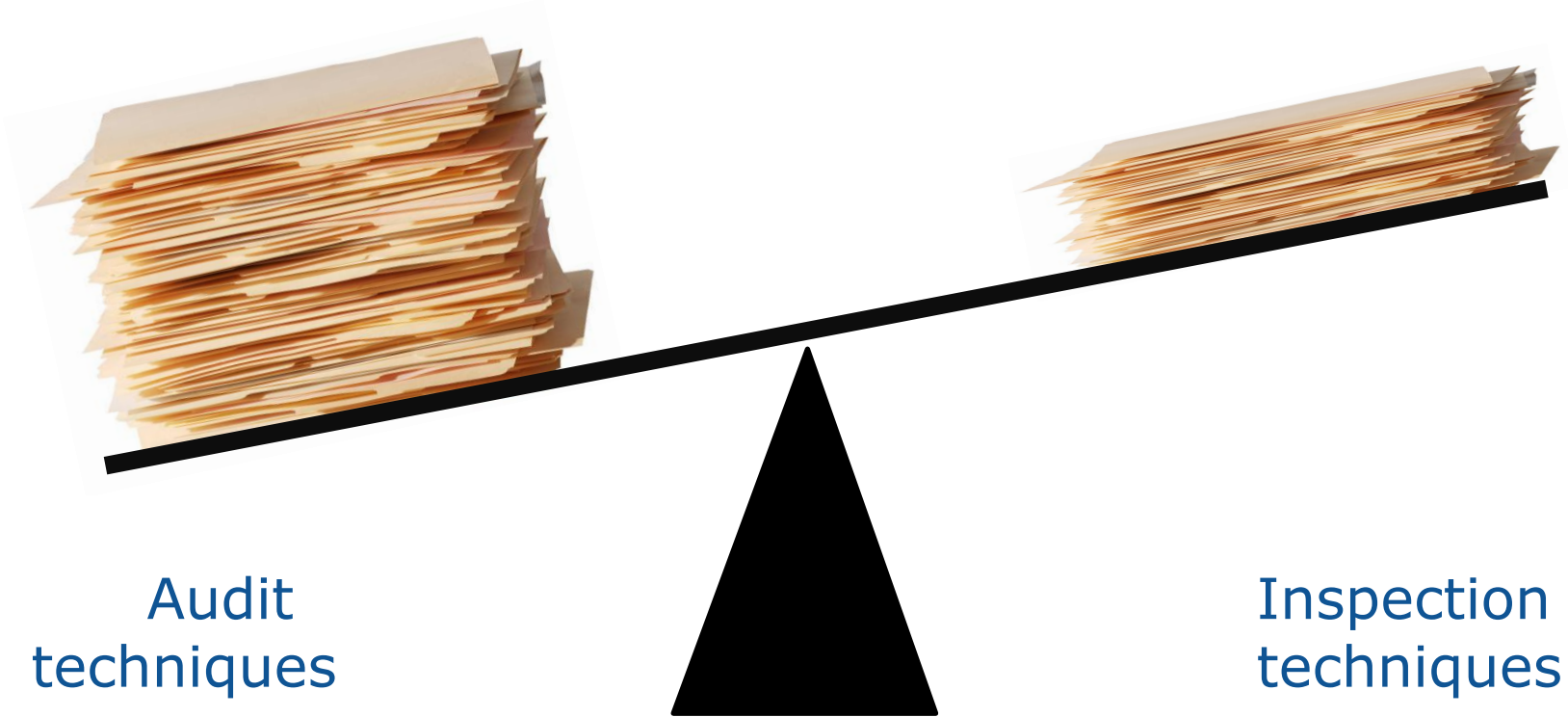
Focus - Present

Compliance with regulations?

Less documentation?

FBO may rely on Officer for advice and verification of procedures?

# Audit v Inspection



# International Auditing Guidance (1)

ISO 19011:2011 Guidelines for auditing quality management systems

ISO 22003:2007 Requirements for bodies providing audit and certification of FSMS

Also relevant:

CD 2006/677/EC Setting out the guidelines laying down the criteria for the conduct of audits under Regulation No 882/2004

- Used by FVO & Central Competent Authority when conducting audits



# Audit of HACCP based procedures

Should be:

- Systematic
- Independent
- Documented

The auditor collects and evaluates **objective evidence** to assess whether the requirements have been met

# Why Document the Audit?

To demonstrate that a systematic audit approach has been followed

To assure consistency between auditors

To justify the audit findings and conclusions

To provide evidence in event of a dispute.

We need to Document:

- The scope and criteria of the audit
- Documents examined and people interviewed
- Procedures and practices observed

# Audit Terms and Definitions

**Audit Scope** – extent and boundaries of an audit

**Audit Criteria** – policies, procedures or requirements used as a reference against which audit evidence is compared

**Audit Evidence** – records, statements of fact or other information which are relevant to audit criteria & verifiable

**Audit Findings** – results of the evaluation of the collected *audit evidence* against the *audit criteria*

*(Based on ISO 19011:2011)*

# Types of Audit (1)

## INTERNAL (1<sup>st</sup> Party)

Carried out by a company (business) on its own operation

## EXTERNAL (2<sup>nd</sup> Party)

Carried out by a company on its suppliers where there is a contract to supply or intention of purchasing goods

## THIRD PARTY

- Competent Authorities
- Certification bodies
- Others

## Types of Audits (2)

An Audit can be:

Full – covers all aspects & includes systems & compliance

or

Partial – concentrates on specific sections or activities



# Competent Authority Audits of HACCP based procedures

Confirmation of compliance by FBO with EU Hygiene Regulations

To establish that the business is able to make or distribute safe food/feed

Conformance by Competent Authority with Regulations (EC) 882/2004 and 854/2004

# Regulation EC 882/2004

## Article 10 Control Activities and Techniques

- d) Assessment of procedures on Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Farming Practices (GAP) and HACCP...
- e) Examination of written material and other records that may be relevant to the assessment of compliance with feed and food law
- f) Interviews of feed and food operators and their staff.

# Regulation EC 854/2004

Audits of good hygiene practices

Audits of HACCP based procedures

Products of animal origin:

- Comply with microbiological criteria (Regulation EC 2073/2005)
- Comply with Community legislation on residues, contaminants and prohibited substances, and
- Do not contain physical hazards, such as foreign bodies



# Regulation EC 854/2004

When carrying out auditing tasks the competent authority shall take special care:

- to determine whether staff and activities comply with the relevant requirements of the regulations
- to verify the food business operators relevant records
- to take samples whenever necessary, and
- to document elements taken into account and the findings of the audit

# Audit Activities

- Audit Initial Planning
- Pre-Audit Document review
- Audit final preparation
- On-site activities
- Preparing and presenting the Audit report

# Audit Initial Planning

May include:

Determine audit team (if more than 1 auditor)

Identifying audit type, scope and criteria

Establish initial contact with auditee (the FBO)

- Date & time
- FBO hygiene & safety rules
- Availability of documentation & personnel

# Pre- Audit Document Review

## Optional at this stage of the audit.

Documentation requested in advance may include:

- Copy of Site layout plan
- Copy of the HACCP plan or an extract

(The HACCP Plan will be examined later during the on-site audit)

Review previous audit report(s) & other information on file

# Audit Final Preparation

May include:

Prepare an Audit plan

If relevant agree tasks between auditors

Prepare Audit documentation:

- Checklist/aide-memoire
- Recording forms

Refresh details of relevant Legislation/codes of practice/guidelines

# Sequence of On-site Audit Activities

May include:

- Opening meeting
- Confirmation of flow diagram
- Document review (HACCP Plan and prerequisite programmes)
- Review of CCP procedures, practices and records
- Collation and review of findings
- Closing meeting (presenting conclusions).

# 'Agenda' of Opening Meeting

- Introductions (including Guide)
- Confirmation of audit type, scope and criteria
- Assurance of confidentiality
- Reminder that audit is sampling of available information
- Plan/timings for the audit
- Closing Meeting (expected time, place, attendees)

# Confirmation of Flow Diagram

Does the flow diagram include all steps of the process?

Does it include sufficient technical data ?

Has the potential for delays and/or re-work been considered?



# Document Review (1)

May include:

The HACCP plan

Prerequisite food hygiene requirements

Records of validation activities

Records of verification and review activities

## Document Review (2)

Ensure sufficient documentation examined

Auditor to select the documentation

Take time to audit the documentation thoroughly

Include historical data

Corroborate findings where possible

## Review of CCPs (1)

A typical HACCP Plan may contain a number of CCPs

It may not be possible within the time available to examine every CCP in detail

It is established practice to select a limited number of CCPs for more detailed examination

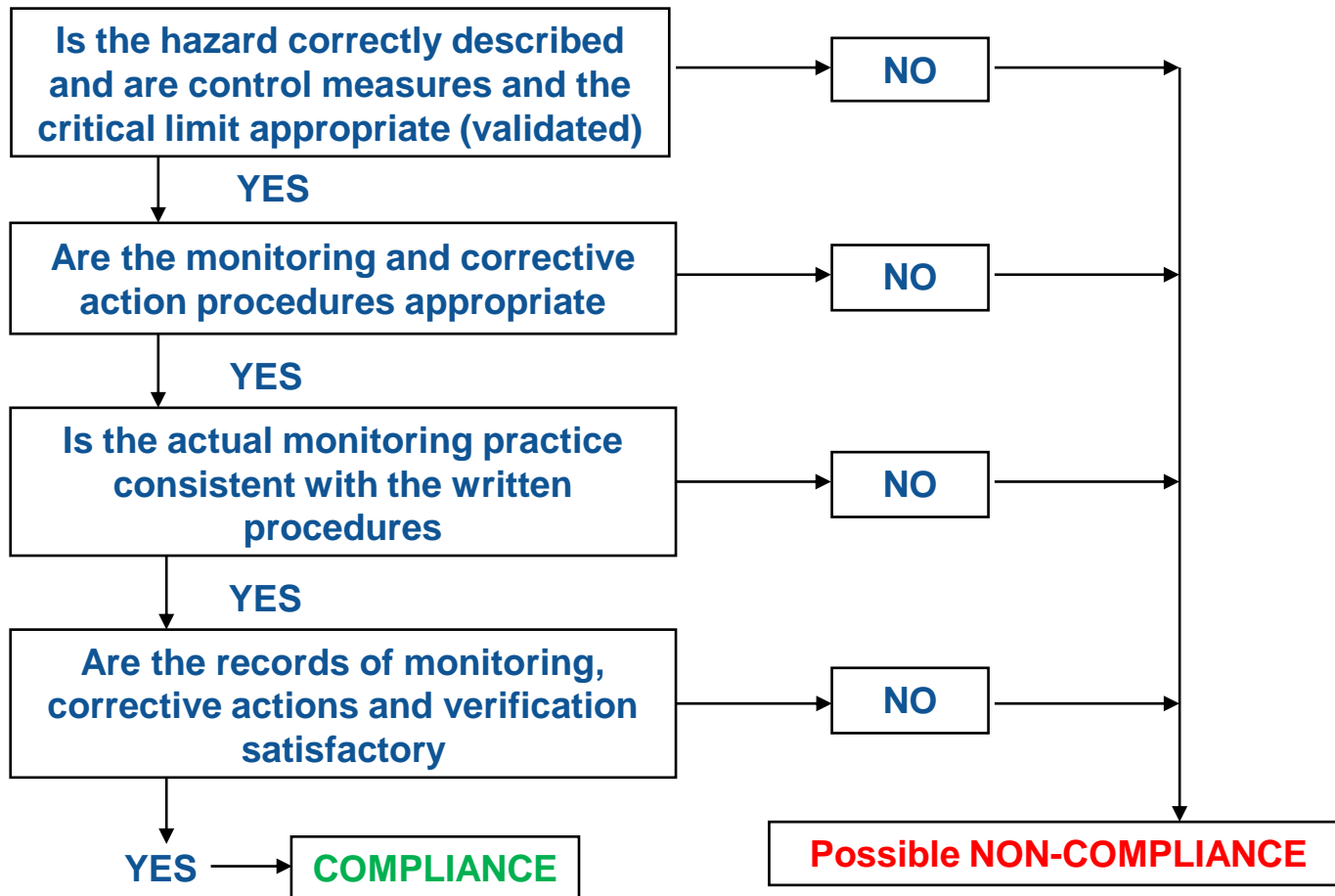
A Regulatory Audit might focus on **2** or **3** CCPs depending on the audit time available or the number of auditors

## Review of CCPs (2)

Obtain evidence of:

- Training and competency of the monitor
- Monitoring activity correctly performed
- Planned frequency achieved
- Records correctly completed
- Corrective actions understood
- Correct application of supporting prerequisites

# Auditing a CCP- An Overview



# Review and Evaluation of Evidence

'Private' time during the audit may be necessary to:

- Review progress and timings

Final 'quiet' time prior to closing meeting to:

- Summarise findings
- Consider significance of findings
- Determine non-compliances

# Closing Meeting

May include:

Thanks

Restate scope of audit & criteria used

Sampling disclaimer

Present the findings, including significance

Time scale to correct non-compliances and submission of evidence

Outline next step

# Audit Approach for Small Businesses

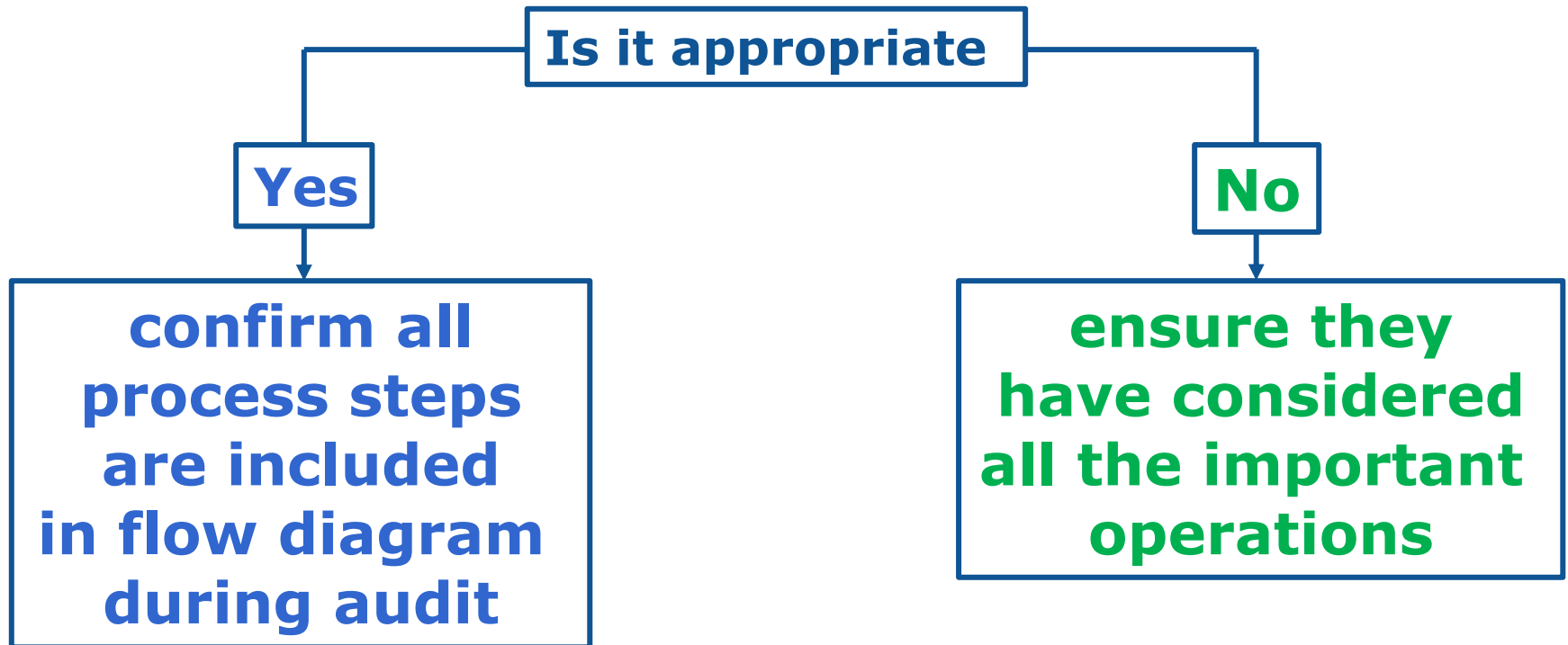
Apply basic principles of auditing

Modified audit content according to the:

- Size and nature of the business
- Extent of documentation & records (required by Article 5 Reg 852/2004 & EC DG SANCO Guidance)



# Confirmation of Flow Diagram in Smaller Businesses ?



# Document Review for Smaller Businesses

Flexibility allows for a variety of documentation approaches e.g.

- Guide to good practice
- Generic HACCP guide
- Recording by exception

Are the documented HACCP based procedures applicable, sufficient and up to date

# Procedure Review for Smaller Businesses

Obtain evidence that:

- Checks have been correctly performed
- Competency of staff
- Completion of records (e.g. diary)
- Problems recorded

# AUDIT SKILLS AND TECHNIQUES

# Auditor Requirements

Trained in auditing skills

HACCP/FSMS knowledge

Technology knowledge

Independent/impartial

Communication/professional

Inter-personal/polite

Systematic/logical

*(Reference WHO Consultation on the Role of Government Agencies in Assessing HACCP)*

# Data and Evidence Gathering (1)

Interviews & questions

Observation of activities and work environment

Review of documentation (e.g. HACCP plan, prerequisites, procedures, records)

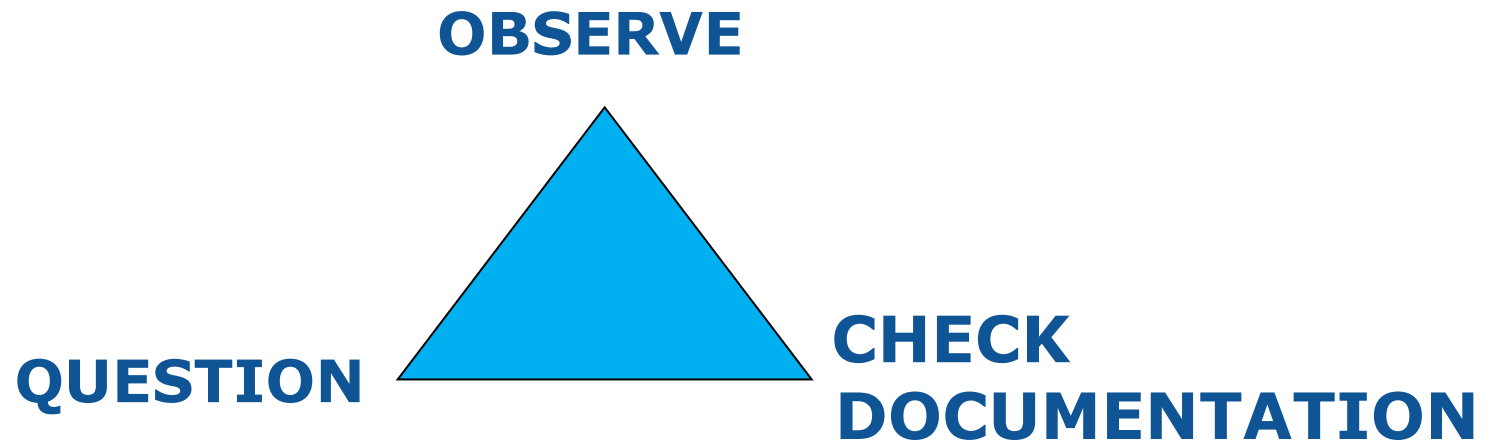
Request measurements and checks to be undertaken

Ensure sufficient sample of activities, procedures and records are included

Establish potential audit trails

# Data and Evidence Gathering (2)

Use Audit triangle to establish and confirm facts



look for facts, not opinions

ensure observations can be verified/witnessed

# Interview Techniques: Questioning

- Open:** stimulate discussion and elicits lots of information (what, when, how, why, who)
- Closed:** too many of these will bring audit to a halt! But effective to confirm a fact (i.e. require a yes/no answer)
- Specific:** obtain specific information and data
- Hypothetical:** useful to gauge if errors would be correctly recognised / reacted to (what if..., what would you do...)



# Interview Techniques: Non-Verbal Communications

Eye contact

Gestures

Facial expressions

Body motion and posture

Eye level

Spatial distance

Silence

# Interview Techniques: General Skills

Develop techniques which establish and maintain rapport

Do not interrogate, put people at ease!

Listening skills - Record the facts!

Confirm facts with guide or management

Thank each person for their co-operation

**REMEMBER YOUR AIM IS TO BE AS NATURAL AS POSSIBLE - SO RELAX!!**

# Recording Information During the Audit

Advise the auditee that you intend to take notes

Ensure notes are factual and accurate

Record good points too

Record areas where you may not have sufficient information, for follow up later (the audit trails)

# Information to be Recorded

Personnel interviewed

- name, title, role & responsibility

Documentation examined

- title, version number, reference

Equipment examined

- function, position, serial/reference number

Product/process details

Non-compliances

Areas not assessed.

# What is a Non-Compliance / Non-Conformance?

Failure to comply with the Regulations

- E.g. Regs. 852/2004, 853/2004, 178/2002

Failure to comply with “standard”

- DG SANCO Guidance

Failure to conform with documented procedure

- E.g. monitoring, verification

Commercial Standards use the term conformance / non-conformance only.

**Remember a non-compliance is against a requirement not against your opinion.**

# Recording Audit Non-Compliances

Clear and unambiguous

Factually correct and written objectively

Need sufficient detail:

- ‘An operator was not following the procedure’ is not sufficient
- Should include detail of the identified record, procedure, section of HACCP Plan; activity, operative, equipment, confirm the witnessed observation

# Additional Information

# Benefits of Auditing

## Verification of an established system

- “fresh pair of eyes”
- independent review
- peer review
- aid to customer relationship?
- Confidence in system and product
- Identification of weaknesses before they become failures
- Means of maintaining and improving the system