

# **CONSULTATIONS AND WORKSHOPS**

---

---

---

---

## **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



Issued by the World Health Organization in collaboration with the  
Food and Agriculture Organization of the United Nations

---

---

---

FOOD SAFETY UNIT  
WORLD HEALTH ORGANIZATION

**NCP.03237**

HACCP Principle	Checklist
Preparation	<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>Principle 1  <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> <li>- Have all necessary CCPs been identified?</li> </ul> <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>